# Out-Licensing Catalogue

2025 Edition

MEDOCHEMIE

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# Every human being has the right to quality medicines at affordable prices.

This is what we believe in.
This is what fuels our efforts every day.

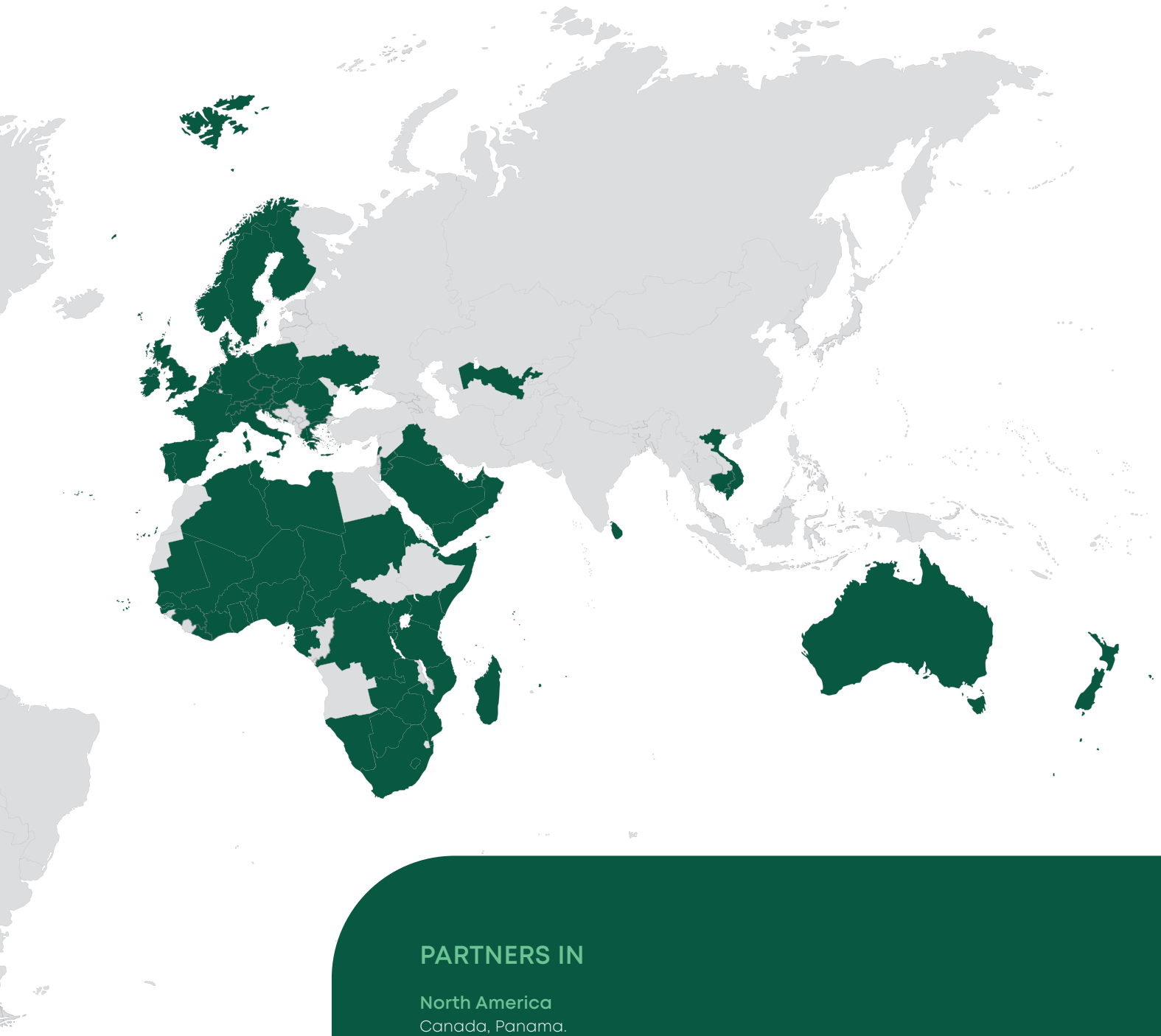
# Medochemie Out-Licensing

**Medochemie Ltd has over 30 years of Out-Licensing experience, partnering with leading generic pharmaceutical companies around the world.**

Our global customer base spans more than 90 countries, from major multinationals to established local firms. We have an impressive track record of maintaining partnerships beyond the expiration of contractual obligations, which demonstrates our customers' high satisfaction levels with our products and services.

# Fact Sheet

- **30** years of out-licensing experience
- **65+** customers including leading generic companies
- **90+** countries where products are out-licensed
- **80** new and upcoming dossiers currently available for out-licensing
- **80+** generic products out-licensed so far
- **50+** molecules / dossiers in the pipeline
- dedicated medical affairs team
- dedicated regulatory affairs team
- dedicated graphic design team



## PARTNERS IN

**North America**
Canada, Panama.

**Europe**
Austria, Belgium, Bulgaria, Croatia, Czech Rep., Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, U.K., Ukraine.

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Bahrain, Cambodia, Iraq, Jordan, Kingdom of Saudi Arabia, Kuwait, Lebanon, Oman, Qatar, Sri-Lanka, United Arab Emirates, Uzbekistan, Vietnam, Yemen.

**Australia**
Australia, New Zealand.

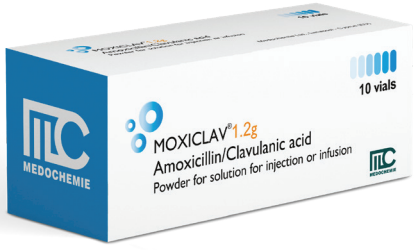
# Highlighted Products


## AMPICILLIN

250mg, 500mg, 1g, 2g - vials

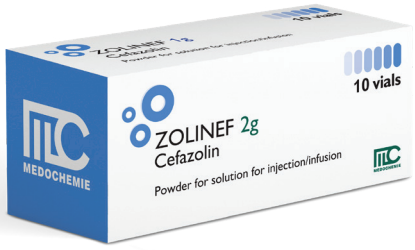

## AMOXICILLIN

250mg, 500mg, 1g, 2g - vials




## AMOXICILLIN/CLAVULANIC ACID

550mg, 1.2g, 2.2g - vials




## CEFAZOLIN

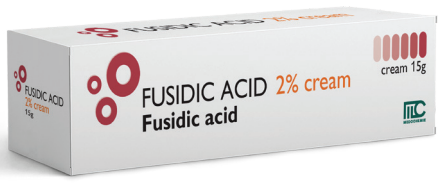
2g - vials


## CEFEPIME
500mg, 1g, 2g - vials


## CEFIXIME
200mg, 400mg - tablets


## CLOXACILLIN
250mg, 500mg, 1g, 2g - vials


## FLUCLOXACILLIN
250mg, 500mg, 1g, 2g - vials




## FUSIDIC ACID
2% cream


## GENTAMICIN

20mg/2ml, 40mg/2ml, 80mg/2ml, 160mg/2ml & 400mg/10ml - ampoules


## PIPERACILLIN/TAZOBACTAM

2g/0.25g, 4g/0.5g - vials


## PITAVASTATIN

1mg, 2mg, 4mg tablets


## ACECLOFENAC

100mg - film-coated tablets


## DICLOFENAC DIETHYLAMINE

**1.16% - emulgel** (Dossier ready)


## DICLOFENAC DIETHYLAMINE
2.32% - emulgel


## NEFOPAM
20mg/2ml - ampoules


## NEFOPAM
30mg - tablets


## HYDROCORTISONE
100mg - vials


## TRANEXAMIC ACID
500mg - tablets

*boxes are for illustration purposes only

# Anti-infectives

**Ampicillin 250mg, 500mg, 1g and 2g dry powder for injection in vials**
(DCP successful, upgraded CTD ready)

Pharmacotherapeutic group: Penicillins with extended spectrum, Beta-lactam antibacterials, Penicillins, ATC code J01CA01.

Ampicillin is a semisynthetic penicillin with a broad spectrum of bactericidal activity against many gram-positive and gram – negative microorganisms. It acts by inhibiting the biosynthesis of cell wall mucopeptide. It is a broad-spectrum penicillin antibiotic and is indicated for the treatment of a wide range of bacterial infections caused by ampicillin sensitive organisms.

**Amoxicillin 500mg capsules** (ready CTD)

Pharmacotherapeutic group: penicillins with extended spectrum.

Amoxicillin is oral broad spectrum semi-synthetic penicillin structurally related to ampicillin. The presence of a benzyl ring in the side chain extends the antibacterial activity to gram-negative bacteria. It is indicated for the treatment of a wide range of bacterial infections caused by susceptible organisms such as upper and lower respiratory tract infections, gastrointestinal tract infections, skin and skin structure infections, genitourinary tract infections. It is also indicated for prophylaxis of endocarditis.

**Amoxicillin 250 mg, 500 mg, 1g and 2g dry powder for injection in vials**
(DCP successful, upgraded CTD ready)

Pharmacotherapeutic group: penicillins with extended spectrum, ATC code: J01CA04.

Amoxicillin is a semisynthetic penicillin (beta-lactam antibiotic) that inhibits one or more enzymes (often referred to as penicillin-binding proteins, PBPs) in the biosynthetic pathway of bacterial peptidoglycan, which is an integral structural component of the bacterial cell wall. Inhibition of peptidoglycan synthesis leads to weakening of the cell wall, which is usually followed by cell lysis and death. It is indicated for the treatment of a wide range of bacterial infections caused by susceptible organisms such as acute bacterial sinusitis, acute otitis media, acute streptococcal tonsillitis and pharyngitis, acute exacerbations of chronic bronchitis, community acquired pneumonia, acute cystitis, asymptomatic bacteriuria in pregnancy, acute pyelonephritis, typhoid and paratyphoid fever, dental abscess with spreading cellulitis, prosthetic joint infections, helicobacter pylori eradication and lyme disease. It is also indicated for the prophylaxis of endocarditis.

**Amoxicillin/Clavulanic Acid 550mg, 1.2g & 2.2g powder for solution for injection/infusion** (DCP ongoing, RMS: LV)

Pharmacotherapeutic group: Combinations of penicillins, incl. beta-lactamase inhibitors, ATC code: J01CR02.

Amoxicillin is a semisynthetic penicillin (beta-lactam antibiotic) that inhibits one or more enzymes in the biosynthetic pathway of bacterial peptidoglycan, which is an integral structural component of the bacterial cell wall. Clavulanic acid is a beta-lactam structurally related to penicillins. It inactivates some beta-lactamase enzymes thereby preventing inactivation of amoxicillin. It is indicated for the treatment of the following infections in adults and children: severe infections of the ear, nose and throat and sinusitis, acute exacerbations of chronic bronchitis, community acquired pneumonia, cystitis, pyelonephritis, skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis, bone and joint infections, in particular osteomyelitis, intra-abdominal infections and female genital infections.

## **Cefotaxime 500 mg, 1g & 2g dry powder for injection in vials**
(ready CTD + zone IVa stability)

**Pharmacotherapeutic group: Antibacterials for systemic use, ATC code: J01DD01.**

Cefotaxime is a broad-spectrum third-generation bactericidal cephalosporin antibiotic. Cefotaxime is exceptionally active in vitro against Gram-negative organisms sensitive or resistant to first or second-generation cephalosporins. It is similar to other cephalosporins in activity against Gram-positive organisms.It is used parenterally for the treatment of infections of lower respiratory tract, skin and skin structure, urinary tract, bone and joint, obstetric and gynaecological infections, gonorrhoea, septicaemias, meningitis and other sensitive infections suitable for parenteral antibiotic therapy. The administration of cefotaxime prophylactically may reduce the incidence of certain post-operative infections in patients undergoing surgical procedures that are classified as contaminated or potentially contaminated or in clean operations where infections would have serious effects.

## **Cefazolin 500mg & 1g dry powder for injection in vials**
(ready CTD + zone IVa & IVb stability)

**Pharmacotherapeutic group: Beta-lactam antibiotics, first-generation cephalosporins, ATC code: JO1DB04.**

Cefazolin is a semisynthetic cephalosporin antibiotic for parenteral use. It is first-generation cephalosporin with greater activity against gram-positive bacteria than most other cephalosporins. Cefazolin is indicated in treatment of the following infections caused by susceptible bacteria: biliary tract infections, bone and joint infections, endocarditis, genito-urinary tract infections, respiratory tract infections, skin and soft tissue infections, septicaemia. It may also be used as a prophylactic, for perioperative administration to patients undergoing contaminated or potentially contaminated surgical procedures, or in whom postoperative infection would be serious.

## **Cefazolin 2g dry powder for injection in vials** (DCP successful, RMS: CY)

**Pharmacotherapeutic group: Beta-lactam antibiotics, first-generation cephalosporins, ATC code: JO1DB04.**

Cefazolin is a semisynthetic cephalosporin antibiotic for parenteral use. The bactericidal effect of cefazolin is based on inhibition of bacterial cell wall synthesis. It is indicated for the treatment of serious infections caused by cefazolin-susceptible micro-organisms such as respiratory tract infections, infections of the urinary and genital tract, infections of the biliary tract, skin and soft tissue infections, bones and joints infections, septicaemia, endocarditis and perioperative prophylaxis.

## **Cefepime 500mg, 1g and 2g powder for solution for injection/infusion** (Dossier ready)

**Pharmacotherapeutic group: 4th generation cephalosporin, ATC code: J01DE01**

Cefepime is a broad spectrum 4th generation cephalosporin for intravenous and intramuscular use. Cefepime is a bactericidal agent that acts by inhibition of bacterial cell wall synthesis. Cefepime has a broad spectrum antibacterial, that acts both to gram-positive and gram-negative bacteria, inclusive most of strains resistant to aminoglycosides and to 3rd generation of cephalosporins. Cefepime is highly resistant to hydrolysis by most beta-lactamases and exhibits rapid penetration into gram –negative bacterial cells. Cefepime has a low affinity for chromosomally-encoded beta-lactamases.

## **Cefixime 400mg film coated tablets** (DCP successful, RMS CY), **Cefixime 200 mg film-coated tablets** (Q3 2025, RMS: CY)

**Pharmacotherapeutic group: Third generation cephalosporins, Antibacterials for systemic use, ATC code: J01DD08.**

Cefixime is an oral third generation cephalosporin which has marked in vitro bactericidal activity against a wide variety of Gram-positive and Gram-negative organisms. It is indicated for the treatment of the following acute infections when caused by susceptible micro-organisms: upper Respiratory Tract Infections (URTI), lower Respiratory Tract Infections and urinary Tract Infections. Clinical efficacy has been demonstrated in infections caused by commonly occurring pathogens including Streptococcus pneumoniae, Streptococcus pyogenes, Escherichia coli, Proteus mirabilis, Kliebsiella species, Haemophilus influenzae, Branhamella catarrhalis and Enterobacter species.

## **Ceftazidime 1g & 2g dry powder for injection in vials**
(DCP successful, RMS NL)

**Pharmacotherapeutic group: Antibacterials for systemic use. Third-generation cephalosporins, ATC code: J01DD02.**

Ceftazidime inhibits bacterial cell wall synthesis following attachment to penicillin binding proteins (PBPs). This results in the interruption of cell wall (peptidoglycan) biosynthesis, which leads to bacterial cell lysis and death. It is indicated in adults and children including neonates (from birth) for the treatment of infections such as nosocomial pneumonia, broncho-pulmonary infections in cystic fibrosis, bacterial meningitis, chronic suppurative otitis media, malignant otitis externa, complicated urinary tract infections, complicated skin and soft tissue infections, complicated intra-abdominal infections, bone and joint infections and peritonitis associated with dialysis in patients on CAPD. Ceftazidime may also be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection and in the peri-operative prophylaxis of urinary tract infections for patients undergoing trans-urethral resection of the prostate (TURP).

## Ceftizoxime 500mg, 1g, 2g powder for solution for infusion
(DCP successful, RMS: SK)

Pharmacotherapeutic group: Antibacterials for systemic use, ATC code: J01DD07.

Ceftizoxime is a semi-synthetic broad-spectrum beta-lactamase-resistant cephalosporin antibiotic intended for intravenous or intramuscular administration. It acts against a wide range of gram-negative and gram-positive bacteria with a significant effect on E. coli , Klebsiella sp. , Proteus sp. , Providencia sp. , and H. influenzae. It is also effective against citrobacter, enterobacter, seraria and anaerobic bacteria. Ceftizoxime is used to treat severe infections caused by bacteria sensitive to ceftizoxime such as lower respiratory tract infections, intra-abdominal infections including biliary tract, gynecological infections, urinary tract infections, septicemia, skin and soft tissue infections, bone and joint infections and meningitis.

## Clindamycin 300mg/2ml, 600mg/4ml, 900mg/6ml solution for infusion
(Q1-Q2 2027, RMS: TBC)

Pharmacotherapeutic group: Lincosamide antibiotics, ATC Code J01FF01.

Clindamycin is a lincosamide antibiotic with a primarily bacteriostatic action against gram-positive aerobes and a wide range of anaerobic bacteria. It is indicated in serious infections caused by susceptible gram-positive organisms, staphylococci (both penicillinase- and non-penicillinase-producing), streptococci (except Streptococcus faecalis) and pneumococci. It is also indicated in serious infections caused by susceptible anaerobic pathogens such as Bacteroides spp, Fusobacterium spp, Propionibacterium spp, Peptostreptococcus spp. and microaerophilic streptococci.

## Cloxacillin 250mg, 500mg, 1g, 2g dry powder for injection in vials
(upgraded CTD ready, in-use study available)

Pharmacotherapeutic group: Beta-lactamase resistant penicillins, Antibacterials for systemic use, ATC code: J01CF02.

Cloxacillin is a semi-synthetic, penicillinase-resistant penicillin of the isoxazolyl penicillin group. It is indicated for the treatment of sensitive staphylococcal infections: respiratory infections, otorhinolaryngologic infections, renal infections, urogenital infections, neuro-meningeal infections, bone and joint infections, endocarditis, and treatment of skin infections caused by sensitive staphylococci and/or streptococci. Cloxacillin is also indicated as preventive treatment of postoperative infections in neurosurgery. It is not effective for methicillin-resistant Staphylococcus aureus (MRSA).

## Flucloxacillin 1g & 2g dry powder for injection in vials (DCP ongoing, RMS: NL)

Pharmacotherapeutic group: beta-lactamase resistant penicillins, ATC code: J01CF05.

Flucloxacillin is a semisynthetic penicillin (β-lactam group of antibiotics; isoxazolylpenicillin) with a narrow-spectrum activity primarily against Gram-positive organisms, including β-lactamase-producing strains. It is indicated for the treatment of infections caused by susceptible staphylococci. Flucloxacillin is suitable for the treatment of infections caused by streptococcus β-hemolytic group A.

## Fusidic acid 2% cream (Q2 2026, RMS: NL)

Pharmacotherapeutic group: Other antibiotics for topical use, ATC code: D06AX01

Fusidic acid is a potent antibacterial agent. Fusidic acid and its salts show fat and water solubility and strong surface activity and exhibit unusual ability to penetrate intact skin. It is indicated either alone or in combination with systemic therapy, in the treatment of primary and secondary skin infections caused by sensitive strains of Staphylococcus aureus, Streptococcus spp and Corynebacterium minutissimum. Primary skin infections that may be expected to respond to treatment with fusidic acid applied topically include: impetigo contagiosa, superficial folliculitis, sycosis barbae, paronychia and erythrasma; also such secondary skin infections as infected eczematoid dermatitis, infected contact dermatitis and infected cuts/abrasions.

## Gentamicin 20mg/2ml, 40mg/2ml, 80mg/2ml & 160mg/2ml solution for injection in amps formulation without preservatives, (DCP ongoing, RMS DK)

Pharmacotherapeutic group: Other aminoglycosides, Anti-infectives for systemic use, ATC code: J01GB03.

Gentamicin is a mixture of antibiotic substances produced by the growth of micromonospora purpurea. It is bactericidal with greater antibacterial activity than streptomycin, neomycin or kanamycin. It is indicated in urinary-tract infections, chest infections, bacteraemia, septicaemia, severe neonatal infections and other systemic infections due to sensitive organisms.

## Imipenem/Cilastatin 500mg/500mg powder for solution for injection
(DCP successful, RMS: PT)

Pharmacotherapeutic group: Antibacterials for systemic use, ATC code: J01D H51.

Imipenem is a beta-lactam antibacterial agent of the carbapenem class. It exerts its antibacterial action by inhibiting bacterial cell wall synthesis. Cilastatin sodium is a competitive, reversible, and specific inhibitor of dehydropeptidase-I, the renal enzyme which metabolises and inactivates imipenem. Cilastatin sodium does not exert any antibacterial activity. It is indicated for the treatment of severe infections due to susceptible organisms such as nosocomial pneumonia, complicated community acquired pneumonia requiring hospitalisation, complicated intra-abdominal infections, complicated genito-urinary infections and complicated skin and soft tissue infections.

## **Lincomycin 300mg/1ml & 600mg/2ml ampoules** (ready CTD)

**Pharmacotherapeutic group: Lincosamides, Anti-bacterials for systemic use, ATC code: J01FF02.**

Depending on the sensitivity of the organism and the concentration of the antibiotic, lincomycin may have a bactericidal or bacteriostatic action. It is indicated for the treatment of serious infections caused by aerobic Gram-positive, sensitive to lincomycin, such as streptococci, pneumococci and staphylococci, or bacteria anaerobic sensitive such as: upper respiratory tract infections, certain cases of chronic otitis media suppurating or as adjunctive therapy with an antibiotic active against gram-negative aerobic organisms, lower respiratory tract infections, serious infections of the skin and soft tissue infections caused by germs resistant to penicillins, bone and joint infections, septicaemia and endocarditis and selected cases of sepsis and/or endocarditis.

## **Linezolid 600mg film coated tablets** (DCP successful, RMS SE)

**Pharmacotherapeutic group: Other antibacterials, ATC code: J01XX08.**

Linezolid is a synthetic, antibacterial agent that belongs to a new class of antimicrobials, the oxazolidinones. It has in vitro activity against aerobic Gram positive bacteria and anaerobic micro-organisms. Linezolid selectively inhibits bacterial protein synthesis via a unique mechanism of action. Linezolid is indicated in adults for the treatment of community acquired pneumonia and nosocomial pneumonia when known or suspected to be caused by susceptible Gram positive bacteria. Linezolid is also indicated in adults for the treatment of complicated skin and soft tissue infections only when microbiological testing has established that the infection is known to be caused by susceptible Gram positive bacteria.

## **Meropenem 500 mg & 1 g dry powder for injection in vials** (DCP successful, RMS PT + zone IVa & IVb stability)

**Pharmacotherapeutic group: anti-bacterials for systemic use, carbapenems, ATC code: J01DH02.**

Meropenem exerts its bactericidal activity by inhibiting bacterial cell wall synthesis in Gram-positive and Gram-negative bacteria through binding to penicillin-binding proteins (PBPs). It is indicated for the treatment of the following infections in adults and children aged 3 months and older: severe pneumonia, including hospital and ventilator-associated pneumonia, broncho-pulmonary infections in cystic fibrosis, complicated urinary tract infections, complicated intra-abdominal infections, intra- and post-partum infections, complicated skin and soft tissue infections, acute bacterial meningitis. It also may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.

## **Moxifloxacin 400mg film coated tablets** (DCP successful, RMS NL)

**Pharmacotherapeutic group: Quinolone antibacterials, fluoroquinolones, ATC code: J01MA14.**

Moxifloxacin is a fourth-generation synthetic fluoroquinolone antibacterial agent. It is approved as a once-daily 400 mg antibiotic in patients of 18 years and older for the treatment of different infections. An estimated 140 million prescriptions have been issued for moxifloxacin worldwide, and the drug is included as an effective alternative in guidelines and/or recommendations for each of approved indications. It is used in treatment of Acute bacterial sinusitis, Acute exacerbations of chronic bronchitis, Community acquired pneumonia, Mild to moderate pelvic inflammatory disease, Complicated skin and skin structure infections. It is also used for the symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome.

## **Piperacillin/Tazobactam 2g/250mg** (DCP successful, RMS NL) **& 4g/0.5g** (DCP ongoing, RMS: NL, line extension) **powder for solution for infusion**

**Pharmacotherapeutic group: Antibacterials for systemic use, Combinations of penicillins incl. beta-lactamase inhibitors, ATC code: J01C R05.**

Piperacillin, a broad-spectrum, semisynthetic penicillin exerts bactericidal activity by inhibition of both septum and cell-wall synthesis. Tazobactam, a beta-lactam structurally related to penicillins, is an inhibitor of many beta-lactamases, which commonly cause resistance to penicillins and cephalosporins, but it does not inhibit AmpC enzymes or metallo beta-lactamases. Tazobactam extends the antibiotic spectrum of piperacillin to include many beta-lactamase-producing bacteria that have acquired resistance to piperacillin alone. It is indicated in adults and children over 2 years of age for the treatment of infections such as severe pneumonia including hospital-acquired and ventilator-associated pneumonia, complicated urinary tract infections (including pyelonephritis), complicated intra-abdominal infections and complicated skin and soft tissue infections (including diabetic foot infections).

# CNS drugs

**Aripiprazole 7.5 mg/ml solution for IM injection (ampoules) - short acting injection** (DCP successful, RMS: CY)

Pharmacotherapeutic group: Psycholeptics, other antipsychotics, ATC code: N05AX12.

It has been proposed that aripiprazole's efficacy in schizophrenia and Bipolar I Disorder is mediated through a combination of partial agonism at dopamine D2 and serotonin 5-HT1A receptors and antagonism of serotonin 5-HT2A receptors. It is indicated for the rapid control of agitation and disturbed behaviours in adult patients with schizophrenia or with manic episodes in Bipolar I Disorder, when oral therapy is not appropriate.

**Aripiprazole 1mg, 2.5mg & 5mg tablets** (DCP successful, RMS: NL)

Pharmacotherapeutic group: Psycholeptics, other antipsychotics, ATC code: N05AX12.

Aripiprazole doses ranging from 1mg to 30 mg. It is indicated for the treatment of schizophrenia in adults and in adolescents aged 15 years and older, for the treatment of moderate to severe manic episodes in Bipolar I Disorder and for the prevention of a new manic episode in adults who experienced predominantly manic episodes and whose manic episodes responded to aripiprazole treatment and for the treatment up to 12 weeks of moderate to severe manic episodes in Bipolar I Disorder in adolescents aged 13 years and older.

**Aripiprazole 5mg, 10mg, 15mg, 20mg & 30mg tablets** (DCP successful, RMS EE)

Same as above.

**Amisulpride 50mg, 100mg, 200mg & 400mg tablets** (DCP successful, RMS DK)

Pharmacotherapeutic group: Psycholeptics, antipsychotics, benzamides, ATC code: N05AL05.

Amisulpride is a second-generation (atypical) antipsychotic. It is indicated for the treatment of acute and chronic schizophrenic disorders with positive symptoms (such as delusions, hallucinations, thought disorders, hostility and paranoid delusions) and negative symptoms (such as blunted affect, emotional and social withdrawal). Amisulpride has one of the lowest potentials for weight gain of all the antipsychotic agents, and is associated with clearly lower use of antiparkinsonian medication and with fewer dropouts due to adverse events than conventional antipsychotics.

**Duloxetine 30mg & 60mg capsules** (DCP successful, RMS NL)

Pharmacotherapeutic group: Other antidepressants, ATC code: N06AX21.

Duloxetine is a combined serotonin (5-HT) and noradrenaline (NA) reuptake inhibitor. Duloxetine 20mg and 40mg capsules are indicated for women for the treatment of moderate to severe Stress Urinary Incontinence (SUI). Duloxetine 30mg and 60mg capsules are indicated for Treatment of major depressive disorder, diabetic peripheral neuropathic pain and generalised anxiety disorder.

**Entacapone 200 mg tablets** (DCP successful, RMS NL)

Pharmacotherapeutic group: other dopaminergic agents, ATC code: N04BX02.

Entacapone is a catechol-O-methyl transferase (COMT) inhibitors. It is a reversible, specific, and mainly peripherally acting COMT inhibitor designed for concomitant administration with levodopa preparations. It is indicated as an adjunct to standard preparations of levodopa/benserazide or levodopa/carbidopa for use in adult patients with Parkinson's disease and end-of-dose motor fluctuations, who cannot be stabilised on those combinations.

## **Escitalopram 5 mg, 10 mg, 15 mg & 20 mg tablets** (DCP successful, RMS EE)

**Pharmacotherapeutic group: antidepressants, selective serotonin reuptake inhibitors, ATC code: N06AB10.**

Escitalopram is the S-enantiomer of the selective serotonin reuptake inhibitor (SSRI) citalopram, which contains equal amounts of the S- and R- forms in a racemic mixture. Escitalopram is the most selective SSRI, with almost no significant affinity to other tested receptors.

It is indicated for treatment of major depressive episodes, treatment of panic disorder with or without agoraphobia, treatment of social anxiety disorder (social phobia), treatment of generalised anxiety disorder and treatment of obsessive-compulsive disorder.

## **Eslicarbazepine 800 mg tablets** (DCP successful, RMS PT)

**Pharmacotherapeutic group: Antiepileptics, carboxamide derivatives, ATC code: N03AF04.**

Eslicarbazepine acetate and its active metabolites prevented the development of seizures in nonclinical models predictive of anticonvulsant efficacy in man. In humans, the pharmacological activity of eslicarbazepine acetate is primarily exerted through the active metabolite eslicarbazepine. It is indicated as monotherapy in the treatment of partial-onset seizures, with or without secondary generalisation, in adults with newly diagnosed epilepsy and as adjunctive therapy in adults, adolescents and children aged above 6 years, with partial-onset seizures with or without secondary generalisation.

## **Levodopa/Carbidopa 100mg/25mg & 250mg/25mg film coated tablets** (DCP successful, RMS MT)

**Pharmacotherapeutic group: Dopa and dopa derivatives, levodopa and decarboxylase inhibitor.**

Levodopa is a precursor of dopamine, and is given as replacement therapy in Parkinson's disease. Carbidopa is a peripheral dopa decarboxylase inhibitor. It prevents metabolism of levodopa to dopamine in the peripheral circulation, ensuring that a higher proportion of the dose reaches the brain, where dopamine acts. It is indicated for treatment of Parkinson's disease and syndrome. It is useful in relieving many of the symptoms of Parkinsonism, particularly rigidity and bradykinesia. It is frequently helpful in the management of tremor, dysphagia, sialorrhoea, and postural instability associated with Parkinson's disease and syndrome. Clinical effect of levodopa in Parkinson's disease was first demonstrated in the early 1970s and remains the "gold standard" treatment for this condition.

## **Levosulpiride 25mg, 50mg & 100mg tablets** (DCP successful, RMS IT)

**Pharmacotherapeutic group: Psycholeptics, antipsychotics, ATC code: N05AL07.**

Levosulpiride is the levo-enantiomer of sulpiride. It has shown greater central antidopaminergic activity, antiemetic and antidyspeptic effects and lower acute toxicity than both the racemicand dextro forms. Levosulpiride 25mg tablets are indicated in dyspeptic syndrome from delayed gastric emptying related to organic factors and / or functional factors, essential headache: vasomotor forms and muscle-tensive forms , nausea and vomiting (post-operative or induced by anticancer drugs) and dizziness, by central or peripheral origin. Levosulpiride 50mg and 100mg tablets are indicated in endogenous and reactive depression, somatoform disorders and acute and chronic schizophrenia.

## **Lorazepam 4mg/ml ampoules** (DCP successful, RMS NL)

**Pharmacotherapeutic group: Benzodiazepine derivatives, Anxiolytics, ATC Code: N05 CD06.**

Lorazepam is a benzodiazepine with anxiolytic, sedative, hypnotic, anticonvulsant and muscle relaxant properties. It is indicated for pre-operative medication or premedication for uncomfortable or prolonged investigations, e.g. bronchoscopy, arteriography, endoscopy, the treatment of acute anxiety states, acute excitement or acute mania, and the control of status epilepticus.

## **Lorazepam 2 mg/ml ampoules** (DCP successful, RMS: NL)

**Pharmacotherapeutic group: Benzodiazepine derivatives, Anxiolytics, ATC Code: N05 CD06.**

Lorazepam is a benzodiazepine with anxiolytic, sedative, hypnotic, anticonvulsant and muscle relaxant properties. It is indicated for pre-operative medication or premedication for uncomfortable or prolonged investigations, e.g. bronchoscopy, arteriography, endoscopy, the treatment of acute anxiety states, acute excitement or acute mania, and the control of status epilepticus.

## **Lorazepam 0.5 mg, 1mg & 2.5mg tablets** (DCP successful, RMS NL)

**Pharmacotherapeutic group: Benzodiazepine derivatives, Anxiolytics, ATC Code: N05 CD06.**

Lorazepam is a short acting benzodiazepine with anxiolytic, sedative, hypnotic and muscle relaxant properties. It is indicated for short term treatment of unacceptable disabling or distressful anxiety states including anxiety associated with psychosomatic, organic and psychotic illness, and the short term treatment of insomnia associated with anxiety. It may also be used as premedication before operative dentistry and general surgery. The duration of treatment varies from a few days to 4 weeks.

## **Memantine 5mg, 10mg, 15mg & 20mg tablets** (DCP successful, RMS NL)

**Pharmacotherapeutic group: Other Anti-dementia drugs, ATC code: N06DX01.**

Memantine is a voltage-dependent, moderate-affinity uncompetitive NMDA-receptor antagonist. It modulates the effects of pathologically elevated tonic levels of glutamate that may lead to neuronal dysfunction. It is indicated in treatment of patients with moderate to severe Alzheimer's disease.

## **Pregabalin 75mg, 150mg & 300mg capsules** (DCP successful, RMS NL)

**Pharmacotherapeutic group: Antiepileptics, other antiepileptics, ATC code: N03AX16.**

Pregabalin, has a similar pharmacological profile to that of its predecessor gabapentin, but showed greater analgesic activity in rodent models of neuropathic pain. The antiallodynic and antihyperalgesic effects of pregabalin were observed at dosages 2- to 4-fold lower than those of gabapentin. It is indicated for the treatment of peripheral and central neuropathic pain in adults, as adjunctive therapy in adults with partial seizures with or without secondary generalisation and for the treatment of Generalised Anxiety Disorder (GAD) in adults.

## **Risperidone 1mg/ml oral solution** (DCP successful, RMS CY)

**Pharmacotherapeutic group: Other antipsychotics, ATC code: N05AX08.**

Risperidone is a selective monoaminergic antagonist with unique properties. It has a high affinity for serotoninergic 5-HT2 and dopaminergic D2 receptors. Risperidone binds also to alpha1-adrenergic receptors, and, with lower affinity, to H1-histaminergic and alpha2-adrenergic receptors. It is indicated for the treatment of schizophrenia, moderate to severe manic episodes associated with bipolar disorders, the short-term treatment (up to 6 weeks) of persistent aggression in patients with moderate to severe Alzheimer's dementia unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others and the short-term symptomatic treatment (up to 6 weeks) of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation diagnosed according to DSM-IV criteria, in whom the severity of aggressive or other disruptive behaviours require pharmacologic treatment.

## **Trazodone 50mg and 100mg tablets** (ready CTD)

**Pharmacotherapeutic group: Other antidepressants, ATC code: NO6AX05.**

Trazodone hydrochloride is a triazolopyridine derivative, with no chemical or structural relationship to known tricyclic, tetracyclic, and other antidepressant agents. Trazodone is an antidepressant, with anxiety reducing properties. Trazodone has negligible effects on noradrenaline reuptake mechanism. It is indicated for the relief of symptoms in all types of depression including depression accompanied by anxiety.

## **Trazodone 150mg & 300mg prolonged release tablets** (Q1 2026, RMS: NL)

**Pharmacotherapeutic group: Other antidepressants, ATC code: NO6AX05.**

Trazodone hydrochloride is a triazolopyridine derivative, with no chemical or structural relationship to known tricyclic, tetracyclic, and other antidepressant agents. Trazodone is an antidepressant, with anxiety reducing properties. Trazodone has negligible effects on noradrenaline reuptake mechanism. It is indicated for the relief of symptoms in all types of depression including depression accompanied by anxiety.

## **Vortioxetine 5mg, 10mg, 15mg and 20mg film-coated tablets** (Q4/2025, RMS: NL)

**Pharmacotherapeutic group: Psychoanaleptics; Other antidepressants, ATC code: N06AX26.**

The mechanism of action of vortioxetine is thought to be related to its direct modulation of serotonergic receptor activity and inhibition of the serotonin (5-HT) transporter. It is used for the treatment of major depressive episodes in adults.

# Respiratory / Anti-Allergic drugs

**Ambroxol HCl 15mg/5 ml & 30 mg/5 ml oral solution** (DCP successful; RMS PT, VN production site)

Pharmacotherapeutic group: mucolytics, ATC code: R05CB06.

Ambroxol hydrochloride has been shown to increase respiratory tract secretion. It increases the secretion of surfactant in the lung and increases the ciliary activity. These actions result in improved mucus secretion and transport (mucociliary clearance). Stimulation of the secretion and mucociliary clearance facilitates expectoration and smoothes cough. It is indicated as secretolytic, for the treatment of acute bronchial disorders or acute episodes of chronic bronchopneumopathy or other chronic bronchopulmonary disorders associated with abnormal mucous secretion and impaired mucus transport.

**Butamirate Citrate 1.5mg/ml oral solution** (DCP successful; RMS LV, VN: production site)

Pharmacotherapeutic group: Cough suppressant, ATC code: R05DB13.

Butamirate (or brospamin) is a cough suppressant. A study found it to bind to the cough center in the medulla oblongata. As a 2-(2-diethylaminoethoxy)ethyl ester, it is chemically related to oxeladin and pentoxyverine, which are in the same class. It is indicated for the symptomatic treatment of dry, irritant cough of various origins.

**Dextromethorphan 1.5 mg/ml syrup** (DCP successful, RMS EE)

Pharmacotherapeutic group: Opium alkaloids and derivatives, ATC code: N07XX59.

Dextromethorphan is an antitussive drug. It exerts its antitussive activity by acting on the cough centre in the medulla oblongata, raising the threshold for the cough reflex. A single oral dose of 10-20 mg dextromethorphan produces its antitussive action within 1 hour and lasts for at least 4 hours. It is indicated as an antitussive, for the relief of persistent, dry, irritating cough.

**Diphenhydramine 25mg & 50mg tablets** (Q2 2026, RMS: TBC)

Pharmacotherapeutic classification: Antihistamines for Systemic Use - aminoalkyl ethers.
ATC code: R06AA02

Diphenhydramine is an ethanolamine-derivative antihistamine. It is an antihistamine with anticholinergic and marked sedative effects. It acts by inhibiting the effects on H1-receptors. Diphenhydramine is effective in reducing sleep onset (i.e. time to fall asleep) and increasing the depth and quality of sleep.

# Cardiovascular drugs

**Apixaban 2.5 & 5 mg/tab film coated tablets** (DCP ongoing, RMS: LV)

Pharmacotherapeutic group: Antithrombotic agents, direct factor Xa inhibitors, ATC code: B01AF02.

Apixaban is a potent, oral, reversible, direct and highly selective active site inhibitor of factor Xa. It is indicated for the prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery, prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age ≥ 75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class ≥ II), treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

**Irbesartan/HCTZ 150mg/12.5mg, 300mg/12.5mg, 150mg/25mg & 300mg/25mg tablets** (DCP successful, RMS NL)

Pharmacotherapeutic group: angiotensin-II antagonists, combinations.

Irbesartan/HCTZ is a combination of an angiotensin-II receptor antagonist, irbesartan, and a thiazide diuretic, hydrochlorothiazide. The combination of these ingredients has an additive antihypertensive effect, reducing blood pressure to a greater degree than either component alone.This fixed dose combination is indicated for treatment of essential hypertension in adult patients whose blood pressure is not adequately controlled on irbesartan or hydrochlorothiazide alone.

**Ivabradine 5mg & 7.5mg film coated tablets** (DCP successful, RMS LV)

Pharmacotherapeutic group: Other cardiac preparations, ATC code: C01EB17.

Ivabradine is a heart rate lowering agent, acting by selective and specific inhibition of the cardiac pacemaker If current that regulates heart rate. It is a well-tolerated drug. Clinical studies showed that < 1% of patients withdraw because of side effects. This is due to the characteristic pharmacodynamics of ivabradine. Ivabradine is indicated for the symptomatic treatment of chronic stable angina pectoris in coronary artery disease adults with normal sinus rhythm and heart rate ≥ 70 beats per minute (bpm). It is also indicated in chronic heart failure NYHA II to IV class with systolic dysfunction, in patients in sinus rhythm and whose heart rate is ≥ 75 bpm, in combination with standard therapy including beta-blocker therapy or when beta-blocker therapy is contraindicated or not tolerated.

**Pitavastatin 1mg, 2mg & 4mg film coated tablets** (DCP successful, RMS NL)

Pharmacotherapeutic group: HMG-CoA reductase inhibitors, ATC code: C10AA08.

Pitavastatin is an inhibitor of HMG-CoA reductase, the enzyme that catalyses the first step of cholesterol synthesis. Pitavastatin is indicated for the reduction of elevated total cholesterol (TC) and LDL-C, in adults, adolescents and children aged 6 years or older with primary hypercholesterolemia, including heterozygous familial hypercholesterolemia, and combined (mixed) dyslipidaemia, when response to diet and other non-pharmacological measures is inadequate.

## **Rivaroxaban 15 mg, 20 mg tablets** (DCP successful, RMS DK)

**Pharmacotherapeutic group: Antithrombotic agents, direct factor Xa inhibitors, ATC code: B01AF01.**

Rivaroxaban is a highly selective direct factor Xa inhibitor with oral bioavailability. It is indicated for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke or transient ischaemic attack, treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. It is also indicated for the treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years and weighing from 30 kg to 50 kg (15mg) and weighing more than 50 kg (20mg) after at least 5 days of initial parenteral anticoagulation treatment.

## **Rivaroxaban 2.5 mg tablets** (DCP successful, RMS: DK)

**Pharmacotherapeutic group: Direct factor XA Inhibitor, ATC code: B01AF01.**

Rivaroxaban is an anticoagulant medication (blood thinner) used to treat and prevent blood clots. Rivaroxaban 2.5mg co-administered with acetylsalicylic acid (ASA) alone or with ASA plus clopidogrel or ticlopidine, is indicated for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers. Rivaroxaban 2.5mg co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events.

## **Rosuvastatin 5mg, 10mg, 20mg & 40mg tablets** (DCP successful, RMS DK)

**Pharmacotherapeutic group: HMG-CoA reductase inhibitors, ATC code: C10AA07.**

Rosuvastatin is a selective and competitive inhibitor of HMG-CoA reductase. The primary site of action of rosuvastatin is the liver, the target organ for cholesterol lowering. Rosuvastatin reduces elevated LDL-cholesterol, total cholesterol and triglycerides and increases HDL- cholesterol. It also lowers ApoB, nonHDL-C, VLDL-C, VLDL-TG and increases ApoA-I. Rosuvastatin also lowers the LDL-C/HDL-C, total C/HDL-C and nonHDL-C/HDL-C and the ApoB/ApoA-I ratios. It is indicated in the treatment of hypercholesterolaemia and prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.

## **Spironolactone 25mg (divisible), 50mg & 100mg tablets** (DCP successful, RMS LT)

**Pharmacotherapeutic group: potassium-sparing agents, ATC code C03DA01.**

Spironolactone, as a competitive aldosterone antagonist, increases sodium excretion whilst reducing potassium loss at the distal renal tubule. It has a gradual and prolonged action. It is indicated for congestive cardiac failure, hepatic cirrhosis with ascites and oedema, malignant ascites, nephrotic syndrome and diagnosis and treatment of primary aldosteronism.

## **Sacubitril/Valsartan 24mg/26mg, 49mg/51mg, 97mg/103mg film-coated tablets** (Q1 2027, RMS: EE)

**Pharmacotherapeutic group: Agents acting on the renin-angiotensin system; angiotensin II receptor blockers (ARBs), other combinations, ATC code: C09DX04.**

Sacubitril/valsartan exhibits the mechanism of action of an angiotensin receptor neprilysin inhibitor by simultaneously inhibiting neprilysin (neutral endopeptidase; NEP) via LBQ657, the active metabolite of the prodrug sacubitril, and by blocking the angiotensin II type-1 (AT1) receptor via valsartan. The complementary cardiovascular benefits of sacubitril/valsartan in heart failure patients are attributed to the enhancement of peptides that are degraded by neprilysin, such as natriuretic peptides (NP), by LBQ657 and the simultaneous inhibition of the effects of angiotensin II by valsartan. NPs exert their effects by activating membrane-bound guanylyl cyclase-coupled receptors, resulting in increased concentrations of the second messenger cyclic guanosine monophosphate (cGMP), which could result in vasodilation, natriuresis and diuresis, increased glomerular filtration rate and renal blood flow, inhibition of renin and aldosterone release, reduction of sympathetic activity, and anti-hypertrophic and anti-fibrotic effects.

## **Ticagrelor 60mg and 90mg film coated tablets** (DCP successful, RMS DK)

**Pharmacotherapeutic group: Antithrombotic agents; Platelet aggregation inhibitors excl. heparin, ATC code: B01AC24.**

Ticagrelor, a member of the chemical class cyclopentyltriazolopyrimidines (CPTP), is an oral, direct acting, selective and reversibly binding P2Y12 receptor antagonist that prevents ADP-mediated P2Y12 dependent platelet activation and aggregation. It is indicated, co-administered with acetylsalicylic acid (ASA) for the prevention of atherothrombotic events in adult patients with acute coronary syndromes (ACS) or a history of myocardial infarction (MI) and a high risk of developing an atherothrombotic event.

## **Valsartan 80mg & 160mg film coated tablets** (DCP successful, RMS SE + zone IVa & IVb stability)

**Pharmacotherapeutic group: Agents acting on the renin-angiotensin system, angiotensin II antagonists, plain, ATC code: C09CA03.**

Valsartan is an orally active, potent, and specific angiotensin II (Ang II) receptor antagonist. It acts selectively on the AT1 receptor subtype, which is responsible for the known actions of angiotensin II. The anti-hypertensive effect of valsartan persists for 24 hours after dosing. It is indicated in the treatment of essential hypertension in adults, and hypertension in children and adolescents 6 to 18 years of age; Recent myocardial infarction; Heart failure. It is also used for the symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome.

# Analgesics

**Aceclofenac 100mg film-coated tablets** (DCP ongoing, RMS: SK)

**Pharmacotherapeutic group: Non-steroidal agent with marked anti-inflammatory and analgesic properties, ATC code: M01AB16.**

The mode of action of aceclofenac is largely based on the inhibition to prostaglandin synthesis. Aceclofenac is a potent inhibitor of the enzyme cyclo-oxygenase, which is involved in the production of prostaglandins.

**Diclofenac diethylamine 1.16%** (Dossier ready) **& 2.32% emulgel** (DCP successful, RMS: NL)

**Pharmacotherapeutic group: Topical products for joint and muscular pain; Anti-inflammatory preparations, non-steroids for topical use, ATC code: M02AA15.**

Diclofenac is a potent non-steroidal anti-inflammatory drug. It develops its therapeutic efficacy mainly via inhibition of prostaglandin synthesis by cyclooxygenase 2 (COX-2). It is indicated for adults and adolescents aged 14 years and over for the short-term local, symptomatic treatment of mild to moderate pain in acute strains, sprains or contusions following blunt trauma.

**Diclofenac potassium 12.5mg tablets** (DCP successful, RMS NL)

**Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroids, acetic acid derivatives and related substances, diclofenac, ATC code: M02AA15.**

Diclofenac potassium is a non-steroidal analgesic with anti-inflammatory and antipyretic properties. It is indicated for use in adults and children aged 14 years and over in rheumatic pain, muscular pain, headache, dental pain, symptomatic treatment of primary dysmenorrhea, acute low back pain, cold and flu symptoms, including fever relief, sore throats and colds. In some markets this strength is an O.T.C.

**Dexketoprofen 12.5 mg & 25 mg film coated tablets** (DCP successful, RMS CY)

**Pharmacotherapeutic group: propionic acid derivatives, ATC code: M01AE17.**

Dexketoprofen trometamol is the tromethamine salt of S-(+)-2-(3-benzoylphenyl)propionic acid, an analgesic, anti-inflammatory and antipyretic drug, which belongs to the non-steroidal anti-inflammatory group of drugs. Dexketoprofen has been demonstrated to be an inhibitor for COX-1 and COX-2 activities in experimental animals and humans. It is used in the symptomatic treatment of pain of mild to moderate intensity, such as musculo-skeletal pain, dysmenorrhoea, dental pain.

**Ibuprofen lysine 342 mg & 684 mg film coated tablets** (DCP successful, RMS PT)

**Pharmacotherapeutic group: Anti-inflammatory and anti-rheumatic products, non-steroids; propionic acid derivative , ATC code: M02AA13.**

Ibuprofen lysine is the lysine salt of ibuprofen. Ibuprofen is a propionic acid derivative NSAID that has demonstrated its efficacy by inhibition of prostaglandin synthesis. In humans, ibuprofen reduces inflammatory pain, swellings and fever. Furthermore, ibuprofen reversibly inhibits platelet aggregation. Clinical evidence demonstrates that ibuprofen, in the form of salts such as ibuprofen sodium and ibuprofen lysine, acts significantly faster than standard ibuprofen acid tablets for the relief of mild-moderate pain. It is used to treat mild to moderate pain, such as: Headaches, migraines, toothaches, period pain, muscle aches, rheumatic pain, backache, neuralgia. It is also used for the symptomatic treatment of cold and flu and fever lasting less than 3 days.

## **Nefopam 20 mg/2ml ampoules** (DCP successful, RMS EE)

**Pharmacotherapeutic group: Other analgesics and antipyretics, Analgesics, ATC code: N02BG06.**

Nefopam is a potent and rapidly acting analgesic. It is totally distinct from other centrally acting analgesics such as morphine, codeine, pentazocine and propoxyphene. Unlike the narcotic agents, Nefopam has been shown not to cause respiratory depression. It is indicated for the short term relief of acute pain.

## **Nefopam 30mg film-coated tablets** (Q4 2025, RMS: EE)

Same as above.

## **Nimesulide 30mg/g gel** (Q3 2026, RMS: TBC)

**Pharmacotherapeutic group: Non-steroidal anti-inflammatory drug for topical use, ATC code: M02AA.**

Nimesulide is a non-steroidal anti-inflammatory drug (NSAID) that primarily acts as an inhibitor of the prostaglandin synthesis enzyme cyclooxygenase. It also exhibits other pharmacological effects, including analgesic and antipyretic properties. It is used for symptomatic relief of pain associated with sprains and acute traumatic tendinitis in adults and children of 12+ years of age. When Nimesulide 3% w/w gel is applied topically, plasma concentrations of nimesulide are very low in comparison with those achieved following oral intake. After a single application of 200mg of nimesulide, in the gel form, the highest plasma level of 9.77 ng/ml was noted after 24 hours. At steady-state (day 8) peak plasma concentrations were higher (37.25 ± 13.25 ng/ml) but almost 100 times lower than those measured following repeated oral administration.

## **Paracetamol 24mg/ml oral solution** (Q3 2025, CY)

**Pharmacotherapeutic group: Analgesic, antipyretic, ATC code: N02BE01.**

Paracetamol is an anilide derivative with corresponding analgesic and antipyretic properties such as acetylsalicylic acid. Paracetamol, in contrast to acetylsalicylic acid, does not cause gastrointestinal irritation and is well tolerated even by patients with ulcers. Paracetamol affects nor platelet aggregation or bleeding time. Paracetamol is generally well tolerated by patients with hypersensitivity to aspirin. indications. Therapeutic indications are: Headache, toothache, fever with colds, menstrual pain, muscle and joint pain, as an analgesic in rheumatic pains, hyperpyrexia.

## **Sufentanil 0.005 mg/ml & 0.05 mg/ml ampoules** (DCP successful, RMS DK)

**Pharmacotherapeutic group: Analgesics, opioids, ATC code: N01AH03.**

Sufentanil is a synthetic, potent opioid with highly selective binding to μ-opioid receptors. Sufentanil acts as a full agonist in μ-opioid receptors. Sufentanil does not induce histamine release. All effects of sufentanil can immediately and completely be blocked by administration of a specific antagonist such as naloxone. When used in balanced general anesthesia, sufentanil has been reported to be as much as 10 times as potent as fentanyl. When administered intravenously as a primary anesthetic agent with 100% oxygen, sufentanil is approximately 5 to 7 times as potent as fentanyl. It is indicated for intravenous administration in adults and pediatric patients: as an analgesic adjunct in the maintenance of balanced general anesthesia in patients who are intubated and ventilated; As a primary anesthetic agent for the induction and maintenance of anesthesia with 100% oxygen in patients undergoing major surgical procedures, in patients who are intubated and ventilated, such as cardiovascular surgery or neurosurgical procedures in the sitting position, to provide favorable myocardial and cerebral oxygen balance or when extended postoperative ventilation is anticipated ; For epidural administration as an analgesic combined with low dose (usually 12.5 mg per administration) bupivacaine during labor and vaginal delivery.

## **Tapentadol HCl 25mg, 50 mg, 75 mg & 100 mg film coated tablets** (DCP successful, RMS NL)

**Pharmacotherapeutic group: Analgesics; opioids; other opioids, ATC code: N02AX06.**

Tapentadol is a strong analgesic with μ-agonistic opioid and additional noradrenaline reuptake inhibition properties. Tapentadol exerts its analgesic effects directly without a pharmacologically active metabolite. Tapentadol demonstrated efficacy in preclinical models of nociceptive, neuropathic, visceral and inflammatory pain; In general the analgesic effect of tapentadol in nociceptive pain trials was similar to that observed with a strong opioid used as comparator. Effects on the cardiovascular system: In a thorough human QT trial, no effect of multiple therapeutic and supratherapeutic doses of tapentadol on the QT interval was shown. Similarly, tapentadol had no relevant effect on other ECG parameters. It is indicated for the relief of moderate to severe acute pain in adults, which can be adequately managed only with opioid analgesics.

## **Tapentadol HCl 50 mg, 100 mg and 150 mg prolonged release tablets** (DCP successful, RMS NL)

**Pharmacotherapeutic group: Analgesics; opioids; other opioids, ATC code: N02AX06.**

Tapentadol is a strong analgesic with μ-agonistic opioid and additional noradrenaline reuptake inhibition properties. It is indicated for the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics.

# Antidiabetics

## **Empagliflozin 10mg & 25mg film coated tablets** (DCP successful, RMS NL)

**Pharmacotherapeutic group: Drugs used in diabetes, Sodium-glucose co-transporter 2 (SGLT2) inhibitors, ATC code: A10BK03.**

Empagliflozin is a reversible, highly potent (IC50 of 1.3 nmol) and selective competitive inhibitor of sodium-glucose co-transporter 2 (SGLT2). Empagliflozin does not inhibit other glucose transporters important for glucose transport into peripheral tissues and is 5 000 times more selective for SGLT2 versus SGLT1, the major transporter responsible for glucose absorption in the gut. It is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise either as monotherapy when metformin is considered inappropriate due to intolerance or in addition to other medicinal products for the treatment of diabetes.

## **Empagliflozin/Metformin 5mg/850mg, 5mg/1000mg, 12.5mg/850mg, 12.5mg/1000mg film-coated tablets** (Q4 2026, RMS: NL)

**Pharmacotherapeutic group: Drugs used in diabetes, combinations of oral blood glucose lowering drugs, ATC code: A10BD20.**

Combines two antihyperglycaemic medicinal products with complementary mechanisms of action to improve glycaemic control in patients with type 2 diabetes: empagliflozin, an inhibitor of sodium-glucose co-transporter 2 (SGLT2), and metformin hydrochloride, a member of the biguanide class. It is indicated in adults and children aged 10 years and above for the treatment of type 2 diabetes mellitus as an adjunct to diet and exercise in patients insufficiently controlled on their maximally tolerated dose of metformin alone and in combination with other medicinal products for the treatment of diabetes, in patients insufficiently controlled with metformin and these medicinal products and in patients already being treated with the combination of empagliflozin and metformin as separate tablets.

## **Linagliptin 5 mg film coated tablets** (DCP successful, RMS CY)

**Pharmacotherapeutic group: Drugs used in diabetes, dipeptidyl peptidase 4 (DPP-4) inhibitors, ATC code: A10BH05.**

Linagliptin is an inhibitor of the enzyme DPP-4 (dipeptidyl peptidase 4) an enzyme which is involved in the inactivation of the incretin hormones GLP-1 and GIP. It is indicated in adults with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control as monotherapy when metformin is inappropriate due to intolerance, or contraindicated due to renal impairment or as combination therapy in combination with other medicinal products for the treatment of diabetes, including insulin, when these do not provide adequate glycaemic control.

## **Metformin 500mg, 850mg & 1g film coated tablets** (DCP successful, RMS EE, VN production site + Zone IVb Stability)

**Pharmacotherapeutic group: Oral antidiabetic agent, Biguanide, ATC code: A10BA02.**

Metformin is a biguanide with antihyperglycaemic effects, lowering both basal and postprandial plasma glucose. It does not stimulate insulin secretion and therefore does not produce hypoglycaemia. In clinical studies, use of metformin was associated with either a stable body weight or modest weight loss. In humans, independently of its action on glycaemia, metformin has favourable effects on lipid metabolism. This has been shown at therapeutic doses in controlled, medium-term or long-term clinical studies: metformin reduces total cholesterol, LDL cholesterol and triglyceride levels. It is indicated for the treatment of type 2 diabetes mellitus, particularly in overweight patients, when dietary management and exercise alone does not result in adequate glycaemic control. It may be used as monotherapy or in combination with other oral antidiabetic agents, or with insulin.

## **Sitagliptin (as Phosphate) 25 mg, 50 mg & 100 mg film coated tablets**
(DCP successful, RMS SE + Zone IVb Stability)

**Pharmacotherapeutic group: Drugs used in diabetes, Dipeptidyl peptidase 4 (DPP-4) inhibitors, ATC code: A10BH01.**

Sitagliptin is a member of a class of oral anti-hyperglycaemic agents called dipeptidyl peptidase 4 (DPP-4) inhibitors. The improvement in glycaemic control observed with this medicinal product may be mediated by enhancing the levels of active incretin hormones. Sitagliptin improved glycaemic control when used as monotherapy or in combination treatment. It is indicated in the treatment of type 2 diabetes mellitus in adults as monotherapy, as dual oral therapy in combination with a sulphonylurea and a thiazolidinedione, and as triple oral therapy in combination with sulphonylurea and metformin. It is also indicated for use in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control.

## **Sitagliptin (as HCl) 25 mg, 50 mg & 100 mg film coated tablets**
(DCP successful, RMS SE)

**Pharmacotherapeutic group: Drugs used in diabetes, Dipeptidyl peptidase 4 (DPP-4) inhibitors, ATC code: A10BH01.**

Sitagliptin is a member of a class of oral anti-hyperglycaemic agents called dipeptidyl peptidase 4 (DPP-4) inhibitors. The improvement in glycaemic control observed with this medicinal product may be mediated by enhancing the levels of active incretin hormones. Sitagliptin improved glycaemic control when used as monotherapy or in combination treatment. It is indicated in the treatment of type 2 diabetes mellitus in adults as monotherapy, as dual oral therapy in combination with a sulphonylurea and a thiazolidinedione, and as triple oral therapy in combination with sulphonylurea and metformin. It is also indicated for use in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control.

## **Sitagliptin/Metformin, 50/850 mg & 50/1000 mg film coated tablets** (DCP successful, RMS SE, VN production site)

**Pharmacotherapeutic group: combinations Drugs used in diabetes, Dipeptidyl peptidase 4 (DPP-4) inhibitors, incl. Biguanide.**

Sitagliptin – from Sita mono / Metformin – from Met mono. Sitagliptin/metformin is a combination medication used to treat type 2 diabetes. It is indicated as an adjunct to diet and exercise to improve glycaemic control in patients inadequately controlled on their maximal tolerated dose of metformin alone or in combination with a sulphonylurea (i.e., triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea or as triple combination therapy with a peroxisome proliferator-activated receptor gamma (PPARγ) agonist (i.e., a thiazolidinedione) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a PPARγ agonist. Sitagliptin/Metformin is also indicated as add-on to insulin (i.e., triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients when stable dose of insulin and metformin alone do not provide adequate glycaemic control.

## **Vildagliptin 50mg tablets** (DCP successful, RMS SE + Zone IVb Stability)

**Pharmacotherapeutic group: Drugs used in diabetes, Dipeptidyl peptidase 4 (DPP-4) inhibitors, ATC code: A10BH02.**

Vildagliptin, a member of the islet enhancer class, is a potent and selective DPP-4 inhibitor. Vildagliptin improves glycaemic control. Vildagliptin is indicated in the treatment of type 2 diabetes mellitus in adults as monotherapy, as dual oral therapy in combination with a sulphonylurea and a thiazolidinedione, and as triple oral therapy in combination with sulphonylurea and metformin. It is also indicated for use in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control.

# Gastrointestinal drugs

**Butylscopolamine 20 mg/ml ampoule** (DCP successful, RMS SE)

Pharmacotherapeutic group: Belladonna alkaloids, semisynthetic, quaternary ammonium compounds, ATC code: A03BB01.

Butylscopolamine is an antispasmodic agent which relaxes smooth muscle of the organs of the abdominal and pelvic cavities. It is believed to act predominantly on the intramural parasympathetic ganglia of these organs. It is indicated in acute spasm, as in renal or biliary colic, in radiology for differential diagnosis of obstruction and to reduce spasm and pain in pyelography, and in other diagnostic procedures where spasm may be a problem, e.g. gastro-duodenal endoscopy.

**Itopride 50 mg tablets** (DCP successful, RMS EE)

Pharmacotherapeutic group: Drugs for functional gastrointestinal disorders, Propulsives, ATC code: A03FA07.

Itopride activates the gastrointestinal propulsive motility by antagonistic action on dopamine D2 receptors and inhibitory action on acetylcholine esterase. Itopride has also an antiemetic action, based on the interaction with dopamine D2 receptors located in the chemoreceptor area. Itopride accelerates gastric emptying in humans. It has highly specific action in the upper gastrointestinal tract. It is indicated in adults as a treatment of gastrointestinal symptoms in functional, non-ulcer dyspepsia (chronic gastritis), such as: flatulence, gastric fullness, upper abdominal pain, anorexia, heartburn, nausea and vomiting.

**Prucalopride (as Succinate) 1 mg & 2 mg film coated tablets**
(DCP successful, RMS NL)

Pharmacotherapeutic group: Other drugs for constipation, ATC code: A06AX05.

Prucalopride is a dihydrobenzofurancarboxamide with gastrointestinal prokinetic activities. It is indicated for symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief.

**Racecadotril 10mg and 30mg granules for oral suspension (sachets)**
(Q3/2025, RMS: CY)

Pharmacotherapeutic group: Other antidiarrhoeals, ATC code: A07XA04.

Racecadotril is a pro-drug that needs to be hydrolysed to its active metabolite thiorphan, which is an inhibitor of enkephalinase, a cell membrane peptidase enzyme located in various tissues, notably the epithelium of the small intestine. It is indicated as a complementary symptomatic treatment of acute diarrhoea in infants (older than 3 months) and in children together with oral rehydration and the usual support measures, when these measures alone are insufficient to control the clinical condition, and when causal treatment is not possible.

# Endocrine drugs

**Dexamethasone 4mg/ml solution for injection/infusion** (DCP successful, RMS NL)

Pharmacotherapeutic group: Corticosteroids for systemic use, plain, Glucocorticoids,
ATC Code: H02AB02.

Dexamethasone is a synthetic glucocorticoid with an anti-inflammatory potency about seven-fold that of prednisolone. As with other glucocorticoids, dexamethasone also possesses anti-allergic, antipyretic and immunosuppressive properties. It is indicated for use in all forms of general and local glucocorticoid injection therapy and in acute cases in which oral glucocorticoid therapy is not feasible and intravenous glucocorticoid therapy maybe lifesaving.

**Hydrocortisone 100mg dry powder for injection in vials** (DCP ongoing, RMS: NL)

Pharmacotherapeutic group: Glucocorticoids, ATC code: H02AB09

Hydrocortisone is an anti-inflammatory agent. Hydrocortisone is indicated for any condition in which rapid and intense corticosteroid effect is required such as: Endocrine disorders, Collagen diseases, Dermatological diseases, Allergic states, Gastro-intestinal diseases, Respiratory diseases and Medical emergencies. Hydrocortisone is indicated in the treatment of shock secondary to adrenocortical insufficiency or shock unresponsive to conventional therapy when adrenocortical insufficiency may be present.

# Miscellaneous

## **Cinnarizine/Dimenhydrinate 20 mg/40 mg tablets** (DCP successful)

**Pharmacotherapeutic group: antivertigo preparations, cinnarizine combination; ATC code: N07CA52.**

Dimenhydrinate acts as antihistamine with anticholinergic (antimuscarinic) properties, exerting parasympatholytic and centrally-depressant effects. The substance exhibits anti-emetic and antivertiginous effects through influencing the chemoreceptor trigger zone in the region of the 4th ventricle. Dimenhydrinate thus acts predominantly on the central vestibular system. Due to its calcium antagonistic properties, cinnarizine acts mainly as a vestibular sedative through inhibition of the calcium influx into the vestibular sensory cells. Cinnarizine thus acts predominantly on the peripheral vestibular system. Both cinnarizine and dimenhydrinate are known to be effective in the treatment of vertigo. The combination product is more effective than the individual compounds in the population studied. It is indicated in the treatment of vertigo symptoms of various origins.

## **Naloxone 0.4mg/1ml ampoules** (DCP successful, RMS DK)

**Pharmacotherapeutic group: Antidotes, ATC code: A06AH04.**

Naloxone hydrochloride is a specific opioid antagonist that acts competitively at opioid receptors. It reveals very high affinity for the opioid receptor sites and therefore displaces both opioid agonists and partial antagonists, such as pentazocine, for example, but also nalorphine. Naloxone does not counteract central depression caused by hypnotics or other non-opioids and does not possess the "agonistic" or morphine-like properties characteristic of other opioid antagonists. Even high doses of the drug (10 times the usual dose) produce insignificant analgesia, only slight drowsiness, and no respiratory depression, psychotomimetic effects, circulatory changes, or miosis. In the absence of opioids or agonistic effects of other opioid antagonists, it exhibits essentially no pharmacologic activity. Because naloxone hydrochloride, unlike nalorphine, does not exacerbate the respiratory depression caused by other substances, it can therefore also be used for differential diagnosis. Naloxone hydrochloride has not been shown to produce tolerance or cause physical or mental dependence. It is indicated for the complete or partial reversal of opioid depression, including mild to severe respiratory depression induced by natural and synthetic opioids; Diagnosis of suspected acute opioid overdosage; Complete or partial reversal of respiratory depression and other CNS depression in neonates whose mothers have received opioids.

## **Palonosetron 0.25mg/5ml ampoules** (DCP successful, RMS SE)

**Pharmacotherapeutic group: Antiemetics and antinauseants, serotonin (5HT3) antagonists, ATC code: A04AA55.**

Palonosetron is a selective high-affinity receptor antagonist of the 5HT3 receptor. It is indicated for the prevention of acute nausea and vomiting associated with moderately and highly emetogenic cancer chemotherapy in adults. It is indicated in paediatric patients 1 month of age and older for the prevention of acute nausea and vomiting associated with moderately and highly emetogenic cancer chemotherapy.

## **Solifenacin succinate 5mg & 10mg film coated tablets** (DCP successful, RMS EE)

**Pharmacotherapeutic group: Urologicals, drugs for urinary frequency and incontinence, ATC code: G04BD08.**

Solifenacin is a competitive inhibitor of the muscarinic M3 subtype receptor. In addition, solifenacin showed to be a specific antagonist for muscarinic receptors by displaying low or no affinity for various other receptors and ion channels tested. It is indicated in the symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome.

## **Tranexamic Acid 500mg/5ml & 1000mg/10ml ampoules**

(DCP successful, RMS SE + zone IVa & IVb stability)

**Pharmacotherapeutic group: Antihemorrhagics, Antifibrinolytics, ATC code: B02AA02.**

Tranexamic acid exerts an anti haemorrhagic activity by inhibiting the fibrinolytic properties of plasmin. It is indicated for prevention and treatment of haemorrhages due to general or local fibrinolysis in adults and children from one year. Specific indications include: Haemorrhage caused by general or local fibrinolysis such as: Menorrhagia and metrorrhagia; Gastrointestinal bleeding; Haemorrhagic urinary disorders, further to prostate surgery or surgical procedures affecting the urinary tract; Ear Nose Throat surgery (adenoidectomy, tonsillectomy, dental extractions); Gynaecological surgery or disorders of obstetric origin; Thoracic and abdominal surgery and other major surgical intervention such as cardiovascular surgery and management of haemorrhage due to the administration of a fibrinolytic agent.

## **Tranexamic Acid 500 mg film coated tablets** (successful, RMS: LT)

**Pharmacotherapeutic group: Antihemorrhagics, Antifibrinolytics, ATC code: B02AA02.**

Tranexamic acid is an antifibrinolytic compound which is a potent competitive inhibitor of the activation of plasminogen to plasmin. It is indicated as short-term use for haemorrhage or risk of haemorrhage in increased fibrinolysis or fibrinogenolysis.

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