**Alimentary tract and metabolism**

**A01AD02 - Benzydamine hydrochloride**
- Active ingredient / dosage: Benzydamine hydrochloride 1.5 mg/ml
- Packaging and form: Bottle of 30 g with dispenser (spray)
- ATC group: A01AD02
- Dossier Status: Available
- Indication: anti-inflammatory, analgesic effect, anaesthetic, disinfectant
- Classification + reference product: Generic – Tantum Verde, liquid, Aziende Chimica Rinunite Angelini Francesco

**Active ingredient / dosage**: Benzydamine hydrochloride 3.0 mg/ml
- ATC group: A01AD02
- Dossier Status: Available
- Indication: anti-inflammatory, analgesic effect, anaesthetic, disinfectant
- Classification + reference product: Generic – Tantum Verde, liquid, Aziende Chimica Rinunite Angelini Francesco

**A03AD02 - Drotaverine**
- Active ingredient / dosage: Drotaverine 40 mg
- Packaging and form: Box of 20, 40 tablets
- ATC group: A03AD02
- Dossier Status: Available
- Indication: Smooth muscle contractions related to bile ducts diseases, urinary tract diseases, supplementary in contractions of alimentary tract smooth muscles and gynecological disorders
- Classification + reference product: Well Established Use

**Active ingredient / dosage**: Drotaverine 80 mg
- ATC group: A03AD02
- Dossier Status: Available
- Indication: Smooth muscle contractions related to bile ducts diseases, urinary tract diseases, supplementary in contractions of alimentary tract smooth muscles and gynecological disorders
- Classification + reference product: Well Established Use

**A06AD11 - Lactulose**
- Active ingredient / dosage: Lactulose 5 g/10 ml
- Packaging and form: Glass bottle of 150 ml syrup
- ATC group: A06AD11
- Dossier Status: Available
- Indication: Constipation, hepatic encephalopathy
- Classification + reference product: Well Established Use

**A07AX03 - Nifuroxazide**
- Active ingredient / dosage: Nifuroxazide 100 mg
- Packaging and form: Box of 24 tablets
- ATC group: A07AX03
- Dossier Status: Available
- Indication: Acute and long-lasting diarrhoea in bacterial infections of the alimentary tract
- Classification + reference product: Generic, Ercefuryl, tablets, 100 mg, Sanofi Synthelabo

**Active ingredient / dosage**: Nifuroxazide 200 mg
- ATC group: A07AX03
- Dossier Status: Available
- Indication: Acute and long-lasting diarrhoea in bacterial infections of the alimentary tract
- Classification + reference product: Generic, Ercefuryl, tablets, 200 mg, Sanofi Synthelabo

**A11CC03 - Cholecalciferol**
- Active ingredient / dosage: Cholecalciferol 0.5 mg/2 ml
- Packaging and form: Drops in glass bottle of 10 ml, unit carton box
- ATC group: A11CC03
- Dossier Status: Available
- Indication: Vitamin deficiency (for babies)
- Classification + reference product: Well Established Use
**Cardiovascular system**

**C05BA03 - Heparin**
- Active ingredient / dosage: Heparin 250 i.u./g
- Packaging and form: Tube of 35g, gel
- ATC group: C05BA03
- Dossier Status: Available
- Indication: Topical supportive treatment of superficial venous diseases: thrombophlebitis, varicose legs, swelling, contusions, hematoma
- Classification + reference product: Well Established Use

**C05BX01 - Calcium dobesilate monohydrate**
- Active ingredient / dosage: Calcium dobesilate monohydrate 250 mg
- Packaging and form: Box of 30 tablets
- ATC group: C05BX01
- Dossier Status: Available
- Indication: Venous and lymphatic insufficiency
- Classification + reference product: Generic, Doxium, 250 mg, tablets, OM Pharma

**Blood and blood forming organs**

**B03B001 - Folic acid**
- Active ingredient / dosage: Folic acid 5 mg
- Packaging and form: Box of 30, 60, 90 tablets
- ATC group: B03B001
- Dossier Status: Available
- Indication: Folic acid deficiency, anemia
- Classification + reference product: Well Established Use

**A12AA20 - Calcium lactogluconate**
- Active ingredient / dosage: Calcium lactogluconate 29.40g/100 ml, Calcium lactobionate 6.40 g/100 ml
- Packaging and form: Bottle of 150 ml, syrup
- Four tastes available: banana / strawberry / orange / cola
- ATC group: A12AA20
- Dossier Status: Available
- Indication: Fever of various origin, e.g. in flu, colds or other infectious diseases as well as in post-vaccinal reaction; headaches, throat and muscle pains, toothaches
- Classification + reference product: Well Established Use
C05CA03 - Diosmine micronized

Active ingredient / dosage: Diosmine micronized 500 mg
Packaging and form: Box of 30 or 60 tablets
ATC group: C05CA03
Dossier Status: Available
Indication: Venous circulation failure, feeling of “heavy legs”
Classification + reference product: Well Established Use

Active ingredient / dosage: Diosmine micronized 1000 mg
Packaging and form: Box of 30 or 60 tablets
ATC group: C05CA03
Dossier Status: Available
Indication: Venous circulation failure, feeling of “heavy legs”
Classification + reference product: Well Established Use

C07AB07 - Bisoprolol fumarate

Active ingredient / dosage: Bisoprolol fumarate 5 mg
Packaging and form: Box of 30 tablets
ATC group: C07AB07
Dossier Status: Available
Indication: Hypertension, cardiac ischemia
Classification + reference product: Generic, Concor, tablets, 5mg, Merck KgaA

Active ingredient / dosage: Bisoprolol fumarate 10 mg
Packaging and form: Box of 30 tablets
ATC group: C07AB07
Dossier Status: Available
Indication: Hypertension, cardiac ischemia
Classification + reference product: Generic, Concor, tablets, 10mg, Merck KgaA

C08AA06 - Quinapril hydrochloride

Active ingredient / dosage: Quinapril hydrochloride 5 mg
Packaging and form: Box of 30 tablets
ATC group: C08AA06
Dossier Status: Available
Indication: ACE inhibitor, plain
Classification + reference product: Generic, Accupro 5 mg, tablets, Pfizer Inc.

Active ingredient / dosage: Quinapril hydrochloride 10 mg
Packaging and form: Box of 30 tablets
ATC group: C08AA06
Dossier Status: Available
Indication: ACE inhibitor, plain
Classification + reference product: Generic, Accupro 10 mg, tablets, Pfizer Inc.

Active ingredient / dosage: Quinapril hydrochloride 20 mg
Packaging and form: Box of 30 tablets
ATC group: C08AA06
Dossier Status: Available
Indication: ACE inhibitor, plain
Classification + reference product: Generic, Accupro 20 mg, tablets, Pfizer Inc.

D07AD01 - Clobetasol 0,50 mg/g

Active ingredient / dosage: Clobetasol 0,50 mg/g
Packaging and form: Tube of 25g, ointment
ATC group: D07AD01
Dossier Status: Available
Indication: Symptomatic treatment of skin diseases reacting to corticosteroids: psoriasis (excluding the generalized changes), lichen planus, systemic lupus erythematosus (SLE), recurrent eczema, skin diseases difficult to cure, unsuccessfully treated with milder corticosteroids
Classification + reference product: Well Established Use

Dermatologics
Genito-urinary system and sex hormones

**G03AC05 - Megestrol acetate**

- Active ingredient / dosage: Megestrol acetate 40 mg / ml
- Packaging and form: Oral suspension in 240 ml glass bottle
- ATC group: G03AC05
- Dossier Status: Available
- Indication: Treatment of anorexia
- Classification + reference product: Generic, Megace, oral suspension, 40 mg / ml, Bristol-Myers Squibb

**G04CX02 - Saw palmetto fruit extr.**

- Active ingredient / dosage: Saw palmetto fruit extr. (serenoa repens) 360 mg
- Packaging and form: Box of 60 softgels
- ATC group: G04CX02
- Dossier Status: Available
- Indication: mild prostate hypertrophy (pollakiuria, frequent urination at night, decrease of urinary flow, urine retention and painful ailments)
- Classification + reference product: Well Established Use

Antiinfectives for systemic use

**J01XE - Furaginum**

- Active ingredient / dosage: Furaginum 50 mg
- Packaging and form: Box of 30, 60 tablets
- ATC group: J01XE
- Dossier Status: Available
- Indication: Treatment of severe and recurrent lower urinary tract infections without complications
- Classification + reference product: Well Established Use

- Active ingredient / dosage: Furaginum 100 mg
- Packaging and form: Box of 15, 30 tablets
- ATC group: J01XE
- Dossier Status: Available
- Indication: Treatment of severe and recurrent lower urinary tract infections without complications
- Classification + reference product: Well Established Use

**J05AB01 - Aciclovir**

- Active ingredient / dosage: Aciclovir 50 mg/g
- Packaging and form: Tube of 5 g lipogel, unit carton box
- ATC group: J05AB01
- Dossier Status: Available
- Indication: Cold sores caused by herpes simplex
- Classification + reference product: Generic, Zovirax, 200 mg, tablets, Glaxo-Wellcome Group

- Active ingredient / dosage: Aciclovir 200 mg
- Packaging and form: Box of 30 tablets
- ATC group: J05AB01
- Dossier Status: Available
- Indication: Cold sores caused by herpes simplex
- Classification + reference product: Generic, Zovirax, 200 mg, tablets, Glaxo-Wellcome Group

- Active ingredient / dosage: Aciclovir 400 mg
- Packaging and form: Box of 30 tablets
- ATC group: J05AB01
- Dossier Status: Available
- Indication: Cold sores caused by herpes simplex
- Classification + reference product: Generic, Zovirax, 400 mg, tablets, Glaxo-Wellcome Group

- Active ingredient / dosage: Aciclovir 800 mg
- Packaging and form: Box of 30 tablets
- ATC group: J05AB01
- Dossier Status: Available
- Indication: Cold sores caused by herpes simplex
- Classification + reference product: Generic, Zovirax, 800 mg, tablets, Glaxo-Wellcome Group
**Musculo-skeletal system**

**M01AC06 - Meloxicam**

- Active ingredient / dosage: Meloxicam 7.5 mg
- Packaging and form: Box of 10, 20, 30 tablets ODT
- ATC group: M01AC06
- Dossier Status: Available
- Indication: Anti-inflammatory pain killing drug, used in bone and joint pain as well as muscle pain related to rheumatoid diseases and degenerative joint disease.
- Classification + reference product: Well established use

**M01AE01 - Ibuprofen**

- Active ingredient / dosage: Ibuprofen 100 mg / 5 ml
- Packaging and form: Bottle 125 ml - two tastes available: banana / raspberry
- ATC group: M01AE01
- Dossier Status: Available
- Indication: Fever of various origin, e.g. in flu, colds or other infectious diseases as well as in post-vaccinal reaction; headaches, throat and muscle pains, toothaches
- Classification + reference product: General, Nurofen suspension, 0.01 g/ml, Boots Healthcare International

- Active ingredient / dosage: Ibuprofen 200 mg / 5 ml
- Packaging and form: Bottle 100 ml, 125 ml - oral suspension two tastes available: banana / raspberry
- ATC group: M01AE01
- Dossier Status: Available
- Indication: Fever of various origin, e.g. in flu, colds or other infectious diseases as well as in post-vaccinal reaction; headaches, throat and muscle pains, toothaches
- Classification + reference product: General, Nurofen susp., 0.02 g/ml, Boots Healthcare Int.

**Nervous system**

**M01AE01 - Lysine Ibuprofen**

- Active ingredient / dosage: Lysine Ibuprofen 684 mg (eqv. Ibuprofen 400mg)
- ATC group: M01AE01
- Dossier Status: Available
- Indication: Severe headache in the course of migraine with or without aura. Tension headache. Various aches (back pain, toothache, muscle and joint ache, painful menstruation, neuralgia). Pain and fever in the course of colds and flu.
- Classification + reference product: Well established use

**N02BE51 - Paracetamol, Diphenhydramine hydrochloride**

- Active ingredient / dosage: Paracetamol 500 mg, Diphenhydramine hydrochloride 25mg
- ATC group: N02BE51
- Dossier Status: Available
- Indication: Headache, bone and joint pain, muscle pain, toothache, menstruation pain, neuralgia, pain related to colds and flu, causing sleep problems.
- Classification + reference product: Well Established Use

**N05AA02 - Levomepromazine**

- Active ingredient / dosage: Levomepromazine 25 mg
- ATC group: N05AA02
- Dossier Status: Available
- Indication: Schizophrenia. Other mental illnesses and disorders with excitement, aggression or psychosis. Anxiety - in small dosages, singular dosage in the evening in sleep disorder. Treatment of chronic pain (e.g. in cancer), to prevent pain in chemotherapy or in combination with other analgesic drugs.
- Classification + reference product: Well Established Use
N05AB10 - Perazine
Active ingredient / dosage - Perazine 25 mg
Packaging and form - Box of 20 tablets
ATC group - N05AB10
Dossier Status - Available
Indication - Antipsychotic (psychosis, schizophrenia)
Classification + reference product - Well Established Use

Active ingredient / dosage - Perazine 100 mg
Packaging and form - Box of 30 tablets
ATC group - N05AB10
Dossier Status - Available
Indication - Antipsychotic (psychosis, schizophrenia)
Classification + reference product - Well Established Use

N05AL01 - Sulpride
Active ingredient / dosage - Sulpride 50 mg
Packaging and form - Box of 24, 30, 60, 120 tablets
ATC group - N05AL01
Dossier Status - Available
Indication - Severe chronic psychosis in schizophrenia, Chronic alcohol related psychosis, psychosomatic disorders, depressive disorders, migraine and dizziness of various etiology [e.g. Ménière’s disease], supplementary in treatment of alcohol dependence
Classification + reference product - Well Established Use

Active ingredient / dosage - Sulpride 100 mg
Packaging and form - Box of 24, 30, 60, 120 tablets
ATC group - N05AL01
Dossier Status - Available
Indication - Severe chronic psychosis in schizophrenia, Chronic alcohol related psychosis, psychosomatic disorders, depressive disorders, migraine and dizziness of various etiology [e.g. Ménière’s disease], supplementary in treatment of alcohol dependence
Classification + reference product - Well Established Use

Active ingredient / dosage - Sulpride 200 mg
Packaging and form - Box of 24, 30, 60, 120 tablets
ATC group - N05AL01
Dossier Status - Available
Indication - Severe chronic psychosis in schizophrenia, Chronic alcohol related psychosis, psychosomatic disorders, depressive disorders, migraine and dizziness of various etiology [e.g. Ménière’s disease], supplementary in treatment of alcohol dependence
Classification + reference product - Well Established Use

N05BB01 - Hydroxyzine
Active ingredient / dosage - Hydroxyzine 10 mg
Packaging and form - Box of 30 tablets
ATC group - N05BB01
Dossier Status - Available
Indication - Symptomatic treatment of anxiety in adults, symptomatic treatment of itchy skin, premedication before surgery
Classification + reference product - Well Established Use

Active ingredient / dosage - Hydroxyzine 25 mg
Packaging and form - Box of 30 tablets
ATC group - N05BB01
Dossier Status - Available
Indication - Symptomatic treatment of anxiety in adults, symptomatic treatment of itchy skin, premedication before surgery
Classification + reference product - Well Established Use

N05C - Valerian dry extract
Active ingredient / dosage - Valerian dry extract 60 mg Hop dry extract 40 mg Passiflora dry extract 40 mg
Packaging and form - Box of 30 softgels
ATC group - N05C
Dossier Status - Available
Indication - Sedative, antidepressant, soothes, eases the process of falling asleep
Classification + reference product - Local regulation

N06BX03 - Piracetam
Active ingredient / dosage - Piracetam 1200 mg
Packaging and form - Box of 10, 20, 30 tablets
ATC group - N06BX03
Dossier Status - Available
Indication - Psychostimulant
Classification + reference product - Well Established Use
Respiratory system

R01BA52 - Paracetamol, Pseudoephedrine hydrochloride, Dextromethorphan hydrobromide

Active ingredient / dosage: Paracetamol 300 mg + Pseudoephedrine hydrochloride 30 mg + Dextromethorphan hydrobromide 12 mg
Packaging and form: box of 10 or 20 softgels
ATC group: R01BA52
Dossier Status: Available
Indication: anti-fever, flu, and related states, sinus inflammatory, cold, cough, running nose, headache, muscle ache
Classification + reference product: Well established use

R01BA52 - Triprolidine hydrochloride, Pseudoephedrine HCL, Dextromethorphan Hydrobromide

Active ingredient / dosage: Triprolidine hydrochloride 1.25 mg, Pseudoephedrine HCL 30 mg, Dextromethorphan Hydrobromide 10 mg
Packaging and form: Glass bottle 100 ml, with metal cap in a unitary box
ATC group: R01BA52
Dossier Status: Available
Indication: flu, colds, and other infections of the upper respiratory tract, anti-cough, in treatment of nasal mucous membrane swelling and watery nasal discharge
Classification + reference product: Well Established Use

R03DX03 - Fenspiride hydrochloride

Active ingredient / dosage: Fenspiride hydrochloride 2mg/ml
Packaging and form: Glass bottle 150 ml, with metal cap in a unitary box
ATC group: R03DX03
Dossier Status: Available
Indication: symptomatic treatment (cough and expectoration) in inflammatory diseases of bronchi and lungs
Classification + reference product: Well Established Use

R05DA09 - Dextromethorphan hydrobromide

Active ingredient / dosage: Dextromethorphan hydrobromide 30 mg
Packaging and form: box of 15 softgels
ATC group: R05DA09
Dossier Status: Available
Indication: acute, dry and hard cough of a different etiology
Classification + reference product: Well Established Use

R05DA13 - Butamirate

Active ingredient / dosage: Butamirate 75 mg/5 ml
Packaging and form: Glass bottle of 100ml, 200 ml with metal cap in a unitary box
ATC group: R05DA13
Dossier Status: Available
Indication: treatment of different types of cough
Classification + reference product: Well Established Use

R05CB06 - Ambroxol Hydrochloride

Active ingredient / dosage: Ambroxol Hydrochloride 30 mg
Packaging and form: Box of 15, 30 tablets
ATC group: R05CB06
Dossier Status: Available
Indication: Severe chronic lung and bronchi diseases, with disorder in mucus secretion and problems with its transport
Classification + reference product: Generic (biowaiver), Mucosolvan, Boehringer Ingelheim International GmbH

Active ingredient / dosage: Ambroxol Hydrochloride 60 mg
Packaging and form: Box of 15, 30 tablets
ATC group: R05CB06
Dossier Status: Available
Indication: Severe chronic lung and bronchi diseases, with disorder in mucus secretion and problems with its transport
Classification + reference product: Generic (biowaiver), Mucosolvan, Boehringer Ingelheim International GmbH

Active ingredient / dosage: Ambroxol Hydrochloride 15 mg/5 ml
Packaging and form: Glass bottle of 150 ml, with metal cap in a unitary box, syrup
ATC group: R05CB06
Dossier Status: Available
Indication: Severe chronic lung and bronchi diseases, with disorder in mucus secretion and problems with its transport
Classification + reference product:Generic (biowaiver), Mucosolvan, Boehringer Ingelheim International GmbH

R06AX13 - Loratadine

Active ingredient / dosage: Loratadine 10 mg
Packaging and form: Box of 7, 10 softgels
ATC group: R06AX13
Dossier Status: Available
Indication: allergic inflammation of the nasal mucosa, chronic idiopathic urticaria
Classification + reference product: Generic, Clavite, tablets, 10 mg, company Schering-Plough