

Product List A / EU-approvable dossiers

Therapeutic Category	Active Ingredient(s)	Pharmaceutical Form	Strength(s)	Packaging Type	Pack Size(s)	ATC Code	Stability Data	Reference Product
 CARDIOLOGY	Bosentan	Film-coated tablets	62.5 mg; 125 mg	Al/PVC blisters	x56	C02KX01	Zone II/IV (36 months)	Tracleer®
	Furosemide	Film-coated tablets	40 mg	Al/PVC blisters	x30	C03CA01	Zone IVb (on-going)	Lasilix®
	Ivabradine	Film-coated tablets	5 mg; 7.5 mg	Al/Al blisters	x56	C01EB17	Zone II/IVb (36 months)	Procoralan®
	Pentoxifylline	Prolonged-release tablets	400 mg; 600 mg	PVC/Al blisters	x40 (400 mg); x20 (600 mg)	C04AD03	Zone II/IVb (36 months)	Trental®
	Procainamide hydrochloride	Solution for injection	100 mg/ml (10 ml)	Glass vials	x1	C01BA02	Zone II (60 months) Zone IVb on-going	N.A.
	Ramipril	Tablets	2.5 mg; 5 mg; 10 mg	PVC/Al blisters	x30	C09AA05	Zone II/IVb (24 months)	Tritace®
	Telmisartan/HCTZ	Tablets	80 mg + 12.5 mg; 80 mg + 25 mg	Al/Al blisters	x28	C09DA07	Zone II/IVb (36 months)	MicardisPlus®
	Valsartan/HCTZ	Film-coated tablets	80 mg + 12.5 mg; 160 mg + 12.5 mg; 160 mg + 25 mg	Al/PVC blisters	x28; x56	C09DA03	Zone II (24 months)	Co-Diovan®
	Verapamil hydrochloride	Film-coated tablets	40 mg; 80 mg	PVC/Al blisters	x30	C08DA01	Zone II/IVb (48 months)	N.A.
 CNS	Carbamazepine	Tablets	200 mg; 400 mg	PVC/Al blisters	x50	N03AF01	Zone II/IVb (48 months)	Tegretol®
	Cinnarizine	Tablets	25 mg	Al/PVC blisters	x50	N07CA02	Zone II (60 months)	Stugeron®
	Edrophonium bromide	Solution for injection	25 mg/2 ml	Glass ampoules	x2	V04CX07	Zone II (60 months) Zone IVb on-going	N.A.
	Levetiracetam	Oral solution	100 mg/ml (150 ml; 300 ml)	Amber glass bottle	x1	N03AX14	Zone II/IVb (36 months)	Keppra®
	Levetiracetam	Film-coated tablets	250 mg; 500 mg; 750 mg; 1 g	Al/PVC blisters	x30; x60	N03AX14	Zone II/IVb (36 months)	Keppra®
	Melatonin	Prolonged-released tablets	2 mg	Al-PVC/PVdC blisters	x7; x20; x21; x30	N05CH01	Zone II (24 months)	Circadin®
	Venlafaxine	Prolonged release capsules	37.5 mg; 75 mg; 150 mg	Al/PVC blisters	x20; x28; x50; x100	N06AX16	Zone II (36 months)	Effexor XR®
 DERMATOLOGY	Ketoconazole⁽²⁾	Shampoo	2 % (60 ml; 100 ml; 120 ml)	PE bottle	x1	D01AC08	Zone II/IVb (36 months)	Nizoral®
 ENDOCRINOLOGY & METABOLISM	Calcium/Vitamin D3	Chewable or suckable tablets	500 mg + 400 IU	Plastic tubes	3x20	A12AX	Zone IVb (36 months)	N.A.
	Sitagliptin	Film-coated tablets	50 mg; 100 mg	PVC/Al blisters	x30	A10BH01	Zone II/IVb (24 months)	Januvia®
	Tocopherol	Soft capsules	500 mg	PVC/PVDC/Al blisters	x30	A11HA03	Zone IVb (36 months)	Toco®
 GASTROENTEROLOGY	Esomeprazole	Powder for solution for injection or infusion	40 mg	Glass vials	x1; x5; x10	A02BC05	Zone II/IVb (24 months)	Nexium IV®
	Famotidine	Film-coated tablets	20 mg; 40 mg	PVC/Al blisters	x30	A02BA03	Zone II/IVb (48 months)	Pepdine®
	Loperamide hydrochloride	Tablets	2 mg	PVC/Al blisters	x10	A07DA03	Zone II/IVb (48 months)	N.A.

⁽¹⁾ Non-European manufacturing site; ⁽²⁾ European manufacturer (non-EU), EU release available.

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 GASTROENTEROLOGY	Omeprazole	Gastro-resistant hard capsules	20 mg	PP containers	x14; x28	A02BC01	Zone II/IVb (36 months)	Losec®
	Omeprazole	Powder (lyophilisate) for solution for infusion	40 mg	Glass vials	x1; x5; x50	A02BC01	Zone II/IVa (24 months)	Losec®
	Omeprazole	Lyophilisate and solvent (macrogol) for solution for injection	40 mg	Glass vials + glass ampoules	x1; x5	A02BC01	Zone II/IVa (24 months)	Losec®
	Ondansetron	Orodispersible tablets	4 mg; 8 mg	Al/PVC blisters	x6; x10; x30	A04AA01	Zone II/IVb (36 months)	Zofran®
	Pantoprazole	Powder for solution for injection or infusion	40 mg	Glass vials	x1; x5; x10	A02BC02	Zone II/IVb (24 months)	Pantoc IV®
	Rabeprazole	Gastro-resistant tablets	10 mg; 20 mg	Al/Al blisters	x14; x28	A02BC04	Zone II/IVb (36 months)	Pariet®
	Sulfasalazine	Gastro-resistant tablets	500 mg	PVC/Al blisters	x50	A07EC01	Zone II/IVb (36 months)	N.A.
 HEMATOLOGY	Dextriferron⁽²⁾	Chewable tablets	100 mg	PVC/PVDC blisters	x30	B03AB05	Zone II/IVb (36 months)	N.A.
 INFECTIOUS DISEASES & IMMUNOLOGY	Aciclovir	Powder for solution for infusion	250 mg	Glass vials	x1; x5; x10	J05AB01	Zone II/IVb (36 months)	Zovirax IV®
	Azithromycin⁽²⁾	Film-coated tablets	500 mg	PVC/PVDC or PA/Al/PVC blisters	x3	J01FA10	Zone I/II/III/IV (36 months)	Zitromax®
	Azithromycin	Powder for solution for infusion	500 mg	Glass vials	x1; x5; x10	J01FA10	Zone II/IVb (36 months)	Zithromax IV®
	Cefotaxime	Powder for solution for injection (available with or without WFI)	1 g; 2 g	Glass vials (+ glass ampoules)	x1; x100 (1 g); x1; x50 (2 g)	J01DD01	Zone II (24 months)	Claforan®
	Cefotaxime	Powder and solvent (lidocaine) for solution for injection (IM)	1 g	Glass vials + glass ampoules	x1	J01DD01	Zone II (24 months)	Claforan®
	Ceftazidime	Powder for solution for injection (available with or without WFI)	1 g; 2 g	Glass vials (+ glass ampoules)	x1; x10; x50 (1 g); x10 (2 g)	J01DD02	Zone II (24 months)	Fortum®
	Ceftriaxone	Powder for solution for injection (available with or without WFI)	1 g; 2 g	Glass vials (+ glass ampoules)	x1 (1 g, 2 g); x100 (1 g)	J01DD04	Zone II (36 months)	Rocephin®
	Ceftriaxone	Powder and solvent (lidocaine) for solution for injection (IM)	1 g	Glass vials + glass ampoules	x1	J01DD04	Zone II (36 months)	Rocephin®
	Ciprofloxacin⁽²⁾	Film-coated tablets	500 mg	PVC/PVDC blisters	x10; x20	J01MA02	Zone I/II/III/IVa (36 months)	Ciproxin®
	Clarithromycin	Powder for solution for injection	500 mg	Glass vials	x1; x5; x10	J01FA09	Zone II/IVb (36 months)	Klacid IV®
	Norfloxacin	Film-coated tablets	400 mg	PVC/PVDC/Al blisters	x20	J01MA06	Zone II (36 months)	Noroxin®
	Vancomycin	Powder for solution for infusion	500 mg; 1000 mg	Glass vials	x1; x5; x10	J01XA01	Zone II/IVb (24 months)	Vancomicina Labesfal
	Zoledronic acid	Concentrate for solution for infusion	4 mg/5 ml	Glass vials	x1	M05BA08	Zone II/IVb (36 months)	Zometa®
 ONCOLOGY	Zoledronic acid	Solution for infusion	5 mg/100 ml	Glass vials	x1	M05BA08	Zone II/IVb (24 months)	Zometa®

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 OPHTHALMOLOGY	Bimatoprost	Eye drops, solution	0.3 mg/ml (3 ml)	Plastic bottle	x1; x3; x6	S01EE03	Zone II/IVb (36 months)	Lumigan®
 PAIN MANAGEMENT & ANALGESICS	Benzydamine⁽²⁾	Solution, oromucosal spray	0.15 mg/g (30 ml)	Plastic container with dosage pump	x1	A01AD02	Zone II/IVb (48 months)	Tantum Verde®
	Ibuprofen	Film-coated tablets	200 mg; 400 mg	Al/PVC blisters	x12; x24; x50 x10; x24	M01AE01	Zone II/IVb (36 months)	Nurofen®
	Ketoprofen	Gel	2.5 % (60 g)	Aluminium tube	x1	M02AA10	Zone IVb (36 months)	Ketum®
	Ketoprofen	Film-coated tablets	50 mg; 100 mg	PVC/Al blisters	x20	M01AE03	Zone II/IVb (60 months)	Profenid®
	Metamizole	Tablets	500 mg	Al/PVC blisters	x10(n); x12(n)	N02BB02	Zone II/IVb (36 months)	Novalgin®
	Nimesulide	Tablets	100 mg	Al/PVC blisters	x10; x20; x30	M01AX17	Zone II (36 months)	Aulin®
	Paracetamol/ Ibuprofen⁽²⁾	Film-coated tablets	500 mg + 200 mg	PVC/PVDC blisters	x10; x20	M01AE51	Zone II/IVb (36/24 months)	N.A.
	Paracetamol	Tablets	500 mg	Al/PVC blisters	x12; x20; x24	N02BE01	Zone II/IVb (36 months)	Panadol®
	Paracetamol	Film-coated tablets	500 mg; 1000 mg	Al/PVC blisters	x16 (500 mg); x8 (1000 mg)	N02BE01	Zone IVb (500 mg; 24 months; 1000 mg; on-going)	Panadol®
	Parecoxib	Powder for solution for injection 40 mg		Glass vials	x1; x5; x10	M01AH04	Zone II/IVb (36 months)	Dynastat®
	Tramadol	Capsules	50 mg	PVC/Al blisters	x10	N02AX02	Zone II/IVb (48 months)	Tramal®
	Tramadol/ Paracetamol	Film-coated tablets	37.5 mg + 325 mg	Al/PVC blisters	x20; x60; x90	N02AJ13	Zone II (36 months) Zone IVb (25 months)	Zaldiar®
 RESPIRATORY & ALLERGY	Cetirizine⁽²⁾	Film-coated tablets	10 mg	PVC/PVDC blisters	x20	R06AE07	Zone I/II/III/IV (36 months)	Zyrtec®
	Cetirizine⁽²⁾	Oral solution	1 mg/ml (120 ml)	Brown glass bottle	x1	R06AE07	Zone II (24 months)	Zyrtec®
	Ketotifen	Tablets	1 mg	PVC/Al blisters	x20	R06AX17	Zone II (24 months)	N.A.
	Montelukast⁽²⁾	Film-coated tablets	10 mg	PA/Al/PVC blisters	x30	R03DC03	Zone II/IVb (36 months)	Singulair®
	Oxomemazine	Oral suspension	0.33 mg/ml (150 ml)	Brown glass bottle	x1	R06AD08	Zone IVb (24 months)	Toplexil®
 RHEUMATOLOGY	Meloxicam	Solution for injection	15 mg/1.5 ml	Glass ampoules	x3; x5; x10	M01AC06	Zone II/IVb (36 months)	Movalis®
 UROLOGY / NEPHROLOGY	Sildenafil⁽²⁾	Film-coated tablets	50 mg; 100 mg	Al/PVC blisters	x4	G04BE03	Zone II/IVb (36 months)	Viagra®
 WOMEN'S HEALTH	Metronidazole/ Clotrimazole⁽²⁾	Pessaries	500 mg + 200 mg	PVC/PE strips	x7	G01AF20	Zone II/IVb (24 months)	Zifex Duo®
	Metronidazole⁽²⁾/ Miconazole/Lidocaine	Pessaries	750 mg + 200 mg + 100 mg	PVC/PE strips	x7	G01AF20	Zone II/IVb (24 months)	N.A.

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