


ALIMENTARY TRACT AND METABOLISM

INN	AVAILABLE STRENGTHS	DOSAGE FORM	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS	MA GRANTED	PRODUCT PROTECTION EXPIRATION (EU)
Calcitriol	0.25 mcg, 0.5 mcg	Soft Capsules	Rocaltrol / Roche Pharma AG	Hypoparathyroidism	Yes	-	-
Cholecalciferol	20.000 IU, 2.000 IU, 1.000 IU	Soft Gel Capsules	Dekristol / Mibe GmbH	Bone Loss (osteoporosis)	Yes	-	-
Dapagliflozin	5 mg, 10 mg	Film Tablets	Forxiga / AstraZeneca GmbH	Anti-Diabetic	Yes	-	2027 (SPC)
Empagliflozin	10 mg, 25 mg	Film Tablets	Jardiance / Boehringer Ingelheim Pharma GmbH	Anti-Diabetic	Jan 2024	-	2030 (SPC)
Sitagliptin	25 mg, 50 mg, 100 mg	Film Tablets	Januvia / Merck Sharp & Dohme B.V.	Anti-Diabetic	Jun 2024	-	-

ANTIINFECTIVES FOR SYSTEMIC USE

INN	AVAILABLE STRENGTHS	DOSAGE FORM	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS	MA GRANTED	PRODUCT PROTECTION EXPIRATION (EU)
Amoxicillin Trihydrate + Potassium Clavulanate	400 mg + 57 mg, 250 mg + 62.5 mg	Oral Suspension	Augmentin / GlaxoSmithKline GmbH	Bacterial Infections	Yes	TR, DE, NL, NZ, CH	-
Amoxicillin Trihydrate + Potassium Clavulanate	500 mg + 125 mg, 875 mg+ 125 mg	Film Tablets	Augmentin Film Tablet 625 mg / Beecham Group plc Augmentan Film Tablet 1000 mg / GlaxoSmithKline GmbH & Co. KG	Bacterial Infections	Yes	TR, DE, NL, CH	-
Pantoprazol	20 mg, 40 mg	Enteric Coated Tablets	Pantozal / Takeda GmbH	Gastric Ulcer	Mar 2024	-	-
Piperacillin + Tazobactam	4.0 g + 0.5 g, 2 g + 0.25 g	Powder For Injection	Tazocin / Pfizer	Bacterial Infections	Mar 2024	-	-
Posaconazole	40 mg/ml	Oral Suspension	Noxafil / Merck Sharp & Dohme B.V.	Fungal Infections	Yes	TR, DE, NL, CH, NZ	-
Posaconazole	100 mg	Enteric Coated Tablets	Noxafil / Merck Sharp & Dohme B.V.	Fungal Infections	Yes (DCP filed in Dec 2022)	-	-
Tenofovir Alafenamide Fumarate 	25 mg	Film Coated Tablets	Vemlidy / Gilead Sciences GmbH	Hepatitis B Virus (HBV) Infection	Dec 2023	-	2026


Antineoplastic and Immunomodulating Agents								
INN		Available Strengths	Dosage Form	Reference Product	Indication	Dossier Readiness	MA Granted	Product Protection Expiration (EU)
Abiraterone Acetate		500 mg	Tablets	Zytiga / Janssen-Cilag GmbH	Prostate Cancer	Yes	-	2022 (ME)
Apremilast		10 mg & 20 mg & 30 mg (starter pack), 30 mg	Film Tablets	Otezla / Amgen GmbH	Psoriatic Arthritis	Yes	-	2026 (ME) / 2028 (patent in appeal)
Cabozantinib	 	20 mg, 40 mg, 60 mg	Film Tablets	Cabometyx / Ipsen Pharma GmbH	Thyroid Cancer, Renal Cell Carcinoma, Hepatocellular Carcinoma	Under Development	-	2029 (SPC)
Cyclosporine		25 mg, 50 mg, 100 mg	Soft Capsules	SANDIMMUN Neoral / Novartis Pharma GmbH	Psoriasis, Organ Rejection	Under Development	-	-
Dasatinib		20 mg, 50 mg, 70 mg, 80 mg, 100 mg, 140 mg	Film Tablets	Sprycel / Bristol-Myers Squibb GmbH & Co. KGaA	Chronic Myeloid Leukemia	Yes	-	-
Enzalutamide**		40 mg, 80 mg	Tablets	Xtandi / Astellas Pharma GmbH	Prostate Cancer	Dec 2024	-	2028 (SPC)
Fingolimod HCl		0.25 mg, 0.5 mg	Capsules	Gilenya / Novartis	Multiple Sclerosis	Yes	DE, NL	2022 (ME) / 2027 (patent)
Hydroxycarbamide		500 mg	Capsules	Hydrea / Bristol-Myers Squibb GmbH & Co. KGaA	Chronic Myelocytic Leukemia	Yes	TR, DE, LU, NZ, CH	-
Ibrutinib**		140 mg, 280 mg, 420 mg, 560 mg	Film Tablets	Imbruvica / Janssen-Cilag GmbH	Lymphoma	Aug 2024	-	2029 (SPC molecule patent)
Imatinib		100 mg, 400 mg	Film Tablets	Glivec / Novartis Pharma GmbH	Acute Lymphoblastic Leukemia, Chronic Myeloid Leukemia	Yes	TR, DE, CH, NL, NZ	-
Lenalidomide		2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 25 mg	Capsules	Revlimid / Bristol-Myers Squibb GmbH & Co. KGaA	Multiple Myeloma	Yes	TR, DE, CH, NL	-
Lenvatinib		4 mg, 10 mg	Capsules	Lenvima / Eisai GmbH	Differentiated Thyroid Cancer	Apr 2024	-	2026 (SPC)
Nilotinib		50 mg, 150 mg, 200 mg	Hard Capsules	Tasigna / Novartis Pharma GmbH	Myeloid Leukemia	Dec 2023	-	2026 (molecule patent)
Nintedanib		100 mg and 150 mg	Soft Capsule	Ofev / Boehringer Ingelheim Pharma GmbH & Co. KG	Lung Cancer	May 2024	-	2025 (indication patent) SPC applies in some countries
Olaparib	 	100 mg, 150 mg	Film Tablets	Lynparza / AstraZeneca GmbH	Advanced Ovarian Cancer	Mar 2025	-	2029 (SPC)
Palbociclib		75 mg, 100 mg, 125 mg	Film Tablets	Ibrance / Pfizer Pharma GmbH	Breast Cancer	Mar 2024	-	2028 (SPC)

Antineoplastic and Immunomodulating Agents							
INN	Available Strengths	Dosage Form	Reference Product	Indication	Dossier Readiness	MA Granted	Product Protection Expiration (EU)
Pazopanib HCl 	200 mg, 400 mg	Film Tablets	Votrient / Novartis Pharma GmbH	Renal Cell Carcinoma	Jun 2023	-	2025 (SPC)
Pomalidomide 	1 mg, 2 mg, 3 mg, 4 mg	Capsules	Imnovid / Bristol-Myers Squibb GmbH & Co. KGaA	Multiple Myeloma	Yes	-	2024 (ME)
Ribociclib 	200 mg	Film Tablets	Kisqali / Novartis Pharma GmbH	Breast Cancer	Dec 2024	-	2032 (SPC)
Ruxolitinib Phosphate  	5 mg, 10 mg, 15 mg, 20 mg	Film Tablets	Jakavi / Novartis Pharma GmbH	Myelofibrosis	Apr 2024	-	2027 (SPC)
Sorafenib Tosylate	200 mg	Film Tablets	Nexavar / Bayer Vital GmbH	Renal Cell Carcinoma	Mar 2024	-	2024 (MoU patent)
Temozolomide	5 mg, 20 mg, 100 mg, 140 mg, 180 mg, 250 mg	Capsules	Temodal / Merck Sharp & Dohme B.V.	Glioblastoma Multi-forme	Yes	DE, NL	-
Teriflunomide** 	7 mg, 14 mg	Film Tablets	Aubagio / Sanofi-Aventis Deutschland GmbH	Multiple Sclerosis	Aug 2024 (Settlement)	-	2027 (SPC)
Tofacitinib	5 mg, 10 mg	Film Tablets	Xeljanz / Pfizer Pharma GmbH	Arthritis	Yes	-	2028 (ME)
Tofacitinib	11 mg	Extended Release Tablets	Xeljanz / Pfizer Pharma GmbH	Arthritis	Dec 2024	-	2034
Antianemia Drugs							
INN	Available Strengths	Dosage Form	Reference Product	Indication	Dossier Readiness	MA Granted	Product Protection Expiration (EU)
Iron Carboxymaltose	50 mg/ml	Injectable, Vial	Ferrinject / Vifor Pharma	Treatment of Iron Deficiency	Mar 2024	-	2027 (indication patent)
Antiparasitics, Insecticides & Repellants							
INN	Available Strengths	Dosage Form	Reference Product	Indication	Dossier Readiness	MA Granted	Product Protection Expiration (EU)
Ivermectin	3 mg	Film Tablets	Stromectol / Merck Sharp & Dohme B.V.	Treatment of Parasitic Diseases	Jan 2024	-	-
Blood and Blood Forming Organs							
INN	Available Strengths	Dosage Form	Reference Product	Indication	Dossier Readiness	MA Granted	Product Protection Expiration (EU)
Apixaban 	2.5 mg, 5 mg	Film Tablets	Eliquis / Bristol-Myers Squibb GmbH & Co. KGaA	Atrial Fibrillation, Stroke Prophylaxis, Thrombosis Prophylaxis	Yes (DCP slot in July 2023)	-	2026 (SPC)



BLOOD AND BLOOD FORMING ORGANS

INN	AVAILABLE STRENGTHS	DOSAGE FORM	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS	MA GRANTED	PRODUCT PROTECTION EXPIRATION (EU)
Eltrombopag 	25 mg, 50 mg, 75 mg	Film Tablets	Revolade / Novartis Pharma GmbH	Thrombocytopenia	Yes	-	2025 (SPC)
Roxadustat**  	20 mg, 50 mg, 70 mg, 100 mg, 150 mg	Film Tablets	Evrenzo / Astellas Pharma GmbH	Anemia	Under Development	-	2031 (ME) / 2029 (SPC)






CARDIOVASCULAR SYSTEM

INN	AVAILABLE STRENGTHS	DOSAGE FORM	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS	MA GRANTED	PRODUCT PROTECTION EXPIRATION (EU)
Ambrisentan	5 mg, 10 mg	Film Tablets	Volibris / GlaxoSmithKline GmbH & Co. KG	Pulmonary Arterial Hypertension	Yes	TR, DE, NL, NZ, CH	-
Candesartan	4 mg, 8 mg, 16 mg, 32 mg	Film Tablets	Atacand / Astazeneca GmbH	Hypertension	Mar 2024	-	-
Candesartan + HCT tablet	8 mg+12.5 mg, 16 mg+12.5 mg, 32 mg+12.5 mg, 32 mg+25 mg	Film Tablets	Atacand Plus / Astazeneca GmbH	Hypertension	Apr 2024	-	-
Tadalafil	5 mg, 20 mg	Film Tablets	Cialis / Elli-Lilly	Pulmonary Arterial Hypertension	Dec 2023	-	-
Ticagrelor	90 mg, 60 mg	Film Tablets	Brilique / AstraZeneca GmbH	Heart Failure	Feb 2024	-	2024 (molecule patent)
Valsartan + Sacubitril 	26 mg + 24 mg, 51 mg + 49 mg, 103 mg + 97 mg	Film Tablets	Entresto / Novartis Pharma GmbH	Heart Failure	Yes	-	2028 (SPC)

CENTRAL NERVOUS SYSTEM

INN	AVAILABLE STRENGTHS	DOSAGE FORM	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS	MA GRANTED	PRODUCT PROTECTION EXPIRATION (EU)
Cariprazine HCl	1.5 mg, 3 mg, 4.5 mg, 6 mg	Hard Capsules	Reagila / Recordati Pharma GmbH	Bipolar Disorder, Schizophrenia	Mar 2024	-	2029 (SPC)
Donazepil	5 mg, 10 mg	Film Tablet	Aricept / Eisai	Alzheimer	Mar 2024	-	-
Levodopa + Benserazide HCl 	100 mg + 25 mg	HBS Capsules	Madopar / Roche	Parkinsons	Yes	TR, DE, LU	-
Levodopa + Benserazide HCl 	50 mg + 12.5 mg, 100 mg + 25 mg, 200 mg + 50 mg	Tablets	Madopar / Roche	Parkinsons	Yes	TR, DE, LU,CH	-
Mirtazapin	15 mg, 30 mg, 45 mg	ODT	Remeron / NV-Organon	Depression and Obsessive Compulsive Disorder	Apr 2024	-	-
Olanzapin	2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg	Film Tablet	Zyprexa / Lilly	Schizophrenia and Bipolar Disorder	May 2024	-	-

RESPIRATORY SYSTEM

INN	AVAILABLE STRENGTHS	DOSAGE FORM	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS	MA GRANTED	PRODUCT PROTECTION EXPIRATION (EU)
Beclometasone Dipropionate + Formoterol Fumarate Dihydrate 	"100 mcg + 6 mcg, 200 mcg + 6 mcg"	MDI	Foster / Chiesi	COPD, Asthma	Mar 2024	-	2023
Beclometasone Dipropionate + Formoterol Fumarate Dihydrate + Glycopyrronium 	87 mcg + 5 mcg + 9 mcg	MDI	Trimbow / Chiesi	COPD, Asthma	May 2025	-	2030
Glycopyrronium + Indacaterol 	43 mcg + 85 mcg	DPI	Ultibro Breezhaler / Novartis	"COPD, Chronic Bronchitis, Emphysema"	Jun 2024	-	2023 (ME) / 2028 (molecule patent)
Salmeterol Xinafoate + Fluticasone Propionate	25 mcg + 250 mcg	MDI	Seretide Evohaler / Glaxo Wellcome UK Limited	Asthma	Yes	TR, DE, SE	-
Salmeterol Xinafoate + Fluticasone Propionate	25 mcg + 125 mcg	MDI	Seretide Evohaler / Glaxo Wellcome UK Limited	Asthma	Yes	DE, SE	-
Salmeterol Xinafoate + Fluticasone Propionate 	25 mcg + 50 mcg	MDI	Seritide / GSK	Asthma	Sep 2024	-	-
Tiotropium Bromide 	18 mcg	DPI	Spiriva / Boehringer Ingelheim	Bronchospasm in COPD, including Chronic Bronchitis and Emphysema.	Mar 2025	-	-

SENSORY ORGANS

INN	AVAILABLE STRENGTHS	DOSAGE FORM	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS	MA GRANTED	PRODUCT PROTECTION EXPIRATION (EU)
Dexpanthenol + Hyaluronic Acid (CE Marked)	2% + 0.15%, 10 ml 2% + 0.15%, 20 x 0.5 ml	Eye Drops	Bepanthen / Bayer	Dry Eye	Yes	-	-
Cyclosporine 	0.1%, 0.3 ml	Ophthalmic Solution	Ikervis / Santen	Dry Eye	May 2025	-	2034 (ME) / 2027 (SPC)
Trehalose + Sodium Hyaluronate (CE Marked)	3% + 0.15%, 10 ml	Ophthalmic Solution	Thealoz Duo / Thea	Ophthalmoxerosis	Yes	-	-

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

INN	AVAILABLE STRENGTHS	DOSAGE FORM	REFERENCE PRODUCT	INDICATION	DOSSIER READINESS	MA GRANTED	PRODUCT PROTECTION EXPIRATION (EU)
Cinacalcet HCl	30 mg, 60 mg, 90 mg	Film Tablets	Mimpara / Amgen GmbH	Secondary Hyperparathyroidism	Yes	TR, DE, CH, NL, NZ	-

ADDITIONAL PRODUCTS (ALREADY GOT APPROVAL AND/OR SUBMITTED IN THE USA)

INN	AVAILABLE STRENGTHS	DOSAGE FORM	DOSSIER READINESS	MA GRANTED	PRODUCT PROTECTION EXPIRATION (EU)
Amoxicillin Trihydrate + Potassium Clavulanate	600 mg + 42.9 mg	Oral Suspension	Under Development (6-9 months)	TR, US (Tentative App.)	
Azilsartan Medoxomil	40 mg, 80 mg	Film Tablets	Under Development (6-9 months)	TR, US (Under Reg.)	
Bimatoprost	0.01%	Ophthalmic Solution	Under Development (6-9 months)	TR, US (Under Reg.)	
Brimonidine Tartrate + Timolol Maleate	0.2% + 0.5%	Ophthalmic Solution	Under Development (6-9 months)	TR, US (Under Reg.)	
Ceftriaxone Sodium	250 mg, 500 mg, 1000 mg, 2000 mg	Powder for Injection	Under Development (6-9 months)	TR, US (Tentative App.)	
Ciclosporin	0.05%	Ophthalmic Emulsion	Under Development (6-9 months)	TR, US (Under Reg.)	
Epinephrine	1 mg/ml	Solution for Injection	Under Development (6-9 months)	US (Under Reg.)	
Esomeprazol Sodium	40 mg	Lyophilized Powder For Injection	Under Development (6-9 months)	TR, US	
Furosemide	10 mg/ml	Solution for Injection	Under Development (6-9 months)	TR, US (Under Reg.)	
Isoproterenol HCl	0.2 mg/ml	Solution for Injection	Under Development (6-9 months)	US (Under Reg.)	
Succinylcholine Chloride**	20 mg/ml, 10 ml	Solution for Injection	Under Development (6-9 months)	US	
Pantoprazol	40 mg	Lyophilized Powder For Injection	Under Development (6-9 months)	TR, US (Under Reg.)	
Sodium Alginate + Sodium Bicarbonate + Calcium Carbonate	500 mg + 267 mg + 160 mg, 10 ml 500 mg + 213 mg + 325 mg, 10 ml	Oral Suspension	Under Development (6-9 months)	TR	



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