

PRODUCT LIST

October 2023

State of the art B2B

AVAILABLE DOSSIERS

INN	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	LACTOSE FREE	STABILITY	SHELF LIFE
Alimentary tract & metabolism						
Dapagliflozin* / Metformin ^{CA}	Film-coated tablets	5 / 850 mg 5 / 1000 mg	Xigduo® / AstraZeneca	Yes	II: on-going IVa: ext. from b IVb: on-going	24 months 18 months available (24m on 10.2023)
Dapagliflozin* ^{CA}	Film-coated tablets	5 mg 10 mg	Forxiga® / AstraZeneca	Yes	II: on-going IVa: ext. from b IVb: on-going	24 months 24 months
Empagliflozin* ^{CA}	Film-coated tablets	10 mg 25 mg	Jardiance® / Boehringer Ingelheim	Yes	II: on-going IVa: ext. from b IVb: on-going	24 months available (Target 36m) 24 months available (Target 36m) - Not store above 30°C
Linagliptin* ^{CA}	Film-coated tablets	5 mg	Trajenta® / Boehringer Ingelheim	Yes	II: on-going IVa: ext. from b IVb: on-going	36 months 36 months
Omeprazole	Powder for solution for infusion or injection	40 mg	Losec® / AstraZeneca	Yes	II: available IVa: not available IVb: not available	24 months
Orlistat	Hard capsules	120 mg	Xenical® / Roche	Yes	II: available IVa: not available IVb: not available	24 months
Orlistat OTC	Hard capsules	60 mg	Alli® / GSK	Yes	II: available IVa: not available IVb: not available	24 months
Pantoprazole	Powder for solution for infusion or injection	40 mg	Pantozol® / Altana	Yes	II: available IVa: not available IVb: not available	36 months
Sitagliptin*	Film-coated tablets	25 mg 50 mg 100 mg	Januvia® / Merck	Yes	II: available IVa: not available IVb: available	36 months
Sitagliptin* + Metformin	Film-coated tablets	50 / 850 mg 50 / 1000 mg	Janumet® / Merck	Yes	II: available IVa: not available IVb: available	24 months
Anti-infectives for systemic use						
Aciclovir	Tablets	200 mg 400 mg 800 mg	Zovirax® / GSK	Yes	II: available IVa: not available IVb: not available	36 months
Clarithromycin	Powder for solution for infusion or injection	500 mg	Klacid IV® / Abbott	Yes	II: available IVa: not available IVb: not available	48 months
Antineoplastic & Immunomodulating Agents						
Apremilast* ^{CA}	Film-coated tablets	10 mg 20 mg 30 mg	Otezla® / Celgene	Yes	II: available IVa: not available IVb: not available	12 months (target 36)
Lenalidomide	Capsules	2.5 mg; 5 mg 7.5 mg; 10 mg 15 mg; 20 mg 25 mg	Revlimid® / Celgene	No	II: available IVa: ext. from b IVb: available	24 months
Blood & Blood forming organs						
Apixaban*	Film-coated tablets	2.5 mg 5 mg	Eliquis® / Bristol-Myers Squibb	No	II: available IVa: ext. from b IVb: available	24 months
Rivaroxaban* ^{CA}	Film-coated tablets	2.5 mg 10 mg 15 mg 20 mg	Xarelto® / Bayer	No	II: on-going IVa: ext. from b IVb: on-going	24 months
Rivaroxaban*	Capsules	10 mg 15 mg 20 mg	Xarelto® / Bayern		II: on going	24 months

* Polpharma Group API

CA Dossier suitable for Canadian market

Products protected by patents (SPC) in Poland are developed solely for the purpose of Regulatory Submissions or R&D purposes intended to support Regulatory Submissions. These products are not offered for sale or made available in countries where such products are subject to patent (SPC) protection and where the offer for sale or any related activity constitutes patent infringement. It is within the buyer's responsibility and liability to check the patent situation of the product in the import market(s).

Based on exemption under art. 5(2) of the Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products Apixaban, Rivaroxaban, Ticagrelor, Dapagliflozin and Linagliptin, which are protected by SPCs in Poland, can be manufactured and offered only for the purpose of export to non-EU countries, provided all requirements of the Regulation are met.

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Ticagrelor*	Film-coated tablets	60 mg 90 mg	Brilique® / AstraZeneca	Yes	II: available IVa: ext. from b IVb: available	36 months
Cardiovascular System						
Amlodipine + Atorvastatin	Film-coated tablets	5 mg + 10 mg 10 mg + 10 mg 10 mg + 20 mg 5 mg + 20 mg	Norvasc® (Amlodipine) + Sortis® (Atorvastatin) / Pfizer	Yes	II: available IVa: not available IVb: available	24 months
Enalapril	Tablets	5 mg 10 mg 20 mg	Xanef® (Vasotec, Renitec) / MSD	Yes	II: available IVa: not available IVb: not available	24 months
Hydrochlorothiazide*	Tablets	12.5 mg 25 mg 50 mg	Esidrex® / Novartis	No	II: available IVa: not available IVb: not available	60 months
Ramipril + Amlodipine	Hard capsules	5 mg + 5 mg 5 mg + 10 mg 10 mg + 5 mg 10 mg + 10 mg	Tritace® (Ramipril) / Sanofi & Norvasc® (Amlodipine) / Pfizer	Yes	II: available IVa: not available IVb: not available	36 months
Rosuvastatin	Film-coated tablets	5 mg 10 mg 20 mg 40 mg	Crestor® / AstraZeneca	No	II: available IVa: not available IVb: not available	36 months
Telmisartan + Amlodipine	Bilayered Tablets	40/5 mg 40/10 mg 80 / 5 mg 80/10 mg	Twynsta® / Boehringer Ingelheim	Yes	II: available IVa: ext. from b IVb: available	36 months
Dermatologicals						
Dimetindene	Gel	1 mg / g (20 g) 1 mg / g (30 g) 1 mg / g (50 g)	Fenistil™ / Novartis	Yes	II: available IVa: ext. from b IVb: available	
Genito-Urinary system & Sex Hormones						
Tadalafil*	Film-coated tablets	2.5 mg 5 mg 10 mg 20 mg	Cialis® / Eli Lilly	No	II: available IVa: ext. from b IVb: available	48 months
Musculoskeletal system						
Ibuprofen + Paracetamol	Film-coated tablets	200 mg / 500 mg	Nurofen Ultima® / Reckitt Benckiser	Yes	II: available IVa: not available IVb: not available	36 months
Nervous system						
Dimethyl Fumarate ^{CA}	Gastro-resistant hard capsules	120 mg 240 mg	Tecfidera® / Biogen Idec	Yes	II: on-going IVa: ext. from b IVb: on-going	36 months / do not store above 30°C (zone II) 24 months / do not store above 30°C (zone IVb)
Memantine hydrochloride	Film-coated tablets	10 mg 20 mg	Ebixa® / Lundbeck	No	II: available IVa: available IVb: no ext. from a	36 months
Metamizole sodium	Film-coated tablets	500 mg	Novalgine® / Sanofi Aventis	No	II: on-going IVa: not available IVb: not available	36 months
Quetiapine	Film-coated tablets	25 mg; 100 mg 150 mg; 200 mg 300 mg	Seroquel® / AstraZeneca	No	II: available IVa: available IVb: available	36 months
Respiratory system						
Xylomethazoline + Dexamphenol OTC	Nasal spray solution	1.0 mg / 50 mg / ml (10 ml) 0.5 mg / 50 mg / ml (10 ml)	Nasic® / Cassella-med	Yes	II: available IVa: ext. from b IVb: available	24 months (0,5mg) 36 months (1,0mg)
Vitamins & Minerals						
Cholecalciferol (Vitamin D3)	Soft capsule	20.000 IU	N/A	Yes	II: available IVa: not available IVb: not available	24 months

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