

PRODUCT LIST

October 2024

State of the art B2B

Under development generics

INN	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT
Alimentary tract & metabolism			
Empagliflozin*/Metformin	Film - coated tablets	5mg / 850mg 5mg / 1000mg 12.5mg / 500mg 12.5mg / 850mg 12.5mg / 1000mg	Synjardy® / Boehringer Ingelheim
Linagliptin* / Metformin	Film - coated tablets	2.5mg / 500mg 2.5mg / 850mg 2.5mg / 1000mg°	Jentadueto® / Boehringer Ingelheim
Allergy/Immuno			
Baricitinib	Film - coated tablets	2mg / 4mg	Olumiaant® / Lilly
Upadacitinib	Prolonged - release tablets	15mg /30mg / 45mg	Rinvoq® / Abbvie
Nervous System			
Ozanimod	Hard capsules	0,23mg / 0,46mg / 0,92mg	Zeposia® / BMS
Respiratory System			
Fluticasone / Vilanterol	Inhalation powder	92mcg / 22mcg / 184mcg / 22mcg	Bro Ellipta® / GSK
Umeclidinium / Vilanterol	Inhalation powder	55mcg / 22 mcg	Anoro Ellipta® /GSK
Fluticasone /Umeclidinium / Vilanterol	Inhalation powder	100mcg / 74,2mcg / 62,5mcg 200mcg / 74,2mcg / 62,5mcg	Trelegy Ellipta® /GSK
Cardiology			
Finerenone	Film-Coated Tablets	10mg / 20mg	Kerendia® / Bayer
Bempedoic Acid	Film-Coated Tablets	180mg	Nilemdo® / Daiichi Sankyo (Esperion)
Bempedoic Acid / Ezitimibe	Film-Coated Tablets	180mg / 10 mg	Nustendi® / Daiichi Sankyo (Esperion)
Anti-infectives for systemic use			
Avibactam / Ceftazidime	Powder for Injection	500mg / 2g	Zavicefta® / Pfizer (Abbvie / Allergan)

*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 subjected 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."

Under development value added

INN	INDICATION	DEVELOPMENT PHASE
Cardiovascular System		
CV31	Hypertension	Clinical development
CV22	Hypertension / Heart Failure	Lab development

Available

INN	PHARMA CEUTICA L FORM	STRENGTH	REFERENCE PRODUCT	Lactose Free	Stability	Shelf life
Alimentary tract & metabolism						
Dapaglifloz in* / Metformin CA	Film - coated tablets	5mg / 850mg 5mg / 1000mg	Xigduo® / AstraZeneca	Yes	II: on-going IVa: ext. from b IVb: on- going	24 months (36 months in Q3 2024) 24 months (36 months in Q3 2024)
Dapaglifloz in*CA	Film - coated tablets	5mg 10mg	Forxiga® / AstraZeneca	Yes	II: on-going IVa: ext. from b IVb: on- going	36 months 36 months
Empaglifloz in*CA	Film - coated tablets	10mg 25mg	Jardiance® / Boehringer Ingelheim	Yes	II: on-going IVa: ext. from b IVb: on- going	36 months 36 months - Not store above 30 oC
Linagliptin* CA	Film - coated tablets	5mg	Trajenta® / Boehringer Ingelheim	Yes	II: on-going IVa: ext. from b IVb: on- going	36 months 36 months
Orlistat	Hard capsules	120mg	Xenical® / Roche	Yes	II: available IVb: not available	24 months
Orlistat OTC	Hard capsules	60mg	Alli® / GSK	Yes	II: available IVa: not available IVb: not available	24 months

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Sitagliptin*	Film - coated tablets	25mg 50mg 100mg	Januvia® / Merck	Yes	II: available IVa: not available IVb: available	36 months
Sitagliptin* / Metformin	Film - coated tablets	50mg / 850mg 50mg / 1000mg	Janumet® / Merck	Yes	II: available IVa: not available IVb: available	24 months
Anti-infectives for systemic use						
Aciclovir	Tablets	200mg 400mg 800mg	Zovirax® / GSK	Yes	II: available IVa: not available IVb: not available	36 months
Antineoplastic & Immunomodulating Agents						
Apremilast *CA	Film - coated tablets	10mg 20mg 30mg	Otezla® / Celgene	Yes	II: available IVa: not available IVb: not available	12 months (target 36)
Blood & Blood forming organs						
Apixaban*	Film - coated tablets	2.5mg 5mg	Eliquis® / Bristol-Myers Squibb	No	II: available IVa: ext. from b IVb: available	36 months
Rivaroxaban*CA	Film - coated tablets	2.5mg 10mg 15mg 20mg	Xarelto® / Bayer	No	II: on-going IVa: ext. from b IVb: on-going	24 months
Rivaroxaban*	Capsules	10mg 15mg 20mg	Xarelto® / Bayer	No	II: on-going	24 months
Ticagrelor*	Film - coated tablets	60mg 90mg	Brilique® / AstraZeneca	Yes	II: available IVa: ext. from b IVb: available	36 months
Cardiovascular System						
Ramipril / Indapamide	Hard capsules (IR dosage form)	5mg / 2.5mg 10mg / 2.5mg 5mg / 1.25mg 10mg / 1.25mg	New combination	No	II: on-going	36 months
Sacubitril / Valsartan	Film - coated tablets	49mg / 51mg 24mg / 26mg 97mg / 103mg	Entresto® / Novartis	Yes	II: available IV: not available	48 months
Hydrochlorothiazide*	Tablets	12.5mg 25mg 50mg	Esidrex® / Novartis	No	II: available IVa: not available IVb: not available	60 months

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Ramipril / Amlodipine	Hard capsules	5mg / 5mg 5mg / 10mg 10mg / 5mg 10mg / 10mg	Tritace® (Ramipil) / Sanofi & Norvasc® (Amlodipine) / Pfizer	Yes	II: available IVa: not available IVb: not available	36 months
Rosuvastatin	Film - coated tablets	5mg 10mg 20mg	Crestor(TM) / AstraZeneca	No	II: available IVa: (12 months) IVb: not available	36 months
Telmisartan / Amlodipine	Bilayered Tablets	40mg / 5mg 40mg / 10mg 80mg / 5mg 80mg / 10mg	Twynsta® / Boehringer Ingelheim	Yes	II: available IVa: ext. from b IVb: available	36 months

Dermatologicals

Dimetindene	Gel	1mg /g (20g) 1mg /g (30g) 1mg /g (50g)	Fenistil(TM) / Novartis	Yes	II: available IVa: ext. from b IVb: available	36 months
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Genito-Urinary System & Sex Hormones

Tadalafil*	Film - coated tablets	2.5mg 5mg 10mg 20mg	Cialis® / Eli Lilly	No	II: available IVa: ext. from b IVb: available	48 months
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Musculoskeletal System

Paracetamol / Ibuprofen	Film - coated tablets	500 mg / 200 mg	Nurofen Ultima® / Reckitt Benckiser	II: available IVa: on-going IVb: on-going	36 months	
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Nervous System

Dimethyl Fumarate CA	Gastro - resistant hard capsules	120mg 240mg	Tecfidera® / Biogen Idec	Yes	II: on-going IVa: ext. from b IVb: on-going	36 months / do not store above 30oC (zone II) 24 months / do not store above 30oC (zone IVb)
Memantine hydrochloride	Film - coated tablets	10mg 20mg	Ebixa® / Lundbeck	No	II: available IVa: available IVb: no ext. from a	36 months
Quetiapine	Film - coated tablets	25mg / 100mg 150mg / 200mg 300mg	Seroquel® / AstraZeneca	No	II: available IVa: available IVb: available	36 months

Respiratory System

Xylometazoline / Dexpanthenol OTC	Nasal spray solution	1.0mg / 50mg / ml (10ml) 0.5mg / 50mg / ml (10 ml)	Nasic(TM) / Cassella-med	Yes	II: available IVa: ext. from b IVb: available	24 months (0.5mg) 36 months (1.0mg)
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Glycopyrronium	Inhalation powder	44mcg	Seebri Breezhaler® / Novartis	No	II: available	24 monts
Glycopyrronium / Indacaterol	Inhalation powder	43mcg / 85mcg	Ultibro Breezhaler® / Novartis	No	II: available IVb: on-going	24 months

Vitamins & Minerals

Cholecalciferol (Vitamin D3)	Soft capsule	20.000 IU	N/A	Yes	II: available IVa: not available	36 months
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