





PRODUCT LIST
March 2024
State of the art B2B

Under Development Generics

INN	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	DOSSIER AVAILABILITY
Alimentary tract & metabolism				
Empagliflozin*/Metformin	Film - coated tablets	5mg / 500mg 5mg / 850mg 5mg / 1000mg 12.5mg / 500mg 12.5mg / 850mg 12.5mg / 1000mg	Synjardy® / Boehringer Ingelheim	EU: Q2 2025
Linagliptin* / Metformin	Film - coated tablets	2.5mg / 500mg 2.5mg / 850mg 2.5mg / 1000mg	Jentaduet® / Boehringer Ingelheim	EU: Q3 2024
Allergy/Immuno				
Baricitinb	Film - coated tablets	2mg / 4mg	Olumiaant® / Lilly	EU: Q4 2026
Respiratory System				
Glycopyrronium / Indacaterol	Inhalation powder	43mcg / 85mcg	Ultibro Breezhaler® / Novartis	EU: Q1 2024
Fluticasone / Vilanterol	Inhalation powder	92mcg / 22mcg / 184mcg / 22mcg	Bro Ellipta® / GSK	EU: Q4 2026
Umedidinium / Vilanterol	Inhalation powder	55mcg / 22 mcg	Anoro Ellipta® /GSK	EU: Q2 2027

Under Development Value Added Generics

INN	INDICATION	LAB DEVELOPMENT	CLINICAL DEVELOPMENT	DOSSIER AVAILABILITY
Cardiovascular System				
CV21	Hypertension			
CV31	Hypertension			

*Polpharma Group API

CA: Dossier suitable for Canadian market

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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."

Available dossiers

INN	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	LACTOSE FREE	STABILITY	SHELF LIFE
Alimentary tract & metabolism						
Dapagliflozin* / Metformin ^{CA}	Film - coated tablets	5mg / 850mg 5mg / 1000mg	Xigduo® / AstraZeneca	Yes	II: on-going IVa: ext. from b IVb: on-going	24 months 24 months
Dapagliflozin* ^{CA}	Film - coated tablets	5mg 10mg	Forxiga® / AstraZeneca	Yes	II: on-going IVa: ext. from b IVb: on-going	24 months 24 months
Empagliflozin* ^{CA}	Film - coated tablets	10mg 25mg	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 30oC
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 IVa: not available IVb: not available	24 months
Orlistat OTC	Hard capsules	60mg	Alli® / GSK	Yes	II: available IVa: not available IVb: not available	24 months
Sitagliptin*	Film - coated tablets	25mg 50mg 100mg	Januvia® / Merck	Yes	II: available IVa: not available IVb: available	36 months
Stiagliptin* +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)

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Blood & Blood forming organs						
Apixaban*	Film - coated tablets	2.5mg 5mg	Eliquis® / Bristol-Myers Squibb	No	II: available IVa: ext. from b IVb: available	24 months
Rivaroxaban*	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
Amlodipine / Atorvastatin	Film - coated tablets	5mg / 10mg 10mg / 10mg 10mg / 20mg 5mg / 20mg	Norvasc® (Amlodi- pine) Sortis® (Atorvasta- tin) / Pfizer	Yes	II: available IVa: not available IVb: available	24 months
Enalapril	Tablets	5mg 10mg 20mg	Xanef® (Vasotec, Renitec) / MSD	Yes	II: available IVa: not available IVb: not available	24 months
Hydrochlorothiazide*	Tablets	12.5mg 25mg 50mg	Esidrex® / Novartis	No	II: available IVa: not available IVb: not available	60 months
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 40mg	Crestor® / AstraZeneca	No	II: available IVa: not available 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

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Dermatologicals						
Dimetindene	Gel	1mg /g (20g)	Fenistil™ / Novartis	Yes	II: available	
		1mg /g (30g)			IVa: ext. from b	
		1mg /g (50g)			IVb: available	
Genito-Urinary System & Sex Hormones						
Tadalafil*	Film - coated tablets	2.5mg	Cialis® / Eli Lilly	No	II: available	48 months
		5mg			IVa: ext. from b	
		10mg			IVb: available	
		20mg				
Musculoskeletal System						
Ibuprofen +Paracetamol	Film - coated tablets	200mg	Nurofen Ultima® / Reckitt Benckiser	Yes	II: available	36 months
		500 mg			IVa: not available IVb: not available	
Nervous System						
Dimethyl Fumarate ^{CA}	Gastro-resistant hard capsules	120mg	Tecfidera® / Biogen Idec	Yes	II: on-going	36 months / do not store above 30°C (zone II)
		240mg			IVa: ext. from b IVb: on-going	
Memantine hydrochloride	Film-coated tablets	10mg	Ebixa® / Lundbeck	No	II: available	36 months
		20mg			IVa: available IVb: no ext. from a	
Metamizole sodium	Film-coated tablets	500mg	Novalgine® / Sanofi Aventis	No	II: on-going	36 months
					IVa: not available IVb: not available	
Quetiapine	Film-coated tablets	25mg / 100mg	Seroquel® / AstraZeneca	No	II: available	36 months
		150mg / 200mg			IVa: available	
		300mg			IVb: available	
Respiratory system						
Xylomethazoline + Dexpanthenol OTC	Nasal spray solution	1.0 mg / 50 mg	Nasic® / Cassella-med	Yes	II: available	24 months (0,5mg)
		/ ml (10 ml)			IVa: ext. from b	
		0.5 mg / 50 mg			IVb: available	
		/ ml (10 ml)				
Glycopyrronium	Inhalation powder	44mcg	Seebri Breezhaler® / Novartis	No	II: available	24 months
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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