

Product list

Farmaprojects polpharma

Under development generics

INN	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT				
Alimentary tract & metabolism							
Empagliflozin*/ Metformin	Film - coated tablets	5mg / 850mg 5mg / 1000mg 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/Immu	ino						
Baricitinb	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)				
Short RNA (Oligonucleotide)							
Nusinersen	Solution for injection	12 mg/5ml vial (2.4mg/ml)	Spinraza® (Biogen)				
Inclisiran	Solution for injection	284 mg/1.5 mL prefilled syringe (189 mg/mL)	Leqvio® (Novartis)				

*Polpharma Group API

CA: Dossier suitable for Canadian market

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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						
Dapagliflozin* / MetforminCA	Film - coated tablets	5mg / 850mg 5mg / 1000mg	Xigduo® / AstraZeneca	Yes	ll: on-going IVa: ext. from b IVb: on- going	24 months (36 months in Q3 2024) 24 months (36 months in Q3 2024)
Dapagliflozin* CA	Film - coated tablets	5mg 10mg	Forxiga® / AstraZeneca	Yes	ll: on-going IVa: ext. from b IVb: on- going	36 months 36 months
Empagliflozin* CA	Film - coated tablets	10mg 25mg	Jardiance® / Boehringer Ingelheim	Yes	ll: 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	ll: on-going IVa: ext. from b IVb: on- going	36 months 36 months
Orlistat	Hard capsules	120mg	Xenical® / Roche	Yes	ll: available IVb: not available	24 months
Orlistat OTC	Hard capsules	60mg	Alli® / GSK	Yes	ll: 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	ll: available IVa: not available IVb: available	24 months
Anti-infective	s for systen	nic use				
Aciclovir	Tablets	200mg 400mg 800mg	Zovirax® / GSK	Yes	ll: available IVa: not available IVb: not available	36 months
Antineoplasti	c & Immun	omodulating Ag	ents			
Apremilast*CA	Film - coated tablets	10mg 20mg 30mg	Otezla® / Celgene	Yes	ll: available IVa: not available IVb: not available	12 months (target 36)
Blood & Blood	d forming o	rgans				
Apixaban*	Film - coated tablets	2.5mg 5mg	Eliquis® / Bristol- Myers Squibb	No	ll: available IVa: ext. from b IVb: available	36 months
Rivaroxaban*C A	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	ll: 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	ll: available IV: not available	48 months
					II: available	

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Hydrochlorothi

azide*

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Tablets

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No

IVa: not

available IVb: not available 60 months

Esidrex® /

Novartis

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12.5mg 25mg

50mg

Ramipril / Amlodipine	Hard capsules	5mg / 5mg 5mg / 10mg 10mg / 5mg 10mg / 10mg	Tritace® (Ramipil) / Sanofi & Norvasc® (Amlodipine) / Pfizer	Yes	ll: available IVa: not available IVb: not available	36 months
Rosuvastatin	Film - coated tablets	5mg 10mg 20mg	Crestor(TM) / AstraZeneca	No	ll: 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	ll: available IVa: ext. from b IVb: available	36 months
Dermatologic	als					
Dimetindene	Gel	1mg /g (20g) 1mg /g (30g) 1mg /g (50g)	Fenistil(TM) / Novartis	Yes	ll: available IVa: ext. from b IVb: available	36 months
Genito-Urinar	y System &	Sex Hormones				
Tadalafil*	Film - coated tablets	2.5mg 5mg 10mg 20mg	Cialis® / Eli Lilly	No	ll: available IVa: ext. from b IVb: available	48 months
Musculoskelet	tal System					
Paracetamol/ Ibuprofen	Film - coated tablets	500 mg / 200 mg	Nurofen Ultima® / Reckitt Benckiser	ll: available IVa: on- going IVb: on-going	36 months	
Nervous Syste	em					
Dimethyl FumarateCA	Gastro - resistant hard capsules	120mg 240mg	Tecfidera® / Biogen Idec	Yes	ll: 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	ll: available IVa: available IVb: no ext. from a	36 months
Quetiapine	Film- coated tablets	25mg / 100mg 150mg / 200mg 300mg	Seroquel® / AstraZeneca	No	ll: available IVa: available IVb: available	36 months
Respiratory System						

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Xylomethazolin e/ Dexpanthenol OTC	Nasal spray solution	1.0mg / 50mg / ml (10ml) 0.5mg / 50mg / ml (10 ml)	Nasic(TM) / Cassella-med	Yes	ll: available IVa: ext. from b IVb: available	24 months (0.5mg) 36 months (1.0mg)	
Glycopyrroniu m	Inhalatio n powder	44mcg	Seebri Breezhaler® / Novartis	No	II: available	24 monts	
Glycopyrroniu m / Indacaterol	Inhalatio n 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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