











# AVAILABLE DOSSIERS

PRODUCT NAME	THERAPEUTIC AREA	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	LACTOSE FREE	ZONE IV	CPP FEASIBILITY
<b>Dapagliflozin</b> <sup>*CA*</sup>	 Alimentary tract & metabolism	Film-coated tablets	<b>5 mg</b> <b>10 mg</b>	Forxiga / Astra Zeneca		II: on-going IVa: ext. From b IVb: on-going	No
<b>Linagliptin</b> <sup>*CA*</sup>	 Alimentary tract & metabolism	Film-coated tablets	<b>5 mg</b>	Trajenta / Boehringer Ingelheim		II: on-going IVa: ext. From b IVb: on-going	No
<b>Omeprazole</b>	 Alimentary tract & metabolism	Powder for solution for infusion or injection	<b>40 mg</b>	Losec / AstraZeneca		II: available IVa: not available IVb: not available	Yes
<b>Orlistat OTC</b>	 Alimentary tract & metabolism	Hard capsules	<b>60 mg</b>	Alli / GSK		II: available IVa: not available IVb: not available	Yes
<b>Orlistat</b>	 Alimentary tract & metabolism	Hard capsules	<b>120 mg</b>	Xenical / Roche		II: available IVa: not available IVb: not available	Yes
<b>Pantoprazole (sodium sesquihydrate)</b>	Alimentary tract & metabolism	Powder for solution for infusion or injection	<b>40 mg</b>	Pantozol / Altana		II: available IVa: not available IVb: not available	Yes
<b>Sitagliptin (hydrochloride)</b>	 Alimentary tract & metabolism	Film-coated tablets	<b>25 mg</b> <b>50 mg</b> <b>100 mg</b>	Januvia / Merck		II: on-going IVa: ext. From b IVb: on-going	No

<b>Sitagliptin (hydrochloride) + Metformin</b>		Alimentary tract & metabolism	Film-coated tablets	<b>50/850 mg</b> <b>50/1000 mg</b>	Janumet / Merck		II: on-going IVa: ext. From b IVb: on-going	No
<b>Aciclovir</b>		Anti-infectives for systemic use	Tablets	<b>200 mg</b> <b>400 mg</b> <b>800 mg</b>	Zovirax / GSK		II: available IVa: not available IVb: not available	Yes
<b>Clarithromycin</b>		Anti-infectives for systemic use	Powder for solution for infusion or injection	<b>500 mg</b>	Klacid IV / Abbott		II: available IVa: not available IVb: not available	Yes
<b>Levofloxacin hemihydrate</b>		Anti-infectives for systemic use	Film-coated tablets	<b>500 mg</b>	Tavanic / Aventis		N/A	No
<b>Lenalidomide</b>		Antineoplastic & Immunomodulating Agents	Capsules	<b>2.5 mg</b> <b>5 mg</b> <b>7.5 mg</b> <b>10 mg</b> <b>15 mg</b> <b>20 mg</b> <b>25 mg</b>	Revlimid / Celgene		II: on-going IVa: ext. From b IVb: on-going	No
<b>Apixaban<sup>^</sup></b>		Blood & Blood forming organs	Film-coated tablets	<b>2.5 mg</b> <b>5 mg</b>	Eliquis / Bristol-Myers Squibb		II: on-going IVa: ext. From b IVb: on-going	No
<b>Rivaroxaban<sup>*CA^</sup></b>		Blood & Blood forming organs	Film-coated tablets	<b>2.5 mg</b> <b>10 mg</b> <b>15 mg</b> <b>20 mg</b>	Xarelto / Bayer		II: on-going IVa: ext. From b IVb: on-going	No
<b>Ticagrelor<sup>*(1)^</sup></b>		Blood & Blood forming organs	Film-coated tablets	<b>60 mg</b> <b>90 mg</b>	Brilique / AstraZeneca		II: available IVa: ext. From b IVb: available	No

<b>Enalapril</b>		Cardiovascular System	Tablets	<b>5 mg</b> <b>10 mg</b> <b>20 mg</b>	Xanef (Vasotec, Renitec) / MSD		II: on-going IVa: not available IVb: not available	No
<b>Amlodipine (besilate) + Atorvastatin (calcium)</b>		Cardiovascular System	Film-coated tablets	<b>5 mg + 10 mg</b> <b>10 mg + 10 mg</b> <b>10 mg + 20 mg</b> <b>5 mg + 20 mg</b>	Norvasc (Amlodipine)+Sortis (Atorvastatin) / Pfizer		II: available IVa: not available IVb: not available	Yes
<b>Hydrochlorothiazide*</b>		Cardiovascular System	Tablets	<b>12.5 mg</b> <b>25 mg</b> <b>50 mg</b>	Esidrex / Novartis		II: available IVa: not available IVb: not available	Yes <sup>(3)</sup>
<b>Ramipril + Amlodipine (besilate)</b>		Cardiovascular System	Hard capsules	<b>5 mg + 5 mg</b> <b>5 mg + 10 mg</b> <b>10 mg + 5 mg</b> <b>10 mg + 10 mg</b>	Tritace (Ramipril) / Sanofi & Norvasc (Amlodipine) / Pfizer		II: available IVa: not available IVb: not available	Yes
<b>Rosuvastatin (calcium)</b>		Cardiovascular System	Film-coated tablets	<b>5 mg</b> <b>10 mg</b> <b>20 mg</b> <b>40 mg</b>	Crestor / AstraZeneca		II: available IVa: not available IVb: not available	Yes
<b>Telmisartan + Amlodipine<sup>(1)</sup></b>		Cardiovascular System	Bilayered Tablets	<b>40/5 mg</b> <b>40/10 mg</b> <b>80/5 mg</b> <b>80/10 mg</b>	Twynsta / Boehringer Ingelheim		II: on-going IVa: ext. From b IVb: on-going	Yes
<b>Dimetindene OTC<sup>(4)</sup></b>		Dermatologicals	Gel	<b>1 mg/g (20 g)</b> <b>1 mg/g (30 g)</b> <b>1 mg/g (50 g)</b>	Fenistil / Novartis		II: available IVa: available IVb: no ext. From a	Yes
<b>Tadalafil*</b>		Genito-Urinary system & Sex Hormones	Film-coated tablets	<b>2.5 mg</b> <b>5 mg</b> <b>10 mg</b> <b>20 mg</b>	Cialis / Eli Lilly		II: available IVa: ext. From b IVb: available	Yes

<b>Dimethyl Fumarate<sup>CA</sup></b>		Nervous system	Gastro-resistant hard capsules <sup>(5)</sup>	<b>120 mg</b> <b>240 mg</b>	Tecfidera / Biogen Idec		II: on-going IVa: ext. From b IVb: on-going	No
<b>Ibuprofen + Paracetamol</b>		Musculoskeletal system	Film-coated tablets	<b>200 mg - 500 mg</b>	Nurofen Ultima / Reckitt Benckiser		II: on-going IVa: not available IVb: not available	No
<b>Dapagliflozin* / Metformin<sup>CA^</sup></b>		Alimentary tract & metabolism	Film-coated tablets	<b>5/850 mg</b> <b>5/1000 mg</b>	Xigduo / Astra Zeneca		II: on-going IVa: ext. From b IVb: on-going	No
<b>Memantine hydrochloride</b>		Nervous system	Film-coated tablets	<b>10 mg</b> <b>20 mg</b>	Ebixa / Lundbeck		II: available IVa: available IVb: no ext. From a	Yes
<b>Metamizole sodium</b>		Nervous system	Film-coated tablets	<b>500 mg</b>	Novalgin / Sanofi Aventis		II: on-going IVa: not available IVb: not available	No
<b>Quetiapine (fumarate)</b>		Nervous system	Film-coated tablets	<b>25 mg</b> <b>100 mg</b> <b>150 mg</b> <b>200 mg</b> <b>300 mg</b>	Seroquel / AstraZeneca		II: available IVa: available IVb: available	Yes
<b>Xylomethazoline (hydrochloride) + Dexamphenol<sup>(4)</sup> OTC</b>		Respiratory system	Nasal spray solution	<b>(1.0 mg + 50 mg)/ml (10 ml)</b> <b>(0.5 mg + 50 mg)/ml (10 ml)</b>	Nasic / Cassella-med		II: available IVa: ext. From b IVb: available <sup>(6)</sup>	Yes
<b>Cholecalciferol (Vitamin D3)</b>		Vitamins & Minerals	Soft capsule	<b>20.000 IU (500 µg)</b> <b>50.000 IU (1250 µg)</b>	N/A		II: on-going IVa: not available IVb: not available	No

**Empagliflozin**



Alimentary tract & metabolism Film-coated tablets

**10 mg**  
**25 mg**

Jardiance /  
Boehringer  
Ingelheim



II: on-going No  
IVa: ext.  
From b  
Ivb: on-  
going

\* Polpharma Group API

CA Dossier suitable for Canadian market

- (1) No CPP feasibility for Hydrochlorothiazide 50 mg
- (2) Dossier availability subject to some restriction
- (3) Delayed release capsules, as per CA standard Terms
- (4) BEQ study against Canadian reference product available
- (5) Pending dossier update (new API Valsartan source required)
- (6) Only for higher Strength: 1 mg/ml + 50 mg/ml (10 ml)

^ This product is not offered for sale or made available in Germany due to patent (SPC) protection



No contains lactose



Dossier ready to file

#### DISCLAIMER

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Dossier list extracted: November 18, 2022, 7:14 am

# DOSSIERS UNDER DEVELOPMENT

PRODUCT NAME	THERAPEUTIC AREA	PHARMACEUTICAL FORM	STRENGTH	REFERENCE PRODUCT	DOSSIER AVAILABILITY
<b>Tofacitinib SR<sup>^</sup></b>	Antineoplastic & Immunomodulating Agents	Prolonged-release tablet	<b>11 mg</b>	Xeljanz / Pfizer	Early stage
<b>Apremilast<sup>*(2)^</sup></b>	Antineoplastic & Immunomodulating Agents	Film-coated tablets	<b>10 mg</b> <b>20 mg</b> <b>30 mg</b>	Otezla / Celgene	2023 Q3 (EU)
<b>Indacaterol / Glycopyrronium<sup>^</sup></b>	Respiratory system	Inhalation powder	<b>85/43 mcg</b>	Ultibro Breezhaler / Novartis	2024 Q1
<b>Glycopyrronium<sup>^</sup></b>	Respiratory system	Inhalation powder	<b>44 mcg</b>	Seebri Breezhaler / Novartis	2023 Q2
<b>Sacubitril / Valsartan<sup>(3)</sup></b>	Cardiovascular System	Film-coated tablets	<b>24mg / 26mg</b> <b>49mg / 51mg</b> <b>97mg / 103mg</b>	Entresto / Novartis	2022 Q4 (CA) / 2023 Q4 (EU)
<b>Nebivolol</b>	Cardiovascular System	Tablets	<b>5 mg</b> <b>10 mg</b>	Nebilet / Menarini	2022 Q4
<b>Linagliptin<sup>*</sup> / Metformin<sup>(2)^</sup></b>	Alimentary tract & metabolism	Film-coated tablets	<b>2.5/500 mg</b> <b>2.5/850 mg</b> <b>2.5/1000 mg</b>	Jentaduetto / Boehringer Ingelheim	2024 Q2
<b>Empagliflozin<sup>*</sup> / Metformin<sup>^</sup></b>	Alimentary tract & metabolism	Film-coated tablets	<b>5mg/500mg</b> <b>5mg/850mg</b> <b>5mg/1000 mg</b> <b>12.5mg/500mg</b> <b>12.5mg/850mg</b> <b>12.5mg/1000mg</b>	Synjardy / Boehringer Ingelheim	2025 Q1
<b>Empagliflozin<sup>*</sup> / Linagliptin<sup>**</sup></b>	Alimentary tract & metabolism	Film-coated tablets	<b>10 mg/5 mg</b> <b>25 mg/5 mg</b>	Glyxambi/ Boehringer Ingelheim	2023 Q4
<b>Aripiprazole<sup>*</sup></b>	Nervous system	Powder and solvent for prolonged-release suspension for injection	<b>300 mg</b> <b>400 mg</b>	Abilify Maintena/Otsuka	2025 Q3
<b>Tofacitinib IR</b>	Antineoplastic & Immunomodulating Agents	Film-coated tablets	<b>5 mg</b> <b>10 mg</b>	Xeljanz / Pfizer	Early stage

<b>Vortioxetine</b>	Nervous system	Film-coated tablets	<b>5 mg</b> <b>10 mg</b> <b>15 mg</b> <b>20 mg</b>	Brintellix / H. Lundbeck	2025 Q1
				A/S	

\* Polpharma Group API

<sup>(1)</sup> BEQ study against Canadian reference product available

<sup>(2)</sup> BEQ study against Canadian reference product on-going

<sup>(3)</sup> BEQ study against Canadian reference product planned

<sup>^</sup> This product is not offered for sale or made available in Germany due to patent (SPC) protection

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