

Product List

2023/2024



FINISHED PRODUCT LIST

Active substance	Dosage form	Strengths	EU-CTD dossier
Aripiprazole	Tablets	5 / 10 / 15 / 30 mg	✓
Atorvastatin + Ezetimibe FDC	Capsules	10 + 10 / 20 + 10 / 40 + 10 mg	✓
Bisoprolol + Amlodipine FDC	Tablets	5 + 5 / 5 + 10 / 10 + 5 / 10 + 10 mg	✓
Cilostazol	Tablets	50 / 100 mg	✓
Dimetindene (OTC)	Gel	1 mg / g	✓
Donepezil	Film-coated tablets	5 / 10 mg	✓
Ezetimibe	Tablets	10 mg	✓
Hemorrhoids rectal (MD)	Ointment		✓
Hemorrhoids rectal (MD)	Suppository		✓
Hyaluronic acid + Lactic acid (MD)	Vaginal gel	75 g, 7x5 g	✓
Nitroglycerin spray	Aerosol	10 g / 22 ml	✓
Ramipril + Amlodipine FDC	Capsules	5 + 5 / 5 + 10 / 10 + 5 / 10 + 10 mg	✓
Ramipril + Bisoprolol FDC	Capsules	5 + 5 / 5 + 10 / 10 + 5 / 10 + 10 mg	✓
Ramipril + Indapamide SR FDC	Capsules	5 + 1,5 / 10 + 1,5 mg	✓
Rivaroxaban	Tablets	2,5 / 10 / 15 / 20 mg	✓
Rosuvastatin	Film-coated tablets	5 / 10 / 20 / 40 mg	✓
Rosuvastatin + Ezetimibe FDC	Capsules	5 + 10 / 10 + 10 / 20 + 10 / 40 + 10 mg	✓
Rosuvastatin + Ramipril FDC	Capsules	10 + 5 / 10 + 10 / 20 + 5 / 20 + 10 mg	✓
Sacubitril + Valsartan FDC	Film-coated tablets	24 + 26 / 49 + 51 / 97 + 103 mg	✓
Sunitinib	Capsules	12,5 / 25 / 50 mg	✓
Dapagliflozin	Film-coated tablets	5 / 10 mg	11.2024
Empagliflozin	Film-coated tablets	10 mg	Q4.2025
Dapagliflozin + Atorvastatin FDC	Capsules	10 + 10 / 10 + 20 / 10 + 40 mg	Q2.2026
Empagliflozin + Atorvastatin FDC	Capsules	10 + 10 / 10 + 20 / 10 + 40 mg	Q4.2026
Dapagliflozin + Ramipril FDC	Capsules	10 + 5 / 10 + 10 mg	Q4.2025
Dapagliflozin + Bisoprolol FDC	Capsules	10 + 2,5 / 10 + 5 / 10 + 10 mg	08.2025
Empagliflozin + Ramipril FDC	Capsules	10 + 5 / 10 + 10 mg	TBD
Dapagliflozin + Rosuvastatin FDC	Capsules	10 + 10 / 10 + 20 / 10 + 40 mg	Q4.2025
Empagliflozin + Rosuvastatin FDC	Capsules	10 + 10 / 10 + 20 / 10 + 40 mg	Q4.2025
Dapagliflozin + Eplerenon FDC	Capsules	10 + 25 / 10 + 50 mg	Q4.2026
Dapagliflozin + Bisoprolol + Eplerenon FDC	Capsules	10 + 5 + 25 / 10 + 10 + 25 / 10 + 5 + 50 / 10 + 10 + 50 mg	Q4.2026
Bempedoic acid	Film-coated tablets	180 mg	Q3.2026

HIGHLY POTENT PORTFOLIO

Active substance	Dosage form	Strengths	EU-CTD dossier availability
Abemaciclib	Tablets	50 / 100 / 150 mg / 200 mg	Q4.2026
Osimertinib	Tablets	40 / 80 mg	Q3.2026
Palbociclib	Film-coated tablets	75 / 100 / 125 mg	Q3.2025
Ribociclib	Tablets	200 mg	Q3.2027

ACTIVE PHARMACEUTICAL INGREDIENTS

COMMERCIALY AVAILABLE

INN	Quality	CEP / BR DMF / CN DMF / US DMF / JP DMF / EU DMF
Allopurinol	EP/JP	JP DMF / CEP
Amlodipine besilate	EP	CN DMF / BR DMF / CEP
Bisoprolol fumarate	EP	CEP
Carvedilol form II	EP	CEP
Chlorpromazine HCl	EP	EU DMF / BR DMF / JP DMF / CEP
Clomiphene citrate	EP	EU DMF
Crotamiton	EP/USP/CP	CN DMF / US DMF / CEP
Donepezil HCl form I	USP/EP	EU DMF
Ethacrynic acid	EP/USP	CEP / US DMF
Ketoprofen	EP	CEP
Levomopromazine maleate	EP	EU DMF / BR DMF / CEP
Methyldopa	EP	CEP
Nifedipine	EP	EU DMF
Nitrendipine	EP	CEP
Promethazine HCl	EP/USP	US DMF / BR DMF / CEP
Quetiapine fumarate	EP	EU DMF / CEP
Ramipril	EP	CEP
Rivaroxaban	EP	EU DMF
Tofisopam	JP/ICH	JP DMF / EU DMF

SOON COMMERCIALY AVAILABLE

INN	Quality	DMF, CEP
Duloxetine	EP	CEP (2024 Q4)
Levocetirizine diHCl	EP	CEP (2025 Q1)

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DRUG SUBSTANCE DEVELOPMENT LIST

ADVANCED STAGE

Kilolab process or pilot scale up is ready, including PAR measurements at least for the last two chemical steps and the DS purification step.

Where we have EGIS own DS form, we have originator's form too.

Documentation is available in Hungarian.

INN	Sample	Quality	Egis own DS form (besides originator's form)	Technical package
Abemaciclib**x	✓	ICH	x	✓
Avapritinib*	✓	ICH	✓	✓
Blarcomesine*	✓	ICH	✓	✓
Dapagliflozin-2-propanediol***	✓	ICH	x	✓
Empagliflozin***	✓	ICH	✓	✓
LCZ 696***	✓	ICH	x	✓
Osimertinib**	✓	ICH	x	✓
Palbociclib***x	✓	ICH	✓	✓
Pimavanserin*	✓	ICH	✓	✓

*: kilolab process development is completed

**: kilolab process development is completed, pilot scale-up in progress

***: kilolab process development is completed, pilot scale-up is completed

x: Products developed under Strategic Cooperation with Polpharma

EARLY STAGE

INN	Sample	Egis own form
Acalabrutinib#	x	x
Alectinib##	✓	x
Deucravacitinib#	✓	✓
Fruquintinib##	✓	✓
Ozanimod##	✓	✓
Ribociclib##	✓	✓
Solriamfetol##	✓	✓
Upadacitinib#	✓	x
Venetoclax##	✓	✓

#: lab synthesis development is in progress

##: lab synthesis development is completed

WISH LIST

INN
Abrocitinib
Entrectinib
Etrasimod x
Resmetirom
Troiluzole

x: Products developed under Strategic Cooperation with Polpharma

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