

## FDF Product list (October 2022)

Product Family Name	Dosage Form	Dosage Strength	Development Status	Dossier Readiness	ATC Group	4B Zone Stability*	Available Territory**
<b>ABACAVIR SULFATE + LAMIVUDINE</b>	Film-coated tablet	600 mg + 300 mg	Ready	EU registered	Anti-infectives for systemic use	No	Global
<b>ABIRATERONE ACETATE</b>	Film-coated tablet	500 mg	Ready	EU registered	Antineoplastic and immunomodulating agents	Yes	Global
<b>ACETYLSALICYLIC ACID</b>	Tablet	50 mg, 100 mg	Ongoing	Q3 2023	Various ATC structures	No	Europe
<b>AGOMELATINE</b>	Film-coated tablet	25 mg	Ready	EU registered	Antidepressant	Can be added	Global
<b>AMLODIPINE</b>	Tablet	2.5 mg, 5 mg, 10 mg	Ready	EU registered	Cardiovascular system	Yes	Europe
<b>AMLODIPINE BESILATE + CANDESARTAN CILEXETIL</b>	Tablet	5 mg + 8 mg 10 mg + 16 mg	Ready	EU registered	Cardiovascular system	No	Europe
<b>AMLODIPINE BESILATE + CANDESARTAN CILEXETIL</b>	Tablet	5 mg + 16 mg	Ready	EU registered	Cardiovascular system	No	Global



Zent2U@zentiva.com



+420 267243231.



Zentiva Group a.s.  
U Kabelovny 529/16  
102 00 Prague 10  
Czech Republic



www.Zent2U.com

Product Family Name	Dosage Form	Dosage Strength	Development Status	Dossier Readiness	ATC Group	4B Zone Stability*	Available Territory**
<b>AMLODIPINE BESILATE + INDAPAMIDE + PERINDOPRIL ERBUMINE</b>	Tablet	5 mg + 1.25 mg + 4 mg 10 mg + 1.25 mg + 4 mg 5 mg + 2.5 mg + 8 mg 10 mg + 2.5 mg + 8 mg	Ready	EU registered	Cardiovascular system	No	Global
<b>AMLODIPINE BESILATE + PERINDOPRIL ERBUMINE</b>	Tablet	5 mg + 4 mg 10 mg + 4 mg 5 mg + 8 mg 10 mg + 8 mg	Ready	EU registered	Cardiovascular system	No	Global
<b>AMLODIPINE BESILATE + VALSARTAN</b>	Film-coated tablet	5 mg + 80 mg 5 mg + 160 mg 10 mg + 160 mg	Ready	EU registered	Cardiovascular system	No	Europe
<b>APIXABAN</b>	Film-coated tablet	2.5 mg, 5 mg	Ready	Filed in EU	Blood and blood forming organs	No	Europe
<b>APREMILAST</b>	Film-coated tablet	10 mg, 20 mg, 30 mg	Ongoing	Q1 2023	Dermatological drugs	At risk	Global
<b>ATORVASTATIN CALCIUM</b>	Film-coated tablet	10 mg, 20 mg, 30 mg 40 mg, 60 mg, 80 mg	Ready	Q4 2022	Cardiovascular system	No	Europe
<b>BISOPROLOL FUMARATE</b>	Tablet	1.25 mg, 2.5 mg, 3.75 mg, 5 mg, 7.5 mg, 10 mg	Ready	EU registered	Cardiovascular system	No	Global
<b>CLOPIDOGREL BISULPHATE</b>	Film-coated tablet	75 mg	Ongoing	Q1 2023	Blood and blood forming organs	Can be added	Global



Product Family Name	Dosage Form	Dosage Strength	Development Status	Dossier Readiness	ATC Group	4B Zone Stability*	Available Territory**
<b>DAPAGLIFLOZIN</b>	Film-coated tablet	5 mg, 10 mg	Ongoing	Q3 2024	Alimentary tract and metabolism	Can be added	Global
<b>DAPAGLIFLOZIN + METFORMIN</b>	Film-coated tablet	5 mg + 850 mg 5 mg + 1000 mg	Ongoing	Q4 2025	Alimentary tract and metabolism	Can be added	Global
<b>DEFERASIROX</b>	Film-coated tablet	90 mg, 180 mg, 360 mg	Ready	EU registered	Various ATC structures	No	Global
<b>DROSPIRENONE + ESTRADIOL</b>	Film-coated tablet	2 mg + 1 mg	Ready	Planned in Q1 2023	Hormone replacement therapy	No	Europe
<b>DULOXETINE HYDROCHLORIDE</b>	Capsule hard gastro-resistant	30 mg, 60 mg	Ready	EU registered	Nervous system	No	Global
<b>DULOXETINE HYDROCHLORIDE</b>	Capsule hard gastro-resistant	20 mg, 40 mg	Ready	EU registered	Urology	No	Europe
<b>EDOXABAN</b>	Film-coated tablet	15 mg, 30 mg, 60 mg	Ongoing	Q3 2023	Cardiovascular system	Can be added	Global
<b>EMPAGLIFLOZIN</b>	Film-coated tablet	10 mg, 25 mg	Ongoing	Q3 2025	Alimentary tract and metabolism	Can be added	Global
<b>EMTRICITABINE + RILPIVIRINE + TENOFOVIR ALAFENAMIDE</b>	Film-coated tablet	200 mg + 25 mg + 25 mg 200 mg+27.5 mg +28mg	Ongoing	Q2 2024	Antivirotic	Can be added	Global



Zent2U@zentiva.com



+420 267243231.



Zentiva Group a.s.  
U Kabelovny 529/16  
102 00 Prague 10  
Czech Republic



www.Zent2U.com

Product Family Name	Dosage Form	Dosage Strength	Development Status	Dossier Readiness	ATC Group	4B Zone Stability*	Available Territory**
<b>EMTRICITABINE + TENOFOVIR ALAFENAMIDE</b>	Film-coated tablet	200 mg + 10 mg 200 mg + 25 mg	Ongoing	Q1 2024	Antiviral	Can be added	Global
<b>ENZALUTAMIDE</b>	Film-coated tablet	40 mg, 80 mg	Ongoing	Q2 2025	Antineoplastic and immunomodulating agents	Can be added	Global
<b>ETORICOXIB</b>	Film-coated tablet	30 mg, 60 mg 90 mg, 120 mg	Ready	EU registered	Musculoskeletal system	No	Europe
<b>FINGOLIMOD</b>	Capsule, hard	0.5 mg	Ready	EU registered	Multiple sclerosis	No	Europe
<b>HYDROCHLOROTHIAZIDE+ LOSARTAN POTASSIUM</b>	Film-coated tablet	12.5 mg + 50 mg 12.5 mg + 100mg 25 mg + 100 mg	Ready	EU registered	Cardiovascular system	No	Global
<b>HYDROCHLOROTHIAZIDE + TELMISARTAN</b>	Tablet	12.5 mg + 40 mg 12.5 mg + 80 mg 25 mg + 80 mg	Ready	EU registered	Cardiovascular system	No	Global
<b>IBANDRONATE SODIUM MONOHYDRATE</b>	Film-coated tablet	150 mg	Ready	EU registered	Musculoskeletal system	No	Europe
<b>IBUPROFEN</b>	Film-coated tablet	200 mg, 400 mg 600 mg, 800 mg	Ready	Filed in EU	Nervous system	No	Global
<b>IBRUTINIB</b>	Film-coated tablet	140 mg, 280 mg 420 mg, 560 mg	Ongoing	Q2 2025	Antineoplastic and immunomodulating agents	Can be added	Global

Product Family Name	Dosage Form	Dosage Strength	Development Status	Dossier Readiness	ATC Group	4B Zone Stability*	Available Territory**
<b>IBRUTINIB</b>	Film-coated tablet	140 mg, 280 mg 420 mg, 560 mg	Ongoing	Q2 2025	Antineoplastic and immunomodulating agents	Can be added	Global
<b>ILOPROST</b>	Nebuliser solution	10 µg / 1 ml	Ready	EU registered	Blood and blood forming organs	No	Europe
<b>ILOPROST</b>	Nebuliser solution	20 µg / 1 ml	Ready	EU registered	Blood and blood forming organs	Yes	Global
<b>ILOPROST</b>	Solution for injection	100 µg / 1 ml (0.5 ml)	Ready	EU registered	Blood and blood forming organs	No	Global
<b>LACOSAMIDE</b>	Film-coated tablet	50 mg, 100 mg 150 mg, 200 mg	Ongoing	Q2 2023	Nervous system	Yes	Global
<b>LEVETIRACETAM</b>	Film-coated tablet	250 mg, 500 mg 750 mg, 1000 mg	Ready	EU registered	Nervous system	No	Global
<b>LINAGLIPTIN</b>	Film-coated tablet	5 mg	Ready	EU registered	Alimentary tract and metabolism	No	Europe
<b>LOPERAMIDE</b>	Capsule	2 mg	Ongoing	Q4 2023	Antipropulsive	Can be added	Global
<b>METAMIZOLE SODIUM</b>	Film-coated tablet	500 mg	Ready	Filed in EU	Nervous system	Yes	To be discussed



Zent2U@zentiva.com



+420 267243231.



Zentiva Group a.s.  
U Kabelovny 529/16  
102 00 Prague 10  
Czech Republic



www.Zent2U.com

Product Family Name	Dosage Form	Dosage Strength	Development Status	Dossier Readiness	ATC Group	4B Zone Stability*	Available Territory**
<b>METAMIZOLE SODIUM</b>	Injection	500 mg/ml (2 ml)	Ready	To be filed in October	Nervous system	Can be added	To be discussed
<b>METFORMIN HYDROCHLORIDE</b>	Film-coated tablet	500 mg, 850 mg, 1000 mg	Ready	EU registered	Alimentary tract and metabolism	Yes	Global
<b>NOREPINEPHRINE</b>	Injection	1 mg / 1 ml	Ongoing	Q4 2023	Cardiovascular system	At risk	Global
<b>PARACETAMOL</b>	Tablet	500 mg, 1000 mg	Ready	EU registered	Nervous system	Yes	Global
<b>PERINDOPRIL ARGININE</b>	Film-coated tablet	2.5 mg, 5 mg, 10 mg	Ready	EU registered	Cardiovascular system	No	Global
<b>PRASUGREL HYDROCHLORIDE</b>	Film-coated tablet	5 mg, 10 mg	Ready	Q2 2023	Blood and blood forming organs	Yes	Global
<b>RAMIPRIL</b>	Tablet	1.25 mg, 2.5 mg, 5 mg, 10 mg	Ongoing	Q1 2024	Cardiovascular system	Can be added	Global
<b>RILMENIDINE</b>	Tablet	1 mg	Ready	EU registered	Cardiovascular system	No	Europe
<b>RIVAROXABAN</b>	Film-coated tablet	2.5 mg, 10 mg, 15 mg, 20 mg	Ready	EU registered	Blood and blood forming organs	No	Europe

Product Family Name	Dosage Form	Dosage Strength	Development Status	Dossier Readiness	ATC Group	4B Zone Stability*	Available Territory**
<b>RIVAROXABAN</b>	Capsule, hard	2.5 mg, 10 mg, 15 mg, 20 mg	Ready	EU registered	Blood and blood forming organs	No	Europe
<b>ROSUVASTATIN CALCIUM</b>	Film-coated tablet	5 mg, 10 mg, 15mg, 20 mg, 30 mg, 40 mg	Ready	EU registered	Cardiovascular system	Yes	Europe
<b>SACUBITRIL + VALSARTAN</b>	Film-coated tablet	24 mg + 26 mg 49 mg + 51 mg 97 mg + 103 mg	Ongoing	Q3 2023	Cardiovascular system	No	Europe
<b>SERTRALINE</b>	Film-coated tablet	25 mg	Ready	EU registered	Nervous system	No	Global
<b>SERTRALINE</b>	Film-coated tablet	50 mg, 100 mg	Ready	To be filed in EU in November	Nervous system	No	Global
<b>SITAGLIPTIN PHOSPHATE</b>	Film-coated tablet	25 mg, 50 mg, 100 mg	Ready	Filed in EU	Alimentary tract and metabolism	Can be added	Global
<b>SITAGLIPTIN PHOSPHATE + METFORMIN</b>	Film-coated tablet	50 mg + 850 mg 50 mg + 1000 mg	Ongoing	Q4 2022	Alimentary tract and metabolism	Can be added	Global
<b>SOLIFENACIN SUCCINATE</b>	Film-coated tablet	5 mg, 10 mg	Ready	EU registered	Genitourinary system and reproductive hormones	No	Europe
<b>TAMSULOSIN HYDROCHLORIDE</b>	Modified-release capsule, hard	0.4 mg	Ready	EU registered	Genitourinary system and reproductive hormones	No	Global

Product Family Name	Dosage Form	Dosage Strength	Development Status	Dossier Readiness	ATC Group	4B Zone Stability*	Available Territory**
<b>TICAGRELOR</b>	Film-coated tablet	60 mg, 90 mg	Ready	EU registered	Blood and blood forming organs	Yes	Global
<b>TORASEMIDE</b>	Tablet	2.5 mg, 5 mg, 10 mg, 20 mg, 50 mg, 100mg, 200mg	Ready	Filed in EU	Cardiovascular system	Yes	Global
<b>VARDENAFIL HYDROCHLORIDE TRIHYDRATE</b>	Film-coated tablet	5 mg, 10 mg, 20 mg	Ready	EU registered	Genitourinary system and reproductive hormones	No	Europe
<b>VILDAGLIPTIN</b>	Tablet	50 mg	Ready	EU registered	Alimentary tract and metabolism	No	Europe
<b>VORTIOXETINE</b>	Film-coated tablet	5 mg, 10 mg, 15 mg, 20 mg	Ongoing	Q4 2023	Nervous system	Can be added	Global

\*Generation of Zone IVb stability can be discussed in case of interest

\*\*Ask for available countries



Zent2U@zentiva.com



+420 267243231.



Zentiva Group a.s.  
U Kabelovny 529/16  
102 00 Prague 10  
Czech Republic



www.Zent2U.com