

FDF Product list (October 2021)

Product Family Name	Dosage Form	Dosage Strength	Development Status	Dossier Readiness	ATC Group	4B Zone Stability*	Available Territory**
ABACAVIR SULFATE + LAMIVUDINE	Film-coated tablet	600 mg + 300 mg	ready	EU registered	Antiinfectives for systemic use	No	Global
ABIRATERONE ACETATE	Film-coated tablet	500 mg	ready	filed in EU	Antineoplastic and immunomodulating agents	Yes	Global
AGOMELATINE	Film-coated tablet	25 mg	ready	registered	Antidepressant	Can be added	Global
ACETYLSALICYLIC ACID	Tablet	100 mg, 500 mg	ready	EU registered	Nervous system	No	Germany
AMLODIPINE	Tablet	2.5 mg, 5mg, 10mg	ready	EU registered	Cardiovascular system	Yes	Global
AMLODIPINE BESILATE + CANDESARTAN CILEXETIL	Tablet	5 mg + 8 mg 10 mg + 16 mg	ready	EU registered	Cardiovascular system	No	Europe
AMLODIPINE BESILATE + CANDESARTAN CILEXETIL	Tablet	5 mg + 16 mg	ready	partially registered	Cardiovascular system	No	Global

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AMLODIPINE BESILATE + INDAPAMIDE + PERINDOPRIL ERBUMINE	Tablet	5 mg + 1.25 mg + 4 mg	ready	filed in EU	Cardiovascular system	No	Global
		10 mg + 1.25 mg + 4 mg					
		5 mg + 2.5 mg + 8 mg					
		10 mg + 2.5 mg + 8 mg					
AMLODIPINE BESILATE + PERINDOPRIL ERBUMINE	Tablet	5 mg + 4 mg	ready	EU registered	Cardiovascular system	No	Global
		10 mg + 4 mg					
		5 mg + 8 mg					
		10 mg + 8 mg					
AMLODIPINE BESILATE + VALSARTAN	Film-coated tablet	5 mg + 80 mg	ready	EU registered	Cardiovascular system	No	Europe
		5 mg + 160 mg					
		10 mg + 160 mg					
APIXABAN	Film-coated tablet	2.5 mg, 5 mg	ongoing	Q2 2022	Blood and blood forming organs	No	Europe
APREMILAST	Film-coated tablet	10 mg, 20 mg, 30 mg	ongoing	Q4 2022	Dermatological drugs	At risk	Global
ATAZANAVIR SULFATE	Capsule, hard	300 mg	ready	EU registered	Antiinfectives for systemic use	Yes	Global

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ATORVASTATIN CALCIUM	Film-coated tablet	10 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg	ready	EU registered	Cardiovascular system	No	Europe
BISOPROLOL FUMARATE	Tablet	1.25 mg, 2.5 mg, 3.75 mg, 5 mg, 7.5 mg, 10 mg	ready	EU registered	Cardiovascular system	No	Global
CLOPIDOGREL BISULPHATE	Film-coated tablet	75 mg	ongoing	Q1 2023	Blood and blood forming organs	can be added	Global
DAPAGLIFLOZIN	Film-coated tablet	5 mg, 10 mg	ongoing	Q3 2024	Alimentary tract and metabolism	can be added	Global
DEFERASIROX	Film-coated tablet	90 mg, 180 mg, 360 mg	ready	EU registered	Various ATC structures	No	Global
DROSPIRENONE + ESTRADIOL 	Film-coated tablet	2 mg + 1 mg	ready	ready	Hormone replacement therapy	No	Europe
DULOXETINE HYDROCHLORIDE	Capsule hard gastro-resistant	30 mg, 60 mg	ready	EU registered	Nervous system	No	Global
DULOXETINE HYDROCHLORIDE	Capsule hard gastro-resistant	20 mg, 40 mg	ready	registered	Urology	No	Europe
EDOXABAN	Film-coated tablet	15 mg, 30 mg, 60 mg	ongoing	Q3 2023	Blood and blood forming organs	can be added	Global

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EMTRICITABINE + RILPIVIRINE +TENOFIVIR ALAFENAMIDE	Film-coated tablet	200 mg + 25 mg + 25 mg 200 mg + 27.5 mg + 28 mg	ongoing	Q2 2024	Antivirotic	can be added	Global
EMTRICITABINE + TENOFIVIR ALAFENAMIDE	Film-coated tablet	200 mg + 10 mg 200 mg + 25 mg	ongoing	Q1 2024	Antivirotic	can be added	Global
EMPAGLIFLOZIN	Film-coated tablet	10 mg, 25 mg	ongoing	Q1 2024	Alimentary tract and metabolisma	can be added	Global
ETORICOXIB	Film-coated tablet	30 mg, 60 mg, 90 mg, 120 mg	ready	EU registered	Musculoskeletal system	No	Europe
FINGOLIMOD	Capsule, hard	0.5 mg	ready	filed in EU	Multiple Sclerosis	No	Europe
HYDROCHLOROTHIAZIDE + LOSARTAN POTASSIUM	Film-coated tablet	12.5 mg + 50 mg 12.5 mg + 100mg 25 mg + 100 mg	ready	registered	Cardiovascular system	No	Global
HYDROCHLOROTHIAZIDE + TELMISARTAN	Tablet	12.5 + 40 mg; 12.5 mg + 80 mg 25 mg + 80 mg	ready	EU registered	Cardiovascular system	No	Global
IBANDRONATE SODIUM MONOHYDRATE	Film-coated tablet	150 mg	ready	EU registered	Musculoskeletal system	No	Europe

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IBUPROFEN	Film-coated tablet	200 mg, 400 mg, 600 mg, 800 mg	ready	filed in EU	Musculoskeletal system	No	Global
ILOPROST	Nebuliser solution	10 µg / 1 ml	ready	EU registered	Blood and blood forming organs	No	Europe
ILOPROST	Nebuliser solution	20 µg / 1 ml	ready	filed in EU	Blood and blood forming organs	Yes	Global
ILOPROST	Solution for injection	100 µg / 1 ml (0.5 ml)	ready	filed in EU	Blood and blood forming organs	glass vial	Global
IVABRADINE HYDROCHLORIDE	Film-coated tablet	5 mg, 7.5 mg	ready	EU registered	Cardiovascular system	No	Global
LACOSAMIDE	Film-coated tablet	50 mg, 100 mg, 150 mg, 200 mg	ready	EU registered	Nervous system	Yes	Global
LEVETIRACETAM	Film-coated tablet	250 mg, 500 mg, 750 mg, 1000 mg	ready	EU registered	Nervous system	No	Europe
LINAGLIPTIN	Film-coated tablet	5 mg	ready	filed in EU	Alimentary tract and metabolism	No	Europe
METAMIZOLE SODIUM	Film-coated Tablet	500mg	ongoing	filed in EU	Nervous system	yes	to be discussed
METAMIZOLE SODIUM	Injection	500 mg/ml (2 ml)	ongoing	Q4 2021	Nervous system	can be added	to be discussed

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METFORMIN HYDROCHLORIDE	Film-coated tablet	500 mg, 850 mg, 1000mg	ready	filed in EU	Alimentary tract and metabolisma	Yes	Global
NOREPINEPHRINE	Injection	1 mg / 1ml	ongoing	Q2 2022	various	at risk	Global
PARACETAMOL	Tablet	500 mg, 1000 mg	ongoing	filed in EU	Nervous system	Yes	Global
PERINDOPRIL ARGININE	Film-coated tablet	2.5 mg, 5 mg, 10 mg	ongoing	filed in EU	Cardiovascular system	No	Global
PRASUGREL HYDROCHLORIDE	Film-coated tablet	5 mg, 10 mg	ready	EU registered	Blood and blood forming organs	Yes	Global
RAMIPRIL	Tablet	1.25 mg, 2.5 mg, 5 mg, 10 mg	ongoing	Q4 2022	Cardiovascular system	can be added	Global
RIVAROXABAN	Film-coated tablet	2.5 mg, 10 mg, 15 mg, 20 mg	ready	EU registered	Blood and blood forming organs (Venous thromboembolism)	No	Europe
RIVAROXABAN	Capsule, hard	2.5 mg, 10 mg, 15 mg, 20 mg	ready	EU registered	Blood and blood forming organs (Venous thromboembolism)	No	Europe
ROSUVASTATIN CALCIUM	Film-coated tablet	5 mg, 10 mg, 15mg 20 mg, 30 mg 40 mg	ready	EU registered	Cardiovascular system	Yes	Europe
SACUBITRIL + VALSARTAN	Film-coated tablet	25 mg + 25 mg 50 mg + 50 mg, 100 mg + 100 mg	ongoing	Q4 2022	Cardiovascular system	No	Europe

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SERTRALINE	Tablet	25 mg	ready	registered	Nervous system	No	Global
SERTRALINE	Tablet	50 mg, 100 mg,	ongoing	Q4 2021	Nervous system	No	Global
SITAGLIPTIN PHOSPHATE	Film-coated tablet	25 mg, 50 mg, 100 mg	ongoing	Q4 2021	Alimentary tract and metabolism	can be added	Global
SITAGLIPTIN PHOSPHATE + METFORMIN	Film-coated tablet	50 mg + 1000 mg 50 mg + 850 mg	ongoing	Q2 2022	Alimentary tract and metabolism	can be added	Global
SOLIFENACIN SUCCINATE	Film-coated tablet	5 mg, 10 mg	ready	registered	Genitourinary system and reproductive hormones	no	Europe
TAMSULOSIN HYDROCHLORIDE	Modified-release capsule, hard	0.4 mg	ready	registered	Genitourinary system and reproductive hormones	No	Global
TICAGRELOR	Film-coated tablet	60 mg, 90 mg	ready	Q2 2021	Blood and blood forming organs	Yes	Global
TORASEMIDE	Tablet	2.5 mg, 5 mg, 10 mg, 20 mg, 50 mg, 100 mg, 200 mg	ongoing	Q1 2022	Cardiovascular system	Yes	Global
VARDENAFIL HYDROCHLORIDE TRIHYDRATE	Film-coated tablet	5mg 10 mg 20 mg	ready	registered	Genitourinary system and reproductive hormones	No	Europe

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VILDAGLIPTIN	Tablet	50 mg	ready	registered	Alimentary tract and metabolisma	No	Europe
VORTIOXETINE 	Film-coated tablet	5 mg, 10 mg, 15 mg, 20 mg	ongoing	Q1 2024	Nervous system	No	Europe

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