

FDF Product list

(January 2024)

Product Family Name	Dosage Form	Dosage Strength	Development Status	Dossier Readiness	ATC Group	Available Territory*
ABACAVIR SULFATE + LAMIVUDINE	Film-coated tablet	600 mg + 300 mg	Ready	Launched	Anti-infectives for systemic use	Global
ACETYLSALICYLIC ACID	Tablet	100 mg	Ready	Filed in EU	Various ATC structures	DE
ACETYLSALICYLIC ACID	Tablet	500 mg	Ready	Launched	Various ATC structures	DE
AGOMELATINE	Film-coated tablet	25 mg	Ready	EU registered	Antidepressant	Global
AMLODIPINE	Tablet	2.5 mg, 5 mg, 10 mg	Ready	Launched	Cardiovascular system	Global
AMLODIPINE BESILATE + CANDESARTAN CILEXETIL	Tablet	5 mg + 8 mg 10 mg + 16 mg	Ready	Launched**	Cardiovascular system	Europe except ES, PT
AMLODIPINE BESILATE + CANDESARTAN CILEXETIL	Tablet	5 mg + 16 mg	Ready	Launched**	Cardiovascular system	Global except DE, ES, PT
AMLODIPINE BESILATE + INDAPAMIDE + PERINDOPRIL ERBUMINE	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	Global except IT, CZ, SK, CEE
AMLODIPINE BESILATE + PERINDOPRIL ERBUMINE	Tablet	5 mg + 4 mg 10 mg + 4 mg 5 mg + 8 mg 10 mg + 8 mg	Ready	Launched	Cardiovascular system	Global
AMLODIPINE BESILATE + VALSARTAN	Film-coated tablet	5 mg + 80 mg 5 mg + 160 mg 10 mg + 160 mg	Ready	EU registered**	Cardiovascular system	Europe
APIXABAN	Film-coated tablet	2.5 mg, 5 mg	Ready	Filed in EU	Blood and blood forming organs	Europe
APREMILAST	Film-coated tablet	10 mg, 20 mg, 30 mg	Ready	Filed in EU	Dermatological drugs	Global
ATAZANAVIR	Capsules, hard	100 mg, 150 mg, 200 mg, 300 mg	Ready	Launched	Anti-infectives for systemic use	Global

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ATORVASTATIN CALCIUM	Film-coated tablet	10 mg, 20 mg, 30 mg 40 mg, 60 mg, 80 mg	Ready	Filed in EU	Cardiovascular system	Europe
DAPAGLIFLOZIN	Film-coated tablet	5 mg, 10 mg	Ongoing	Q2 2025	Alimentary tract and metabolism	Global
DAPAGLIFLOZIN + METFORMIN	Film-coated tablet	5 mg + 850 mg 5 mg + 1000 mg	Ongoing	Q3 2025	Alimentary tract and metabolism	Global
DEFERASIROX	Film-coated tablet	90 mg, 180 mg, 360 mg	Ready	EU registered	Various ATC structures	Global
DEXAMETHASONE	Solution for injection	4 mg/ml	Ongoing	Q4 2025	Various ATC structures	Global
DOLUTEGRAVIR	Film-coated tablet	50 mg	Ongoing	Q2 2025	Anti-infectives for systemic use	Global
DOLUTEGRAVIR + LAMIVUDINE	Film-coated tablet	50 mg + 300 mg	Ongoing	Q2 2026	Anti-infectives for systemic use	Global
DROSPIRENONE + ESTRADIOL	Film-coated tablet	2 mg + 1 mg	Ready	Ready	Hormone replacement therapy	Global
EDOXABAN	Film-coated tablet	15 mg, 30 mg, 60 mg	Ready	Filed in EU	Blood and blood forming organs	WE & outside Europe
EMPAGLIFLOZIN	Film-coated tablet	10 mg, 25 mg	Ongoing	Q1 2025	Alimentary tract and metabolism	Global
EMPAGLIFLOZIN + METFORMIN	Film-coated tablet	5mg + 850mg, 12,5mg + 850 mg, 5mg + 1000mg, 12,5mg + 1000 mg	Ongoing	Q4 2026	Alimentary tract and metabolism	Global
EMTRICITABINE + RILPIVIRINE + TENOFOVIR ALAFENAMIDE	Film-coated tablet	200 mg + 25 mg + 25 mg 200 mg + 27.5 mg +28mg	Ongoing	Q4 2024	Antivirotic	Global
EMTRICITABINE + TENOFOVIR ALAFENAMIDE	Film-coated tablet	200 mg + 10 mg 200 mg + 25 mg	Ongoing	Q3 2024	Antivirotic	Global
ETORICOXIB	Film-coated tablet	30 mg, 60 mg 90 mg, 120 mg	Ready	Launched	Musculoskeletal system	DE, MT, PT, EE, IT, UK, LT
FINGOLIMOD	Capsule, hard	0.5 mg	Ready	Launched	Multiple sclerosis	Europe
HYDROCHLOROTHIAZIDE + LOSARTAN POTASSIUM	Film-coated tablet	12.5 mg + 50 mg 12.5 mg + 100mg 25 mg + 100 mg	Ready	Launched	Cardiovascular system	Global

Product Family Name	Dosage Form	Dosage Strength	Development Status	Dossier Readiness	ATC Group	Available Territory*
IBANDRONATE SODIUM MONOHYDRATE	Film-coated tablet	150 mg	Ready	Launched	Musculoskeletal system	Europe
IBUPROFEN	Film-coated tablet	200 mg, 400 mg 600 mg, 800 mg	Ready	EU registered	Nervous system	Global
IBUPROFEN LYSINATE	Film-coated tablet	400 mg	Ready	Ready	Nervous system	Global
IBUPROFEN	Suspension	100 mg/5 ml (2%), 200 mg/5 ml (4%)	Ongoing	Q4 2025	Nervous system	Global
LACOSAMIDE	Film-coated tablet	50 mg, 100 mg 150 mg, 200 mg	Ready	Ready	Nervous system	Global
LEVETIRACETAM	Film-coated tablet	250 mg, 500 mg 750 mg, 1000 mg	Ready	Launched	Nervous system	Europe
LINAGLIPTIN	Film-coated tablet	5 mg	Ready	EU registered	Alimentary tract and metabolism	Europe
METAMIZOLE SODIUM	Film-coated tablet	500 mg	Ready	Filed in EU	Nervous system	To be discussed
METAMIZOLE SODIUM	Injection	500 mg/ml (2 ml)	Ready	Filed in EU	Nervous system	To be discussed
METFORMIN HYDROCHLORIDE	Film-coated tablet	500 mg, 850 mg, 1000 mg	Ready	EU registered	Alimentary tract and metabolism	Global
NOREPINEPHRINE	Injection	1 mg / 1 ml	Ready	Filed in EU	Cardiovascular system	Global
PARACETAMOL	Tablet	500 mg, 1000 mg	Ready	EU registered	Nervous system	Global
PERINDOPRIL ARGININE	Film-coated tablet	2.5 mg, 5 mg, 10 mg	Ready	Launched	Cardiovascular system	Global
PRASUGREL HYDROCHLORIDE	Film-coated tablet	10 mg	Ready	Ready	Blood and blood forming organs	Global
RILMENIDINE	Tablet	1 mg	Ready	Launched	Cardiovascular system	Europe
RIVAROXABAN	Film-coated tablet	2.5 mg, 10 mg, 15 mg, 20 mg	Ready	EU registered	Blood and blood forming organs	Europe

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RIVAROXABAN	Capsule, hard	2.5 mg, 10 mg, 15 mg, 20 mg	Ready	EU registered	Blood and blood forming organs	Europe
ROSUVASTATIN CALCIUM	Film-coated tablet	5 mg, 10 mg, 20 mg, 40 mg	Ready	Launched	Cardiovascular system	Europe
SACUBITRIL + VALSARTAN	Film-coated tablet	24 mg + 26 mg 49 mg + 51 mg 97 mg + 103 mg	Ongoing	Q4 2024	Cardiovascular system	Europe
SERTRALINE	Film-coated tablet	25 mg	Ready	EU registered	Nervous system	Global except UK, SE, DK
SERTRALINE	Film-coated tablet	50 mg, 100 mg	Ready	Filed in EU	Nervous system	Global
SITAGLIPTIN PHOSPHATE	Film-coated tablet	25 mg, 50 mg, 100 mg	Ready	Filed in EU**	Alimentary tract and metabolism	Global
SITAGLIPTIN PHOSPHATE + METFORMIN	Film-coated tablet	50 mg + 850 mg 50 mg + 1000 mg	Ready	Filed in UK**	Alimentary tract and metabolism	Global
SOLIFENACIN SUCCINATE	Film-coated tablet	5 mg, 10 mg	Ready	Launched	Genitourinary system and reproductive hormones	Europe
TAMSULOSIN HYDROCHLORIDE	Modified-release capsule, hard	0.4 mg	Ready	Launched	Genitourinary system and reproductive hormones	Global
TICAGRELOR	Film-coated tablet	60 mg, 90 mg	Ready	EU registered	Blood and blood forming organs	Global
TORASEMIDE	Tablet	2.5 mg, 5 mg, 10 mg, 20 mg	Ready	Filed in EU	Cardiovascular system	Global except PL, BG, DE
VARDENAFIL HYDROCHLORIDE TRIHYDRATE	Film-coated tablet	5 mg, 10 mg, 20 mg	Ready	Launched	Genitourinary system and reproductive hormones	Europe
VILDAGLIPTIN	Tablet	50 mg	Ready	EU registered**	Alimentary tract and metabolism	Europe
VORTIOXETINE	Film-coated tablet	5 mg, 10 mg, 15 mg, 20 mg	Ongoing	Q4 2024	Nervous system	Global

FDF Value Added Medicines Product list (January 2024)

Product Family Name	Dosage Form	Dosage Strength	Development Status	Dossier Readiness	ATC Group	Available Territory*
ATORVASTATIN	Oral suspension	4 mg/ml	Ongoing	Q3 2025	Cardiovascular system	Global*
BISOPROLOL	Oral solution	0.5 mg/ml	Ongoing	Q1 2024	Cardiovascular system	Global except UK
DASATINIB (pH resistant)	Film-coated tablet	15.8 mg, 35.5 mg, 55.3 mg, 63.2 mg, 79 mg, 110.6 mg	Ready	EU & UK registered	Antineoplastic and immunomodulating agents	Global except CZ, SK, RO
DEXIBUPROFEN	Film-coated tablet	200 mg, 300 mg, 400 mg	Ongoing	Q3 2024	Nervous system	Global
IBUPROFEN IR + SR OTC	IR + SR form in one tablet	200 IR+200 XR	Ready	Filed in EU	Nervous system	Global except CZ, SK, RO, PL, HU, BG
OMEPRAZOLE + ANTACIDUM	Capsule	20mg	Ready	Filed in EU	Alimentary tract and metabolism	Global except CZ, SK, RO, PL, HU, BG
RIVAROXABAN suspension	Oral suspension	5mg/ml	Ready	Ready	Blood and blood forming organs	Europe except UK
ROSUVASTATIN	Film-coated tablet	15mg, 30 mg	Ready	Launched	Cardiovascular system	Europe

*Ask for available countries