

FDF Product list

(April 2024)

Product Family Name	Dosage Form	Dosage Strength	Dossier Status	ATC Group	Main indication
AGOMELATINE	Film-coated tablet	25 mg	Registered in EU	Nervous system	depression
AMLODIPINE	Tablet	2.5 mg, 5 mg, 10 mg	Launched	Cardiovascular system	hypertension
AMLODIPINE BESILATE + CANDESARTAN CILEXETIL	Tablet	5 mg + 8 mg 10 mg + 16 mg	Launched	Cardiovascular system	hypertension
AMLODIPINE BESILATE + CANDESARTAN CILEXETIL	Tablet	5 mg + 16 mg	Launched	Cardiovascular system	hypertension
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	Registered in EU	Cardiovascular system	hypertension
AMLODIPINE BESILATE + PERINDOPRIL ERBUMINE	Tablet	5 mg + 4 mg 10 mg + 4 mg 5 mg + 8 mg 10 mg + 8 mg	Launched	Cardiovascular system	hypertension
AMLODIPINE BESILATE + VALSARTAN	Film-coated tablet	5 mg + 80 mg 5 mg + 160 mg 10 mg + 160 mg	Registered in EU	Cardiovascular system	hypertension
APIXABAN	Film-coated tablet	2.5 mg, 5 mg	Filed in EU	Blood and blood forming organs	stroke prevention, systemic embolism
APREMILAST	Film-coated tablet	10 mg, 20 mg, 30 mg	Filed in EU	Dermatologicals	Psoriasis
ATORVASTATIN CALCIUM	Film-coated tablet	10 mg, 20 mg, 30 mg 40 mg, 60 mg, 80 mg	Filed in EU	Cardiovascular system	lipid lowering agent
DAPAGLIFLOZIN	Film-coated tablet	5 mg, 10 mg	Q2 2025	Alimentary tract and metabolism	diabetes
DAPAGLIFLOZIN + METFORMIN	Film-coated tablet	5 mg + 850 mg 5 mg + 1000 mg	Q3 2025	Alimentary tract and metabolism	diabetes

**Ask for available countries*

Product Family Name	Dosage Form	Dosage Strength	Dossier Status	ATC Group	Main indication
DEFERASIROX	Film-coated tablet	90 mg, 180 mg, 360 mg	Registered in EU	Various ATC structures	chronic iron overload
DEXAMETHASONE	Solution for injection	4 mg/ml	Q4 2025	Various ATC structures	corticosteroide
DEXIBUPROFEN	Film-coated tablet	200 mg, 300 mg, 400 mg	Q3 2024	Nervous system	pain relief, fever reduction
DOLUTEGRAVIR	Film-coated tablet	50 mg	Q2 2025	Anti-infectives for systemic use	HIV
DOLUTEGRAVIR + LAMIVUDINE	Film-coated tablet	50 mg + 300 mg	Q2 2026	Anti-infectives for systemic use	HIV
EDOXYBAN	Film-coated tablet	15 mg, 30 mg, 60 mg	Filed in EU	Blood and blood forming organs	stroke prevention, systemic embolism
EMPAGLIFLOZIN	Film-coated tablet	10 mg, 25 mg	Q1 2025	Alimentary tract and metabolism	diabetes
EMPAGLIFLOZIN + METFORMIN	Film-coated tablet	5mg + 850mg, 12,5mg + 850 mg, 5mg + 1000mg, 12,5mg + 1000 mg	Q3 2026	Alimentary tract and metabolism	diabetes
EMTRICITABINE + RILPIVIRINE + TENOFOVIR ALAFENAMIDE	Film-coated tablet	200 mg + 25 mg + 25 mg 200 mg + 27.5 mg +28mg	Q4 2024	Anti-infectives for systemic use	HIV
EMTRICITABINE + TENOFOVIR ALAFENAMIDE	Film-coated tablet	200 mg + 10 mg 200 mg + 25 mg	Q3 2024	Anti-infectives for systemic use	HIV
ETORICOXIB	Film-coated tablet	30 mg, 60 mg 90 mg, 120 mg	Launched	Musculoskeletal system	osteoarthritis, rheumatoid arthritis pain relief
FINGOLIMOD	Capsule, hard	0.5 mg	Launched	Nervous system	multiple sclerosis
HYDROCHLOROTHIAZIDE + LOSARTAN POTASSIUM	Film-coated tablet	12.5 mg + 50 mg 12.5 mg + 100mg 25 mg + 100 mg	Launched	Cardiovascular system	Hypertension
IBANDRONATE SODIUM MONOHYDRATE	Film-coated tablet	150 mg	Launched	Musculoskeletal system	osteoporosis
IBUPROFEN	Film-coated tablet	200 mg, 400 mg 600 mg, 800 mg	Registered in EU	Nervous system	pain relief, fever reduction

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Product Family Name	Dosage Form	Dosage Strength	Dossier Status	ATC Group	Main indication
IBUPROFEN LYSINATE	Film-coated tablet	400 mg	Ready	Nervous system	pain relief, fever reduction
IBUPROFEN	Suspension	100 mg/5 ml (2%), 200 mg/5 ml (4%)	Q4 2025	Nervous system	pain relief, fever reduction
LACOSAMIDE	Film-coated tablet	50 mg, 100 mg 150 mg, 200 mg	Ready	Nervous system	epilepsy
LEVETIRACETAM	Film-coated tablet	250 mg, 500 mg 750 mg, 1000 mg	Launched	Nervous system	epilepsy
LINAGLIPTIN	Film-coated tablet	5 mg	Registered in EU	Alimentary tract and metabolism	diabetes
METAMIZOLE SODIUM	Film-coated tablet	500 mg	Filed in EU	Nervous system	pain relief, fever reduction
METAMIZOLE SODIUM	Injection	500 mg/ml (2 ml)	Filed in EU	Nervous system	pain relief, fever reduction
METFORMIN HYDROCHLORIDE	Film-coated tablet	500 mg, 850 mg, 1000 mg	Registered in EU	Alimentary tract and metabolism	diabetes
NOREPINEPHRINE	Injection	1 mg / 1 ml (1ml, 4ml, 10ml)	Filed in EU	Cardiovascular system	acute hypotension
PARACETAMOL	Tablet	500 mg, 1000 mg	Registered in EU	Nervous system	pain relief, fever reduction
PERINDOPRIL ARGININE	Film-coated tablet	2.5 mg, 5 mg, 10 mg	Launched	Cardiovascular system	hypertension
PRASUGREL HYDROCHLORIDE	Film-coated tablet	10 mg	Ready	Blood and blood forming organs	myocardial infarction, angina
RILMENIDINE	Tablet	1 mg	Launched	Cardiovascular system	hypertension
RIVAROXABAN	Film-coated tablet	2.5 mg, 10 mg, 15 mg, 20 mg	Registered in EU	Blood and blood forming organs	deep vein thrombosis, pulmonary embolism, stroke
RIVAROXABAN	Capsule, hard	10 mg, 15 mg, 20 mg	Registered in EU	Blood and blood forming organs	deep vein thrombosis, pulmonary embolism, stroke

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Product Family Name	Dosage Form	Dosage Strength	Dossier Status	ATC Group	Main indication
ROSUVASTATIN CALCIUM	Film-coated tablet	5 mg, 10 mg, 20 mg, 40 mg	Launched	Cardiovascular system	lipid lowering agent
SACUBITRIL + VALSARTAN	Film-coated tablet	24 mg + 26 mg 49 mg + 51 mg 97 mg + 103 mg	Q3 2024	Cardiovascular system	heart failure
SERTRALINE	Film-coated tablet	25 mg	Registered in EU	Nervous system	depression
SERTRALINE	Film-coated tablet	50 mg, 100 mg	Filed in EU	Nervous system	depression
SITAGLIPTIN PHOSPHATE	Film-coated tablet	25 mg, 50 mg, 100 mg	Filed in EU	Alimentary tract and metabolism	diabetes
SITAGLIPTIN PHOSPHATE + METFORMIN	Film-coated tablet	50 mg + 850 mg 50 mg + 1000 mg	Filed in UK	Alimentary tract and metabolism	diabetes
SOLIFENACIN SUCCINATE	Film-coated tablet	5 mg, 10 mg	Launched	Genitourinary system and reproductive hormones	overactive bladder, incontinence
TAMSULOSIN HYDROCHLORIDE	Modified-release capsule, hard	0.4 mg	Launched	Genitourinary system and reproductive hormones	benign prostatic hyperplasia
TICAGRELOR	Film-coated tablet	60 mg, 90 mg	Registered in EU	Blood and blood forming organs	acute coronary syndromes, myocardial infarction prevention
TORASEMIDE	Tablet	2.5 mg, 5 mg, 10 mg, 20 mg	Filed in EU	Cardiovascular system	congestive heart failure related, hepatic, pulmonary or renal oedema
VARDENAFIL HYDROCHLORIDE TRIHYDRATE	Film-coated tablet	5 mg, 10 mg, 20 mg	Launched	Genitourinary system and reproductive hormones	erectile dysfunction
VILDAGLIPTIN	Tablet	50 mg	Registered in EU	Alimentary tract and metabolism	diabetes
VORTIOXETINE	Film-coated tablet	5 mg, 10 mg, 15 mg, 20 mg	Q4 2024	Nervous system	depression

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FDF Value Added Medicines Product list (April 2024)

Product Family Name	Dosage Form	Dosage Strength	Dossier Status	ATC Group	Main indication
ATORVASTATIN	Oral suspension	4 mg/ml	Q3 2025	Cardiovascular system	lipid lowering agent
BISOPROLOL	Oral solution	0.5 mg/ml	Q1 2024	Cardiovascular system	hypertension
DASATINIB (pH resistant)	Film-coated tablet	15.8 mg, 35.5 mg, 55.3 mg, 63.2 mg, 79 mg, 110.6 mg	Registered in EU	Antineoplastic and immunomodulating agents	leukaemia
IBUPROFEN IR + SR OTC	IR + SR form in one tablet	200 IR+200 XR	Filed in EU	Nervous system	pain relief, fever reduction
OMEPRAZOLE + ANTACIDUM	Capsule	20 mg	Filed in EU	Alimentary tract and metabolism	gastric and duodenal ulcers, reflux oesophagitis
RIVAROXABAN suspension	Oral suspension	5 mg/ml	Ready	Blood and blood forming organs	deep vein thrombosis, pulmonary embolism, stroke
ROSUVASTATIN	Film-coated tablet	15 mg, 30 mg	Launched	Cardiovascular system	lipid lowering agent

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