

Tradenam e	Strength	Pharmaceutical form	Marketing authorisation holder
Approved authorisations			
Adhesa	5 mg	tablet	ACE Pharmaceuticals BV
Apacross	5 mg/ml	powder for dispersion for infusion	Seacross Pharma (Europe) Limited
AviPro IBD LC-75		lyophilisate for use in drinking water	Elanco GmbH
Bosentan Accord	125 mg	film-coated tablet	Paranova Oy
Bosentan Accord	32 mg	dispersible tablet	Accord Healthcare B.V.
Brivaracetam Desitin	10 mg	film-coated tablet	Desitin Arzneimittel GmbH
Brivaracetam Desitin	50 mg	film-coated tablet	Desitin Arzneimittel GmbH
Brivaracetam Desitin	25 mg	film-coated tablet	Desitin Arzneimittel GmbH
Brivaracetam Desitin	75 mg	film-coated tablet	Desitin Arzneimittel GmbH
Brivaracetam Desitin	100 mg	film-coated tablet	Desitin Arzneimittel GmbH
Daunorubicin Hikma	5 mg/ml	solution for infusion	Hikma Farmacêutica (Portugal) S.A.
Dexamethasone phosphate Panpharma	4 mg/ml	solution for injection	PANPHARMA
Dimethyl fumarate Vivanta	120 mg	gastro-resistant capsule, hard	Vivanta Generics s.r.o.
Dimethyl fumarate Vivanta	240 mg	gastro-resistant capsule, hard	Vivanta Generics s.r.o.
Doxycycline Macure	20 mg/ml	solution for injection	Macure Healthcare Limited
Fatrino	600 mg / 200 mg / 245 mg	film-coated tablet	STADA Arzneimittel AG
Flurbiprofen STADA	8.75 mg	lozenge	STADA Arzneimittel AG
Haemate	1000 IU FVIII / 2400 IU VWF	powder and solvent for solution for injection/infusion	Abacus Medicine A/S
Letrozole Hexal	2.5 mg	film-coated tablet	Hexal A/S
Linagliptin Galenicum	5 mg	film-coated tablet	Galenicum Health S.L.U
Lodixeon	150 mg	Prolonged-release suspension for injection in pre-filled syringe	Viatri s Limited
Lodixeon	25 mg	Prolonged-release suspension for injection in pre-filled syringe	Viatri s Limited
Lodixeon	50 mg	Prolonged-release suspension for injection in pre-filled syringe	Viatri s Limited
Lodixeon	75 mg	Prolonged-release suspension for injection in pre-filled syringe	Viatri s Limited
Lodixeon	100 mg	Prolonged-release suspension for injection in pre-filled syringe	Viatri s Limited
Lodixeon	100 mg + 150 mg	Prolonged-release suspension for injection in pre-filled syringe	Viatri s Limited
Macitentan STADA	10 mg	film-coated tablet	STADA Arzneimittel AG
Metlyra	6 mg/ml	solution for injection in pre-filled pen	Cipla Europe NV
Milbemy cin oxime / Praziquantel Alfamed	4 mg / 10 mg	film-coated tablet	Alfamed
Milbemy cin oxime / Praziquantel Alfamed	16 mg / 40 mg	film-coated tablet	Alfamed
Milbemy cin oxime / Praziquantel Alfamed	2.5 mg / 25 mg	film-coated tablet	Alfamed
Milbemy cin oxime / Praziquantel Alfamed	12.5 mg / 125 mg	film-coated tablet	Alfamed
Mirtazapine Grindeks	15 mg	orodispersible tablet	Grindeks AS

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Mirtazapine Grindeks	45 mg	orodispersible tablet	Grindeks AS
Mirtazapine Grindeks	30 mg	orodispersible tablet	Grindeks AS
Nanoscint	500 microgram(s)	kit for radiopharmaceutical preparation	Radiopharmacy Laboratorium Kft.
Neupedix	0.5 mg/ml	concentrate for solution for infusion	Oresund Pharma ApS (Øresund Pharma)
Palarccio	4 mg	capsule, hard	Sandoz A/S
Palarccio	10 mg	capsule, hard	Sandoz A/S
Paliperidone Viatris	100 mg	Prolonged-release suspension for injection in pre-filled syringe	Viatris Limited
Paliperidone Viatris	100 mg + 150 mg	Prolonged-release suspension for injection in pre-filled syringe	Viatris Limited
Paliperidone Viatris	25 mg	Prolonged-release suspension for injection in pre-filled syringe	Viatris Limited
Paliperidone Viatris	75 mg	Prolonged-release suspension for injection in pre-filled syringe	Viatris Limited
Paliperidone Viatris	150 mg	Prolonged-release suspension for injection in pre-filled syringe	Viatris Limited
Paliperidone Viatris	50 mg	Prolonged-release suspension for injection in pre-filled syringe	Viatris Limited
Pedismof		emulsion for infusion	Fresenius Kabi AB
Pedismof Infant		emulsion for infusion	Fresenius Kabi AB
Pedismof Preterm		emulsion for infusion	Fresenius Kabi AB
Phenocoat Vet	25 mg	film-coated tablet	Alfasan Nederland B.V.
Phenocoat Vet	50 mg	film-coated tablet	Alfasan Nederland B.V.
Phenocoat Vet	12.5 mg	film-coated tablet	Alfasan Nederland B.V.
Phenocoat Vet	5 mg	film-coated tablet	Alfasan Nederland B.V.
Piperacillin/Tazobactam Noridem	2 g / 0.25 g	powder for solution for infusion	Noridem Enterprises Limited
Piperacillin/Tazobactam Noridem	4 g / 0.5 g	powder for solution for infusion	Noridem Enterprises Limited
Pomalidomide Olpha	1 mg	capsule, hard	Olpha AS
Pomalidomide Olpha	2 mg	capsule, hard	Olpha AS
Pomalidomide Olpha	3 mg	capsule, hard	Olpha AS
Pomalidomide Olpha	4 mg	capsule, hard	Olpha AS
Robexera vet	20 mg/ml	solution for injection	KRKA d.d. Novo mesto
Rocuronium Accord	10 mg/ml	solution for injection/infusion in pre-filled syringe	Accord Healthcare B.V.
Sacubitril/Valsartan Krka	97 mg / 103 mg	film-coated tablet	KRKA d.d. Novo mesto
Sacubitril/Valsartan Krka	49 mg / 51 mg	film-coated tablet	KRKA d.d. Novo mesto
Sacubitril/Valsartan Krka	24 mg / 26 mg	film-coated tablet	KRKA d.d. Novo mesto
Sacubitril/Valsartan axunio	24 mg / 26 mg	film-coated tablet	axunio Pharma GmbH
Sacubitril/Valsartan axunio	49 mg / 51 mg	film-coated tablet	axunio Pharma GmbH
Sacubitril/Valsartan axunio	97 mg / 103 mg	film-coated tablet	axunio Pharma GmbH
Sildenafil Adamed	50 mg	film-coated tablet	Adamed Pharma S.A.
Sitagliptin Aspire	25 mg	film-coated tablet	Aspire Pharma (Malta) Limited

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Sitagliptin Aspire	50 mg	film-coated tablet	Aspire Pharma (Malta) Limited
Sitagliptin Aspire	100 mg	film-coated tablet	Aspire Pharma (Malta) Limited
Solu-Medrol	125 mg	powder and solvent for solution for injection	Abacus Medicine A/S
Solu-Medrol	1 g	powder and solvent for solution for injection	Abacus Medicine A/S
Solu-Medrol	500 mg	powder and solvent for solution for injection	Abacus Medicine A/S
Sumatriptan Orion	50 mg	film-coated tablet	Orion Corporation
Sumatriptan Orion	100 mg	film-coated tablet	Orion Corporation
Sumatriptan Orion Pharma	50 mg	film-coated tablet	Orion Corporation
Terlipressin SUN	1 mg	solution for injection	Orifarm Oy
Tranexamic acid Tillomed	100 mg/ml	solution for injection	Tillomed Pharma GmbH
UripheX Vet	50 mg/ml	oral solution	Alfasan Nederland B.V.
Varenicline ViatriS	0.5 mg	film-coated tablet	ViatriS Limited
Varenicline ViatriS	1 mg	film-coated tablet	ViatriS Limited
Varenicline ViatriS	0.5 mg + 1 mg	film-coated tablet	ViatriS Limited
Varenikliini axunio	0.5 mg + 1 mg	film-coated tablet	axunio Pharma GmbH
Varenikliini axunio	0.5 mg	film-coated tablet	axunio Pharma GmbH
Varenikliini axunio	1 mg	film-coated tablet	axunio Pharma GmbH
ZithroTel	500 mg	powder for concentrate for solution for infusion	Orifarm Oy

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Cancelled authorisations			
Atorvastatin ratiopharm	10 mg	film-coated tablet	TEVA Sweden AB
Atorvastatin ratiopharm	20 mg	film-coated tablet	TEVA Sweden AB
Atorvastatin ratiopharm	40 mg	film-coated tablet	TEVA Sweden AB
Atorvastatin ratiopharm	80 mg	film-coated tablet	TEVA Sweden AB
Azacitidine Glenmark	25 mg/ml	powder for suspension for injection	Glenmark Arzneimittel GmbH
Bortezomib Baxter	3.5 mg	powder for solution for injection	Baxter Holding B.V.
Bovilis Ringvac vet.		lyophilisate and solvent for suspension for injection	Intervet International B.V.
Braltus	10 mikrog/ vapautunut annos	inhalation powder, hard capsule	Teva B.V.
Copaxone	40 mg/ml	solution for injection in pre-filled syringe	Abacus Medicine A/S
Grazax	75 000 SQ-T	sublingual lyophilisate	Paranova Oy
Kyleena	19.5 mg	intrauterine delivery system	Orifarm Oy
Kytril	2 mg	film-coated tablet	Atnahs Pharma Netherlands B.V.
Kytril	1 mg	film-coated tablet	Atnahs Pharma Netherlands B.V.
Lamictal	200 mg	chewable/dispersible tablet	Orifarm Oy
Neurobion forte		coated tablet	Orifarm Oy
Neurontin	400 mg	capsule, hard	Paranova Oy
Paracetamol Baxter Viaflo	10 mg/ml	solution for infusion	Baxter Holding B.V.
Pemetrexed Glenmark	100 mg	powder for concentrate for solution for infusion	Glenmark Arzneimittel GmbH
Pemetrexed Glenmark	500 mg	powder for concentrate for solution for infusion	Glenmark Arzneimittel GmbH
Srivasso	18 microgram(s)	inhalation powder, hard capsule	Boehringer Ingelheim International GmbH
Tekcis	2-50 GBq	radionuclide generator	CIS bio international
Tolterodin SanoSwiss	4 mg	prolonged-release capsule, hard	SanoSwiss UAB
Treprostinil Reddy	1 mg/ml	solution for infusion	Reddy Holding GmbH
Treprostinil Reddy	10 mg/ml	solution for infusion	Reddy Holding GmbH
Treprostinil Reddy	2.5 mg/ml	solution for infusion	Reddy Holding GmbH
Treprostinil Reddy	5 mg/ml	solution for infusion	Reddy Holding GmbH
Xonvea	10 mg / 10 mg	gastro-resistant tablet	Paranova Oy