



EU-GMP Dossiers Available

Active substance	Dosage form	Strength	Form	Indication
8-Methoxypsoralen (Oxsoralen®)	Ampoule ^{IVa/b}	0.02 mg/ml (5 ml)		Cutaneous T-Cell Lymphoma
Acetylsalicylic Acid	Gastro-resistant tablet	75 mg, 100 mg, 160 mg		Antithrombotic
	Tablet	75 mg, 100 mg		
Brivaracetam	Film-coated tablet	10 mg, 25 mg, 50 mg, 75 mg, 100 mg		Epilepsy
Buprenorphine	Sublingual tablet	0.2 mg, 0.4 mg		Severe Pain
		1 mg, 2 mg		Opioid Use Disorder
		4 mg, 6 mg, 8 mg, 12 mg, 16 mg		
Buprenorphine + Naloxone	Sublingual tablet ^{IVa/b}	2 mg+0.5 mg, 4 mg+1 mg, 8 mg+2 mg		Opioid Use Disorder
Esketamine	Solution for injection or infusion ^{IVa/b}	5 mg/ml (2 ml, 5 ml, 10 ml), 25 mg/ml (2 ml, 5 ml, 10 ml)		Severe Pain, Narcotic
		5 mg/ml (5 ml, 10 ml, 20 ml), 25 mg/ml (5 ml, 10 ml, 20 ml)		
Eslicarbazepine	Tablet	200 mg, 400 mg, 600 mg, 800 mg		Epilepsy
Eszopiclone	Film-coated tablet ^{IVa}	1 mg, 2 mg, 3 mg		Insomnia
Ethosuximide	Syrup ^{IVa/b}	50 mg/ml (250 ml)		Epilepsy
Fe ²⁺ + Ascorbic Acid + Folic Acid (Ferretab® comp plus)	Capsule	66.7 mg+100 mg+0.8 mg		Anaemia during Pregnancy
Fluoxetine	Film-coated tablet	20 mg ^{IVa/b} 40 mg		Depression
Folic Acid	Tablet	1 mg, 5 mg		Folic Acid Deficiency
Hydromorphone	Film-coated tablet	1.3 mg, 2.6 mg		Severe Pain
	Solution for injection ^{IVa/b}	2 mg/ml (1 ml), 10 mg/ml (1 ml, 10 ml) 20 mg/ml (1 ml), 50 mg/ml (1 ml)		
Ketamine	Solution for injection or infusion ^{IVa/b}	10 mg/ml (2 ml, 5 ml, 10 ml), 50 mg/ml (2 ml, 5 ml, 10 ml)		Severe Pain, Narcotic
		10 mg/ml (5 ml, 10 ml, 20 ml), 50 mg/ml (5 ml, 10 ml, 20 ml)		
Lacosamide	Film-coated tablet ^{IVa/b}	50 mg, 100 mg, 150 mg, 200 mg		Epilepsy
	Oral solution	10 mg/ml (200 ml, 500 ml)		
	Solution for infusion ^{IVa/b}	10 mg/ml (10 ml, 20 ml)		
		10 mg/ml (20 ml)		
Levetiracetam	Oral solution	100 mg/ml (150 ml, 300 ml)		Epilepsy
	Conc. for solution for infusion ^{IVa/b}	100 mg/ml (5 ml)		
Levomethadone	Tablets ^{IVa/b}	2.5 mg, 5 mg, 10 mg, 20 mg, 30 mg	 /  / 	Opioid Use Disorder
	Conc. for oral solution	5 mg/ml (100 ml, 150 ml, 300 ml, 500 ml, 1000 ml)		

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Metamizole	Solution for injection ^{IVa/b}	500 mg/ml (2 ml, 5 ml)		Mild to Moderate Pain
Methadone	Tablet ^{IVa/b}	5 mg, 10 mg, 20 mg, 40 mg, 60 mg		Opioid Use Disorder
	Conc. for oral solution	10 mg/ml (100 ml, 150 ml, 300 ml, 500 ml, 1000 ml)		
Metoclopramide	Oral solution ^{IVa/b}	1 mg/ml (150 ml)		Nausea, Emesis
	Solution for injection or infusion ^{IVa/b}	5 mg/ml (2 ml, 10 ml)		
Miglustat	Capsule 	100 mg		Type 1 Gaucher disease
Morphine	Solution for injection ^{IVa/b}	10 mg/ml (1 ml)		Severe Pain
		10 mg/ml (10 ml), 20 mg/ml (10 ml)		
Oxycodone	Film-coated tablet ^{IVa/b}	5 mg, 10 mg, 20 mg		Severe Pain
	Prolonged-release tablet	5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg		
	Oral solution ^{IVa/b}	1 mg/ml (100 ml, 250 ml, 300 ml)		
		10 mg/ml (30 ml, 100 ml, 120 ml)		
	Solution for injection or infusion ^{IVa/b}	10 mg/ml (1 ml, 2 ml)		
Oxycodone + Naloxone*	Prolonged-release tablet	5 mg+2.5 mg, 10 mg+5 mg, 20 mg+10 mg, 30 mg+15 mg, 40 mg+20 mg		Severe Pain
Perampanel	Film-coated tablet ^{IVa/b}	2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg		Epilepsy
Potassium Iodide	Tablet	65 mg		Radiation Prophylaxis
Tapentadol	Prolonged-release tablet ^{IVa/b}	25 mg, 50 mg, 100 mg, 150 mg, 200 mg, 250 mg		Severe Pain
	Film-coated tablet ^{IVa/b}	25 mg, 50 mg, 75 mg, 100 mg		
	Oral solution ^{IVa/b}	20 mg/ml (100 ml, 200 ml)		
Tizanidine	Tablet ^{IVa/b}	2 mg, 4 mg, 6 mg		Muscle Spasms
Trazodone	Oral solution ^{IVa/b}	10 mg/ml (120 ml)		Depression
Valproic Acid/ Sodium Valproate	Oral solution ^{IVa}	300 mg/ml (100 ml)		Epilepsy
Vitamin B ₁ (B ₁ =Benfotiamine)	Film-coated tablet	50 mg, 150 mg		Vitamin B ₁ Deficiency
		300 mg		
Vitamin B ₁₂ (B ₁₂ =Hydroxocobalamine)	Solution for injection	1 mg/ml (1 ml)		Vitamin B ₁₂ Deficiency
Vitamin B ₁ + B ₆ (B ₁ =Benfotiamine)	Film-coated tablet	100 mg+100 mg		Vitamin B Deficiency
Vitamin B ₁ + B ₆ + B ₁₂ (B ₁ =Benfotiamine)	Film-coated tablet	40 mg+90 mg+0.25 mg		Vitamin B Deficiency

IVa/b: Zone IVa/b stability data available /*No availability in the EU

EU-GMP Dossiers Under Development

Active substance	Dosage form		Strength	Dossier availability	Indication
Buprenorphine + Naloxone	Sublingual tablet		12 mg+3 mg	available	Opioid Use Disorder
Candesartan + Chlortalidone	Tablet		8 mg+12.5 mg, 16 mg+12.5 mg, 32 mg+12.5 mg, 32 mg+25 mg	2026	High Blood Pressure
Cyanocobalamin	Film-coated tablet		1 mg, 2 mg	2026	Vitamin Deficiency
Dapagliflozin	Film-coated tablet		5 mg, 10 mg	available	Diabetes
Dapagliflozin + Metformin	Film-coated tablet		5 mg+850 mg, 5mg+1000 mg	Q4 2025	Diabetes
Empagliflozin	Film-coated tablet		10 mg, 25 mg	Q1 2026	Diabetes
Empagliflozin + Metformin	Film-coated tablet		5 mg+850 mg, 5 mg+1000 mg, 12,5 mg+850 mg, 12,5 mg+1000 mg	Q4 2026	Diabetes
Hydromorphone	Prolonged-release capsule		2 mg, 4 mg, 8 mg, 16 mg, 24 mg	2026	Severe Pain
Vortioxetine	Film-coated tablet		5 mg, 10 mg, 15 mg, 20 mg	available	Depression

Zone IVa/b stability data planned for all products under development

Products protected by valid patents will not be offered for sale or supplied in countries where the respective patents are in force. Please be advised that information on this list is subject to change. For markets with special requirements please check availability with our licensing managers.

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