
























































EU-GMP Dossiers Available

Active substance	Dosage form	Strength	Form	Indication
8-Methoxypsoralen (Oxsoralen®)	Ampoules ^{IVa/b}	0.02 mg/ml (5 ml)		Cutaneous T-Cell Lymphoma
Acetylsalicylic Acid	Gastro-resistant tablets	75 mg, 100 mg, 160 mg		Antithrombotic
	Tablets	75 mg, 100 mg		
Benfotiamine	Film-coated tablets	50 mg, 150 mg		Vitamin B ₁ Deficiency
		300 mg		
Buprenorphine	Sublingual tablets	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 tablets ^{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	Tablets	200 mg, 400 mg, 600 mg, 800 mg		Epilepsy
Eszopiclone	Film-coated tablets ^{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)	Capsules	66.7 mg+100 mg+0.8 mg		Anaemia during Pregnancy
Fluoxetine	Film-coated tablets	20 mg ^{IVa/b}		Depression
		40 mg		
Folic Acid	Tablets	1 mg, 5 mg		Folic Acid Deficiency
Hydromorphone	Solution for injection ^{IVa/b}	2 mg/ml (1 ml), 10 mg/ml (1 ml, 10 ml)		Severe Pain
		20 mg/ml (1 ml), 50 mg/ml (1 ml)		
Hydroxocobalamine	Solution for injection	1 mg/ml (1 ml)		Vitamin B ₁₂ Deficiency
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 tablets ^{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)		










IVa/b: Zone IVa/b stability data available

EU-GMP Dossiers Available

Active substance	Dosage form	Strength	Form	Indication
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)		
Metamizole	Solution for injection ^{IVa/b}	500 mg/ml (2 ml, 5 ml)		Mild to Moderate Pain
Methadone	Tablets ^{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)		
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 tablets ^{IVa/b}	5 mg, 10 mg, 20 mg		Severe Pain
	Prolonged-release tablets	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 tablets	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 tablets ^{IVa/b}	2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg		Epilepsy
Potassium Iodide	Tablets	65 mg		Radiation Prophylaxis
Tapentadol	Prolonged-release tablets ^{IVa/b}	25 mg, 50 mg, 100 mg, 150 mg, 200 mg, 250 mg		Severe Pain
	Film-coated tablets ^{IVa/b}	25 mg, 50 mg, 75 mg, 100 mg		
	Oral solution ^{IVa/b}	20 mg/ml (100 ml, 200 ml)		
Tizanidine	Tablets ^{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 ₆ (B ₁ =Benfotiamin)	Film-coated tablets 	100 mg+100 mg		Vitamin B Deficiency
Vitamin D ₃	Oral solution ^{IVa/b}	14 400 IU/ml (12.5 ml, 30 ml)		Vitamin D ₃ Deficiency
		28 800 IU/ml (12.5 ml, 30 ml, 50 ml)		

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

Dossier Update Pending

Active substance	Dosage form	Strength	Form	Indication
Fe ²⁺ + Ascorbic Acid (Ferretab®)	Capsules	100 mg+20 mg		Anaemia
Fe ²⁺ + Folic Acid (Ferretab® comp)	Capsules	50 mg+0.5 mg		Anaemia during Pregnancy
Tramadol	Solution for injection	50 mg/ml (2 ml)		Moderate to Severe Pain
	Oral drops	100 mg/ml (10 ml, 30 ml, 50 ml)		
Valproic Acid/ Sodium Valproate	Gastro-resistant soft capsules ^{IVa}	150 mg, 300 mg, 500 mg		Epilepsy
	Syrup ^{IVa}	50 mg/ml (100 ml)		
	Solution for injection ^{IVa/b}	100 mg/ml (5 ml)		
Vitamin B ₁ + B ₆ + B ₁₂ (Neuromultivit®)	Film-coated tablets	100 mg+200 mg+0.2 mg		Vitamin B Deficiency, Neuropathic Pain
	Solution for injection	50 mg+50 mg+0.5 mg/ml (2 ml)		

EU-GMP Dossiers Under Development

Active substance	Dosage form	Strength	Dossier availability	Indication
Brivaracetam	Film-coated tablets	10 mg, 25 mg, 50 mg, 75 mg, 100 mg	Q1 2024	Epilepsy
Buprenorphine + Naloxone	Sublingual tablets	1 mg+0.25 mg, 12 mg+3 mg, 16 mg+4 mg	Q4 2023	Opioid Use Disorder
Candesartan + Chlortalidone	Tablets	8 mg+12.5 mg, 16 mg+12.5 mg, 32 mg+12.5 mg, 32 mg+25 mg	2024	High Blood Pressure
Hydromorphone	Film-coated tablets	1.3 mg, 2.6 mg	Q3 2023	Severe Pain
Metamizole	Film-coated tablets	500 mg, 1000 mg	2024	Mild to Moderate Pain
Trazodone	Prolonged-release tablets	75 mg, 150 mg	2025	Depression
Valproic Acid/ Sodium Valproate	Prolonged-release tablets	300 mg, 500 mg	2024	Epilepsy
Vitamin B ₁ + B ₆ + B ₁₂ (B ₁ =Benfotiamin)	Film coated tablets	40 mg+90 mg+0,25 mg	Q3 2023	Vitamin B Deficiency
	hard capsules			

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.

Contact Details

G.L. Pharma GmbH
Schlossplatz 1
8502 Lannach, Austria
E: licensing@gl-pharma.at
T: +43 3136 82 577