

# **B2B-Licensing**

**Product List (Q1 2019)**

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## Products available / Ready for filing

Active substance	Dosage form	Strength	Form	Indication
Acetylsalicylic Acid	Gastro-resistant tablets	75 mg, 100 mg, 150 mg, 160 mg		Antithrombotic
	Tablets	75 mg, 100 mg, 160 mg		
Benfotiamine	Film-coated tablets <sup>IVa/b</sup>	50 mg, 150 mg		Vitamin B <sub>1</sub> Deficiency
		300 mg		
Buprenorphine	Sublingual tablets	2 mg		Opioid Use Disorder
		4 mg, 8 mg		
Buprenorphine + Naloxone	Sublingual tablets <sup>IVa/b</sup>	2 mg+0.5 mg, 4 mg+1 mg, 8 mg+2 mg		Opioid Use Disorder
Esketamine	Solution for injection <sup>IVa/b</sup>	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), 25 mg/ml (5 ml, 10 ml)		
Eslicarbazepine Acetate	Tablets <sup>IVa/b</sup>	200 mg, 400 mg, 600 mg, 800 mg		Epilepsy
Ethambutol	Solution for injection*	100 mg/ml (5 ml)		Tuberculosis
	Tablets	500 mg		
Ethosuximide	Syrup**	50 mg/ml (250 ml)		Epilepsy
Fluoxetine	Film-coated tablets	10 mg, 20 mg, 40 mg, 60 mg		Depression
Folic Acid	Tablets <sup>IVa/b</sup>	1 mg, 5 mg		Folic Acid Deficiency
Hydromorphone	Solution for injection <sup>IVa/b</sup>	2 mg/ml, 10 mg/ml, 20 mg/ml, 50 mg/ml (1 ml), 10 mg/ml (10 ml)		Severe Pain
Hydroxocobalamine	Solution for injection* <sup>IVa/b</sup>	1 mg/ml (1 ml)		Vitamin B <sub>12</sub> Deficiency
Ketamine	Solution for injection <sup>IVa/b</sup>	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), 50 mg/ml (5 ml, 10 ml)		
Lacosamide	Tablets <sup>IVa/b</sup>	50 mg, 100 mg, 150 mg, 200 mg		Epilepsy
	Oral solution <sup>IVa/b</sup>	10 mg/ml (200 ml, 500 ml)		
	Solution for infusion <sup>IVa/b</sup>	10 mg/ml (10 ml) 10 mg/ml (20 ml)		
Levetiracetam	Oral solution <sup>IVa/b</sup>	100 mg/ml (150 ml, 300 ml)		Epilepsy
	Conc. for solution for infusion <sup>IVa/b</sup>	100 mg/ml (5 ml, 10 ml)		
Levomethadone	Tablets <sup>IVb</sup>	2.5 mg, 5 mg, 10 mg, 20 mg, 30 mg		Opioid Use Disorder
	Conc. for oral solution <sup>IVa/b</sup>	5 mg/ml (100 ml, 150 ml, 300 ml, 500 ml, 1000 ml)		
	Syrup <sup>IVa/b</sup>	1 mg/ml (100 ml, 150 ml, 300 ml, 500 ml)		

IVa/b: Zone IVa/b stability data available.

\* Registration dossier in the process of being updated. | \*\* Registration dossier update required.

## Product List (Q1 2019)



## Products available / Ready for filing

Active substance	Dosage form	Strength	Form	Indication
Meloxicam	Solution for injection <sup>IVa/b</sup>	10 mg/ml (1.5 ml)		Inflammatory Pain
Metamizole	Solution for injection <sup>IVa/b</sup>	500 mg/ml (2 ml, 5 ml)		Mild to Moderate Pain
Methadone	Tablets <sup>IVb</sup>	5 mg, 10 mg, 20 mg, 40 mg, 60 mg		Opioid Use Disorder
	Conc. for oral solution <sup>IVa/b</sup>	10 mg/ml (100 ml, 150 ml, 300 ml, 500 ml, 1000 ml)		
	Syrup <sup>IVa/b</sup>	2 mg/ml (100 ml, 150 ml, 300 ml, 500 ml)		
Metoclopramide	Oral solution <sup>IVa/b</sup>	1 mg/ml (150 ml)		Nausea, Emesis
	Solution for injection <sup>IVa/b</sup>	5 mg/ml (2 ml, 10 ml)		
	Tablets <sup>IVb</sup>	10 mg		
Morphine	Solution for injection	10 mg/ml (1 ml)		Severe Pain
		10 mg/ml (10 ml), 20 mg/ml (10 ml)		
		Film-coated tablets	5 mg, 10 mg, 20 mg	
Oxycodone	Prolonged-release tablets	5 mg, 10 mg, 15 mg*, 20 mg, 30 mg*, 40 mg, 60 mg*, 80 mg		Severe Pain
	Syrup <sup>IVa/b</sup>	1 mg/ml (100 ml, 250 ml, 300 ml)		
	Conc. for oral solution <sup>IVa/b</sup>	10 mg/ml (30 ml, 100 ml, 120 ml)		
	Solution for injection or infusion <sup>IVa/b</sup>	10 mg/ml (1 ml, 2 ml)		
Oxycodone + Naloxone	Prolonged-release tablets* <sup>IVa/b</sup>	5 mg+2.5 mg, 10 mg+5 mg, 20 mg+10 mg, 30 mg+15 mg, 40 mg+20 mg		Severe Pain
Phenytoin	Tablets**	100 mg		Epilepsy
	Solution for injection**	50 mg/ml (5 ml)		
Potassium Iodide	Tablets	65 mg		Radiation Prophylaxis
Tramadol	Solution for injection** <sup>IVa/b</sup>	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** <sup>IVa</sup>	150 mg, 300 mg, 500 mg		Epilepsy
	Syrup** <sup>IVa/b</sup>	50 mg/ml (100 ml)		
	Oral solution* <sup>IVa/b</sup>	300 mg/ml (100 ml)		
	Solution for injection** <sup>IVa/b</sup>	100 mg/ml (5 ml)		

<sup>IVa/b</sup>: Zone <sup>IVa/b</sup> stability data available.








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## Product List (Q1 2019)



## Special products by G.L. Pharma

Active substance	Dosage form	Strength	Form	Indication
8-Methoxypsoralen (Oxsoralen®)	Ampoules <sup>Iva/b</sup>	0.02 mg/ml		Cutaneous T-Cell Lymphoma
Diclofenac + Vitamin B <sub>1</sub> /B <sub>6</sub> /B <sub>12</sub> (Diclovit®)	Capsules	50 mg+50 mg+ 50 mg+0.25 mg		Inflammatory Pain
Fe <sup>2+</sup> + Ascorbic Acid (Ferretab®)	Capsules	100 mg+20 mg		Anaemia
Fe <sup>2+</sup> + Ascorbic Acid + Folic Acid (Ferretab® comp plus)	Capsules	66.7 mg+100 mg+0.8 mg		Anaemia during Pregnancy
Fe <sup>2+</sup> + Folic Acid (Ferretab® comp)	Capsules	50 mg+0.5 mg		
Vitamin B <sub>1</sub> /B <sub>6</sub> /B <sub>12</sub> (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)		

<sup>Iva/b</sup>: Zone <sup>Iva/b</sup> stability data available.

## Products under development

Active substance	Dosage form	Strength	Dossier availability	Indication
Buprenorphine	Sublingual tablets <sup>Iva/b</sup>	1 mg, 12 mg, 16 mg	Q3 2019	Opioid Use Disorder
		0.2 mg, 0.4 mg	Q1 2020	
Buprenorphine + Naloxone	Sublingual tablets <sup>Iva/b</sup>	1 mg+0.25 mg, 12 mg+3 mg, 16 mg+4 mg	Q4 2019	Opioid Use Disorder
Desvenlafaxine	Prolonged-release tablets <sup>Ivb</sup>	50 mg, 100 mg	Q1 2020	Depression
Ethosuximide	Soft capsules <sup>Iva/b</sup>	250 mg	Q1 2020	Epilepsy
Naloxone	Solution for injection <sup>Iva/b</sup>	1 mg/ml (2 ml)	Q2 2020	Opioid Overdose
Tizanidine	Tablets <sup>Iva/b</sup>	2 mg, 4 mg, 6 mg	Q4 2019	Muscle Spasms
Tramadol	Prolonged-release tablets <sup>Iva/b</sup>	100 mg, 150 mg, 200 mg	Q1 2021	Moderate to Severe Pain
		75 mg, 150 mg	Q3 2020	
Trazodone	Prolonged-release tablets <sup>Ivb</sup>	75 mg, 150 mg	Q3 2020	Depression
	Oral solution <sup>Iva/b</sup>	10 mg/ml (5 ml)	Q3 2020	
Valproic Acid/ Sodium Valproate	Prolonged-release tablets <sup>Iva/b</sup>	300 mg, 500 mg	Q4 2020	Epilepsy
Vitamin D <sub>3</sub>	Oral solution <sup>Iva/b</sup>	14 400 IU/ml (12.5 ml, 30 ml)	Q1 2019	Vitamin D <sub>3</sub> Deficiency
		28 800 IU/ml (12.5 ml, 30 ml, 50 ml)		
	Tablets <sup>Ivb</sup>	800 IU, 1 000 IU, 2 000 IU, 5 000 IU, 20 000 IU, 28 000 IU	Q4 2019	

<sup>Iva/b</sup>: Zone <sup>Iva/b</sup> stability data available.

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