

API	Formulation	Strength	Originator Product	Regulatory Status		Shelf life in months
Hydromorphone	Immediate release capsule	1.3 - 2.6 mg	Palladone® capsule	Approved in the EU	EU Dossier available	36 months
	Prolonged release tablet - twice daily dosing	4 - 8 - 16 - 24 mg	Palladone® prolonged release capsule	Approved in the EU	EU Dossier available	48 months
	Prolonged release tablet - once daily dosing	4 - 8 - 16 - 32 mg	Jurnista® (therapeutic equivalence demonstrated)	Approved in the EU	EU Dossier available	48 months
Levomethadon	Immediate release tablets	2.5 - 5 - 7.5 - 20 - 30 - 40 mg	L-Polamidon tablet	Approved in the EU	EU Dossier available	48 months
Methylphenidate	Prolonged release tablet	18 - 27 - 36 - 54 mg	Concerta® prolonged release tablet	Approved in the EU	EU Dossier available	48 months (some of MAHs registered 36 months only)
	Prolonged release capsule	5 - 10 - 20 - 30 - 40 - 50 - 60 mg	Medikinet® XL prolonged release capsule	Registration on-going	EU Dossier under registration	18 months (is not final approved shelf-life. Procedure still ongoing)
	Prolonged release capsule	10 - 20 - 30 - 40 - 50 - 60 mg	Equasym® prolonged release capsule	Approved in the EU	EU Dossier available	30 months / 36 months
Oxycodone	Prolonged release tablet - once daily dosing	10 - 20 - 40 - 80 mg	Develco is the originator	Approved in the EU	EU Dossier available	48 months
Oxycodone /Naloxone	Prolonged release tablet	5/2.5 - 10/5 - 20/10 - 30/15 - 40/20 mg	Targin® prolonged release tablet	Approved in the EU	EU Dossier available	36 months
	Prolonged release tablet	60/30 - 80/40 mg	Targin® prolonged release tablet	Approved in the EU	EU Dossier available	36 months
Tapentadol	Prolonged release tablets BID	25 - 50 - 100 - 150 - 200 - 250 mg	Palexia® prolonged release tablet	Approved in the EU	EU Dossier available	36 months
	Immediate release tablet	50 - 75 - 100 mg	Palexia® immediate release tablet	Development on-going	EU Dossier expected for submission by Q4/2024	TBD
Dexmethylphenidate	Prolonged release TBD: Capsule/Tablet	10 - 20 - 30 - 40 - 50 - 60 mg	Focalin XR® prolonged release capsule	Development on-going	TBD	TBD

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