

Methotrexate Solution for Injection

Active ingredient	Methotrexate; 37.5 mg/ml
Strength	5 mg; 7.5 mg; 10 mg; 12.5 mg; 15 mg; 17.5 mg; 20 mg; 22.5 mg; 25 mg; 27.5 mg and 30 mg
Therapeutic indication	<ul style="list-style-type: none"> • Active rheumatoid arthritis in adult patients; • Polyarthritic forms of severe, active juvenile idiopathic arthritis (JIA), when the response to non-steroidal anti-inflammatory drugs (NSAIDs) has been inadequate; • Severe recalcitrant disabling psoriasis vulgaris, which is not adequately responsive to therapy, and severe psoriatic arthritis in adult patients; • Mild to moderate Crohn's disease either alone or in combination with corticosteroids in adult patients refractory or intolerant to thiopurines.
Reference (originator) product	Lantarel FS 25 mg/ml
Pharmaceutical form	Solution for injection
Pack Size	1 syringe in carton box
Packaging	Glass pre-filled syringe with needle shield safety system
Finished product manufacturer	Basic Pharma Manufacturing – The Netherlands
Biostudy	No
Clinical trial	No
Regulatory status	Dossier: e-CTD DCP: RMS NL; CMS: BE
Shelf-life	24 months
Batch size	1.4 kg = registration batch size commercial batch size: tbd

For any other information please contact:

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