METAMIZOLE SODIUM
500 mg film-coated tablets

PROFILE

Classification	Medicinal product, OTC/Rx
ATC code (3rd level)	N02B Other analgesics and antipyretics
Dosage form	Film-coated tablets
Active ingredients	Metamizole sodium monohydrate 500 mg
Therapeutic indication	• Acute severe pain following trauma or surgery • Painful colics • Tumour pain • Other acute or chronic severe pain, if other therapeutic measures are contraindicated • High fever that does not respond to other measures **subject to approval by the National Competent Authorities*
Reference medicinal product	Novalgin 500 mg film-coated tablets MAH: Sanofi-Aventis GmbH

DEVELOPMENT / PRODUCTION STATUS

Packaging	Blister: PVC/PVDC/Al
Pack size	10, 30, 60, 100
Proposed batch size	60.50kg final blend (110 000 film-coated tablets) 605.00kg final blend (1 100 000 film-coated tablets)
Proposed shelf life	24 months
Additional available stability data	N/A

AVAILABLE DOSSIER

N/A (in development)

AVAILABLE MARKETING AUTHORIZATIONS

N/A (in development)

BUSINESS MODEL

- License and supply
- License and supply with transfer of granted MA
- Distribution model

COMPETITIVE EDGE / CLAIM

- Among non-opioids, Metamizole has proven analgesic, antipyretic, spasmolytic and weak anti-inflammatory effects.