



METAMIZOLE + TRAMADOL Film-coated Tablets

The innovative Fixed Dose Combination (FDC) is supported by guidelines from Germany and Austria*

- Indicated for the symptomatic treatment of moderate to severe pain.
 - - It is expected to be most commonly used for conditions such as low back pain, cancer pain, and acute postoperative pain.

Designed for substitution therapy

Available strengths: 500+75mg, 500+37.5mg

Both substances already used in standard therapy of pain

- Tramadol is indicated for the treatment of moderate to severe pain when administered orally as a monotherapy.
- Metamizole (also known as dipyrone) is indicated for the treatment of severe acute and chronic pain, as well as for fever that does not respond to other treatments when administered orally as a monotherapy.
- In the EU markets, there are combinations of paracetamol + tramadol and dextketoprofen + tramadol available.
- There is a high demand for effective pain management in the post-operative phase after hospital discharge, based on discussions with doctors in the Czech Republic.

Improved patient compliance

Reference markets

- Reference markets Show that metamizole solid oral drugs have been widely sold, with approximately 3.1 billion tablets sold (MAT Q2 2023) in the EU27+UK.

*Der Arzneimittelbrief. Available from: <https://www.der-arzneimittelbrief.de/de/Artikel.aspx?SN=7268>

*Eckhard BEUBLER, Hans-Georg KRESS, Burkhard GUSTORFF et al. Konsensus-Statement POSTOPERATIVE SCHMERZTHERAPIE. ÖSTERREICHISCHE SCHMERZGESELLSCHAFT. Available from: <https://www.oesg.at/index.php?eID=dumpFile&t=f&f=99&token=dd9077f924ea57512f85ea20bb10d3014d306788>

Regulatory pathway

- Legal basis: Article 8(3) supported with both literature data as well as clinical studies.

Development status

- Prototype development is currently underway
- The clinical strategy involves a comprehensive approach:
 - Pharmacokinetic (PK) studies
 - Co-prescription data analysis
 - Phase 2 and Phase 3 studies
 - Literature information review

Partnership options

- The product is available for co-development

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