



DEXIBUPROFEN

Film-coated Tablets

- 200mg (OTC) is indicated for the symptomatic short-term treatment of acute mild to moderate pain and inflammation in adults¹. It can be used for various conditions, including:
 - Musculoskeletal pain, such as back pain.
 - Dental pain.
 - Pain after dental extraction.
 - Menstrual pain.
 - Headache.
 - Pain during cold and flu.
- 300mg and 400mg (Rx) are indicated for the following purposes:
 - Symptomatic treatment for the relief of pain and inflammation associated with osteoarthritis.
 - Acute symptomatic treatment of pain during menstrual bleeding (primary dysmenorrhoea).
 - Symptomatic treatment of mild to moderate pain, such as musculoskeletal pain or dental pain.

A safe painkiller with proven efficacy at lower dose using the active isomer only

The same clinical efficacy is proven with half dose of regular ibuprofen

Clinical data show less side effects vs. the racemic form

Available strengths: 200mg; 300mg and 400mg

Reference markets

- Dexibuprofen 200mg, 300mg, and 400mg is already registered in Europe (AT, IT, DK, ES, PT, DE, HU).



Regulatory pathway

- Legal basis: Article 10(1) generic application


Development status



- Registration batches manufactured, stability studies ongoing
- Bioequivalence study planned this year

Partnership options

- The product is available for out-licensing in select European markets
- The product is also available for licensing outside of Europe

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