

Ibuprofen 200 & 400 mg

Orodispersible tablet



Orodispersible facilitates oral intake and improves patients' compliance

Key features

- ODT Athena's technology is a perfect fit for bedridden patients or patients with difficulties in swallowing or chewing conventional solid dosage forms, without need for water at the time of administration.

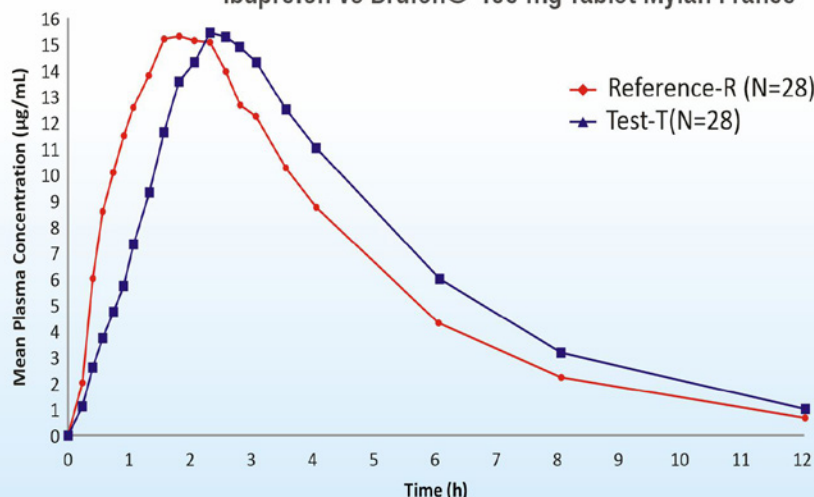
Competitive advantages

- Rated as the safest non-steroidal anti-inflammatory Drug by spontaneous adverse drug reaction reporting in the UK^{1,2}.
- Prominent analgesic & antipyretic activities particularly useful in the management of pain related to dysmenorrhea, headache, postoperative dental pain and rheumatoid arthritis³.
- Ibuprofen among the most prescribed pain-relieving drugs⁴.

Regulatory status

- INN: Ibuprofen
- ATC Code: M01AE
- CAS Registry Number: 115687-27-1
- Reference compound: BRUFEN[®], Mylan.
- Biostudy
 - Patient population: 30 male and female healthy volunteers.
 - Methodology: Randomized, single-dose, 2-way crossover (test without water vs. reference with water).
 - Reference product: BRUFEN[®] 400 mg Mylan, France.
- Zone IV stability data available.
- eCTD dossier available.

Ibuprofen vs Brufen[®] 400 mg Tablet Mylan France



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PAIN / ANTI-INFLAMMATORY

Information at a glance

- Commercial batch size (million doses): 200 mg: 0.5 | 400 mg: 0.25
- Dossier Batch size (million doses): 200 mg: 0.25 | 400 mg: 0.125
- Shelf-life: 3 years
- Storage conditions: Light resistant containers at 15-30°C
- Pack info: PVC-PVDC / Alu blister, 1 carton x 10 blister x 10 tabs
- Tablet weight / strength: 200 mg: 600 mg | 400 mg: 1 200 mg
- Flavour: Orange

Market highlights

- NSAIDs market size is expected to move from \$15.6 billion in 2019 to \$24.4 billion by 2027 exhibiting a CAGR of 5.8% during the forecast period⁴.
- Arthritis segment hold 38.0% NSAIDs market share in 2019 and is likely to lead throughout the forthcoming years⁴.
- Ibuprofen market valued at \$294.4 million in 2020 and expected to reach \$448.0 million by 2026 growing at a CAGR of 6.1% during the forecasted period⁵.

Competitors' landscape

- NSAIDs (NAPROSYN[®]/naproxen, CATAFLAM[®]/diclofenac, ORUDIS[®]/ketoprofen, MOBIC[®]/meloxicam, TORADOL[®]/ketorolac, FELDENE[®]/piroxicam) and COX-2 selective NSAIDs (CELEBREX[®]/celecoxib, VIOXX[®]/rofecoxib, BEXTRA[®]/valdecoxib).

REFERENCES

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3. Pottast H et al J Pharm Sci 94(10):2122 (2005)
4. NSAIDs Market Research, Fortune Business Insights, 2019
5. Global Ibuprofen Market Research Report, Market.Biz (2020)



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Key numbers

- NSAIDs market expected to reach \$24.4 billion by 2026
- NSAIDs market led by arthritis segment with a market share of 38%
- Global ibuprofen market expected to reach \$448 million by 2026 growing at a CAGR of 6.1% during the forecasted period

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