

# Meloxicam 7.5 mg & 15 mg

## Orodispersible tablet



*Orodispersible facilitates oral intake and improves patients' compliance*

## Key features

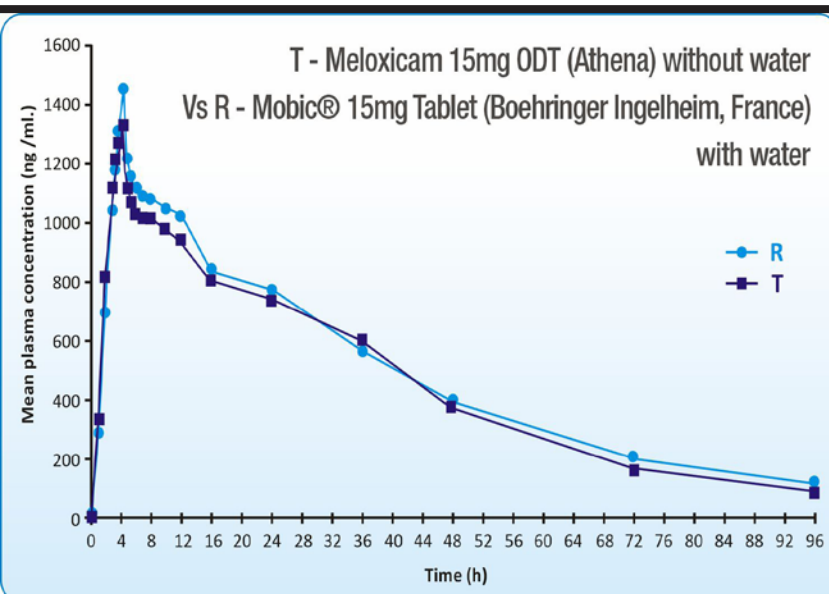
- Meloxicam appears to have better gastrointestinal tolerance than non-selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) thanks to its preferential inhibition of COX-2 vs. COX-1. The Orodispersible tablets enhance patient compliance, administration without water and accuracy of dosage.

## Competitive advantages

- Meloxicam, compared to diclofenac<sup>1</sup> piroxicam<sup>2</sup> or naproxen<sup>3,4</sup>, caused less gastrointestinal related adverse events (respectively 13% vs. 19%; p=0.001; 10.3% vs. 15.4%; p=0.001 and 0.36 events per patient vs. 0.52; p=0.002).
- Once-a-day administration.

## Regulatory status

- NN: meloxicam
- ATC Code: M01AC06
- CAS registry number: 71125-38-7
- Reference compound: MOBIC<sup>®</sup>, Boehringer Ingelheim.
- BioEq. study
  - Patient population: 24 male & female healthy volunteers.
  - Methodology: Randomized 2-way crossover (Test w/o water, reference with water).
  - Reference product: MOBIC<sup>®</sup> 15 mg Boehringer Ingelheim, France.
- Zone IV stability data available.
- CTD dossier available.



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PAIN / ANTI-INFLAMMATORY

## Information at a glance

- Commercial batch size (million doses): 7.5 mg: 0.5 | 15 mg: 0.5
- Dossier Batch size (million doses): 7.5 mg: 0.225 | 15 mg: 0.225
- Shelf-life: 3 years
- Storage conditions: store at 25°C
- Pack info: Alu-Alu paper backed peel off blister / Alu-Alu. pack of 10-tabs blister
- Tablet weight / strength: 7.5 mg: 180 mg | 15 mg: 360 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 period<sup>5</sup>.
- Arthritis segment hold 38.0% NSAIDs market share in 2019 and is likely to lead throughout the forthcoming years<sup>5</sup>.

## Competitors' landscape

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

### REFERENCES

1. Hawkey C et al Br J Rheumatol 37:937-45 (1998)
2. Dequeker J et al Br J Rheumatol 37:948-51 (1998)
3. Singh G et al The American Journal of Medicine, 117;2:100-106 (2004)
4. Wojtulewski JA et al Br J Rheumatol 35(suppl. 1):22-28 (1996)
5. NSAIDs Market Research, Fortune Business Insights, 2019



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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%

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