


Tramadol 37.5 mg + Paracetamol 325 mg

Orodispersible tablet 

PAIN / ANTI-INFLAMMATORY



Orodispersible facilitates oral intake and improves patients' compliance

Key features

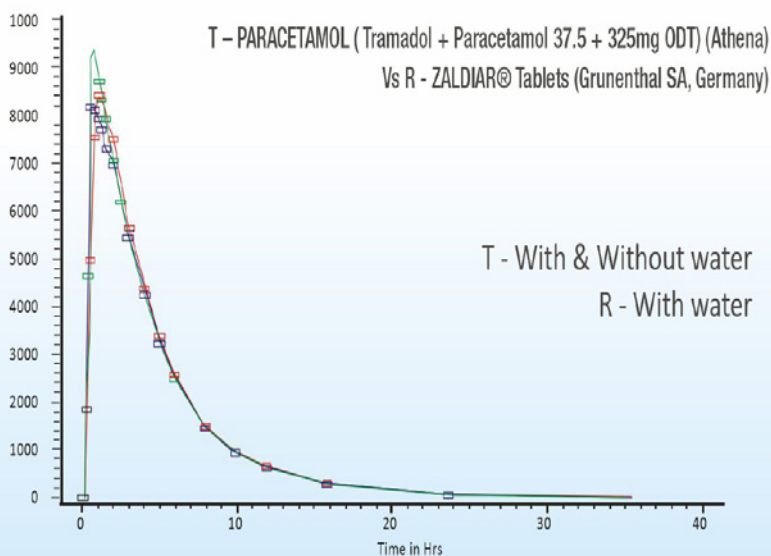
- Fixed-combination, offering a convenient method of intake maximizing analgesic efficacy whilst reducing daily tramadol and paracetamol doses, hence minimizing tramadol's potential for dependence and misuse and paracetamol hepatotoxicity.

Competitive advantages

- Fixed-combination of two well-known and established analgesics, devoid of the gastrointestinal, cardiovascular and renal adverse events associated with Non-Steroidal Anti-inflammatory Drugs (NSAIDs) responsible for 3.500-16.500 death per year in the USA^{1,2}.
- Fixed-dose combination treatment reduces tramadol consumption by 24% vs. Tramadol monotherapy^{3,4}. Fixed-combination extensively evaluated than other combination products⁵. Only fixed-combination where both the dual mechanism of action and synergy between the two compounds have been demonstrated in both preclinical studies and in humans^{6,7,8,9}.

Regulatory status

- INN: Tramadol & Paracetamol
- ATC Code: N02AJ13
- CAS registry number: 147630-10-2
- Reference compound: ZALDIAR[®], Grunenthal.
- BioEq. study
 - Patient population: 37 fasting male and female healthy volunteers.
 - Methodology: single dose, 3-way crossover (test with & without water vs. reference with water).
 - Reference product: ZALDIAR[®] Tablets, Grunenthal SA, Germany.
- Zone IV stability data available.
- CTD dossier available.



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Information at a glance

- Commercial batch size (million doses): 0.5
- Dossier Batch size (million doses): 0.5
- Shelf-life: 3 years
- Pack info: Alu-Alu, Alu-PVC blister strip of 10 & 6 tablets
- Tablet weight / strength: 1 200 mg
- Flavour: Peppermint

Market highlights

- The Global pain management market was valued at \$71.4 billion in 2019 and is projected to reach \$91.6 billion by 2027 registering a CAGR of 3.8% (2020-2027)¹⁰.

Competitors' landscape

- NSAIDs (NAPROSYN[®]/naproxen, CATAFLAM[®]/diclofenac, ORUDIS[®]/ketoprofen, MOBIC[®]/meloxicam, TORADOL[®]/ketorolac, FELDENE[®]/piroxicam), anticonvulsants (TEGRETOL[®]/carbamazepine, TRILEPTAL[®]/oxcarbazepine, APTIOM[®]/eslicarbazepine, NEURONTIN[®]/gabapentin, LYRICA[®]/pregabalin), opioids (OXYCONTIN[®]/oxycodone, DUROGESIC[®]/fentanyl, DOLOPHINE[®]/methadone, DEMEROL[®]/meperidine, codeine, SUBUTEX[®]/buprenorphine) and nonnarcotic analgesics.

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Key numbers

- Global pain market: \$71.4 billion in 2019 and \$91.6 billion by 2027
- CAGR: 3.8% (2020-2027)

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