

Prednisolone 1mg & 5mg

Orally Disintegrating Tablet



An innovative form of Prednisolone for Paediatric use

Key features

- These corticosteroids occur naturally in the body and help to maintain health and well-being. Boosting the body with extra corticosteroids such as Prednisolone ODT is an effective way to treat various illnesses involving inflammation in the body. Prednisolone reduces this inflammation, which could otherwise go on making the condition worse.

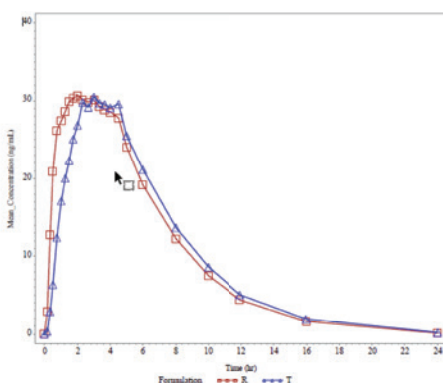
Competitive advantages

- Prednisolone is highly effective and significantly more effective than Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) in rheumatoid arthritis and may be used intermittently¹.
- Prednisolone is the active metabolite of prednisone and prednisone's efficacy is related to the patient's hepatic function capacity to convert prednisone to prednisolone².
- Prednisolone is on the World Health Organization's List of Essential Medicine³.

Regulatory status

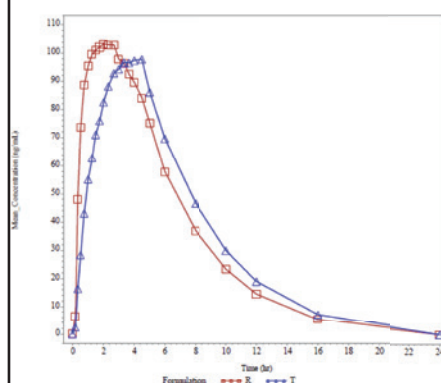
- INN: Prednisolone
- ATC: S02BA03
- CAS registry number: 50-24-8
- Zone IVb stability data ongoing
- eCTD dossier Available (1 dossier per strength, including BE)

BE results: 1mg strength:



Single-Dose Oral Bioequivalence Study of Prednisolone 1 mg Orodispersible tablet of Athena versus Prednisolone 1 mg tablet of Accord-UK Ltd, in 28 healthy adults under Fed conditions.

BE results: 5mg strength:



Single-Dose Oral Bioequivalence Study of Prednisolone 5 mg Orodispersible tablet of Athena versus Prednisolone 5 mg tablet of Accord-UK Ltd, in 27 healthy adults under Fed conditions.



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PAIN / ANTI-INFLAMMATORY

Market highlights

- The global corticosteroid therapy market is expected to grow from \$4.56 billion in 2021 to \$5.33 billion by 2025 at a CAGR of 4% over the forecasted period⁴.

Competitors' landscape

- CORTEF[®]/Hydrocortisone, DECADRON[®]/dexamethasone, DELTASONE[®]/prednisone, CORTONE[®]/cortisone, KENALOG[®]/triamcinolone, CELESTONE[®]/betamethasone, MEDROL[®]/methylprednisolone.

Information at a glance

- Batch size (million doses): 1mg: 0.5, 5mg: 0, 25
- Shelf-life: 24 months
- Storage conditions: Store below 25°C.
- Pack info: Aluminum (140 µm) /Aluminum (25 µm) blister
- Tablet weight: 1 mg: 150mg mg | 5 mg: 300 mg

References

1. Gotzche P et al, Cochrane Library Cochrane Database Syst Rev. CD00189 (2005)
2. Torrest K, SingleCare (2019)
3. World Health Organization model list of essential medicines: 21st list (2019)
4. Research and Markets : Global Corticosteroids Market Report 2021. 13th May 2021



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Key numbers

- US market for Prednisone tablets is about \$30 million- IQVIA MAT September 2020 data

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