PRODUCT INFORMATION

DIFFLAM FORTE ANTI-INFLAMMATORY THROAT SPRAY

Composition

Each mL of Difflam Forte Anti-Inflammatory Throat Spray contains 3.0mg of benzydamine hydrochloride in mL. Each spray delivers approximately 0.5mg of benzydamine hydrochloride. It also contains ethanol, saccharin sodium, methyl hydroxybenzoate, glycerol, PEG-40 hydrogenated castor oil, purified water and mint flavouring. It does not contain gluten, lactose, sugar or colour.

Pharmacology

Benzydamine is an anti-inflammatory analgesic agent structurally unrelated to the steroid group. Benzydamine differs chemically from other non-steroidal anti-inflammatory agents in that it is a base rather than an acid.

Animal models show that, when administered systemically, benzydamine is effective against pain and oedema due to inflammatory conditions. It also inhibits granuloma formation. At concentrations used for topical treatment, benzydamine possesses local anaesthetic action. Benzydamine does not cause erosion of the gastric mucosa when given orally to rats at doses of up to 100mg/kg.

The analgesic activity of benzydamine was more pronounced in models involving an experimental inflammation rather than in non-inflammatory pain. In common with the aspirin-like drugs, benzydamine possesses an antipyretic activity. Peripheral reflexes were transiently inhibited after intravenous administration to cats.

Pharmacodynamics

The mechanism of anti-inflammatory action of benzydamine is not related to stimulation of the pituitary-adrenal axis. Like other non-steroidal anti-inflammatory agents, benzydamine inhibits the biosynthesis of prostaglandins under certain conditions, but its properties in this respect have not been fully elucidated. The stabilising effect on cellular membranes may also be involved in the mechanism of action.

Pharmacokinetics

Benzydamine is well absorbed following oral administration. Following topical administration, benzydamine is well absorbed into the inflamed local mucosa where it exerts anti-inflammatory and local anaesthetic actions. Plasma benzydamine levels following use are low and proportionate to the amount actually ingested.

Benzydamine and its metabolites are excreted largely in the urine. Metabolism is largely by oxidative pathways, although dealkylation can be shown.
Benzydamine has been detected in blood and urine following gargling of solution form. Most of the absorbed dose is eliminated in the first 24 hours. Repeated administration for 7 days does not result in accumulation of benzydamine in plasma.

Indications

Difflam Forte Anti-Inflammatory Throat Spray is indicated for the temporary relief of painful conditions of the mouth and throat including tonsillitis, sore throat, radiation mucositis, aphthous ulcers, pharyngitis, swelling, redness, inflammatory conditions, post orosurgical and periodontal procedures.

Contraindications

Patients with known hypersensitivity to benzydamine or to the other components listed.

Precautions

If a sore throat is either caused or complicated by a bacterial infection, appropriate antibacterial therapy should be considered in addition to the use of Difflam Forte Anti-Inflammatory Throat Spray.

Use in Pregnancy

Category B2. Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of foetal damage. The safety of benzydamine hydrochloride has not been established in pregnant patients. Risk to benefit ratio should be established if Difflam Forte Anti-Inflammatory Throat Spray is to be used in these patients.

Drug Interactions

There are no known drug interactions with benzydamine.

Adverse Reactions

Difflam Forte Anti-Inflammatory Throat Spray is generally well tolerated and side-effects are minor. The following adverse reactions have been reported after use of benzydamine hydrochloride in solution form:

Local Adverse Reactions:
The most commonly reported reaction is oral numbness (2.6% of treated cases). Occasional burning or stinging sensation may occur (1.4%). Other local adverse effects were less common and included dryness or thirst (0.2%), tingling (0.2%), warm feeling in mouth and altered sense of taste (0.1%).

Systemic Adverse Reactions:
These were uncommon and consisted mainly of nausea, vomiting, retching, gastrointestinal disorders (0.4%), dizziness (0.1%), headache and drowsiness (0.1%).
Hypersensitivity reactions occur very rarely but may be associated with pruritis, rash, urticaria, photodermatitis and occasionally laryngospasm or bronchospasm.

**Dosage and Administration**

Adults and children over 12 years: 2-4 sprays (1-2 mg) directly onto the sore/inflamed area and swallow gently. Repeat every 1½ to 3 hours as necessary.

Children (6-12 years): 2 sprays (1 mg) directly onto sore/inflamed area and swallow gently. Repeat every 1½ to 3 hours as necessary.

Children under 6 years: Not recommended.

Uninterrupted treatment should not exceed seven days, unless under medical supervision.

*Cleaning Instructions:* After use, wipe the nozzle with a clean tissue to prevent blockage.

**Overdosage**

Immediately contact the Poisons Information Centre (telephone 131 126) for advice if an overdose occurs.

There are no known cases of overdosage with Difflam Forte Anti-Inflammatory Throat Spray. Adverse CNS effects have been reported following overdosage with high doses of Difflam Solution. There is no specific antidote for benzydamine. If an excessive quantity is ingested, the treatment should be symptomatic.

**Presentation**

White, metered dose, aerosol pump with a green lid containing 15mL of clear solution.

**Storage**

Protect from light and store below 25°C.

**Poisons schedule**

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**Sponsor**

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