Actives : Benzydamine hydrochloride 3 mg Inactive: Isomalt, saccharin sodium

Benzydamine is 1-Benzyl-3-(3- dimethyl-aminopropoxy)-1H-indazole. Benzydamine hydrochloride is a white, odourless, crystalline powder with a bitter taste, soluble in water, ethanol, methanol and chloroform. It is sparingly soluble in ether and petroleum ether.

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

The analgesic activity of benzydamine was more pronounced in models involving an experimental inflammation rather than in

In common with the aspirin-like drugs, benzydamine possesses an antipyretic activity. Peripheral reflexes were transiently inhibited after intravenous administration to cats.

Isomalt is a sugar-substitute. It is a dissaccharide alcohol and is an approximately equimolar mixture of glucose-mannitol and glucose-sorbitol. Isomalt produces no measurable changes in blood glucose levels.

#### Pharmacodynamics

The mechanism of anti-inflammatory action is not related to stimulation of the pituitary-adrenal axis. Like other nonsteroidal 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

### Absorption

Benzydamine is well absorbed following oral administration. Following topical administration of benzydamine hydrochloride in solution form, benzydamine is well absorbed into the inflamed oral mucosa where it exerts anti-inflammatory and local anaesthetic actions. Plasma benzydamine levels following use of benzydamine orally are low and parallel the amount actually ingested.

### Excretion

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 with Difflam solutions. Most of the absorbed dose was eliminated in the first 24 hours. Repeated administration for 7 days did not result in accumulation of benzydamine in plasma.

For the temporary relief of painful conditions of the oral cavity including tonsillitis, sore throat, radiation mucositis, aphthous ulcers, post-orosurgical and periodontal procedures, pharyngitis, swelling, redness and inflammatory conditions.

## CONTRAINDICATIONS

Patients with known hypersensitivity to benzydamine or to any of the components of the vehicle.

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 Anti-inflammatory Lozenges.

For use in patients with hepatic or renal impairment see Dosage and Administration section. Excess consumption of products containing isomalt may have a laxative effect.

## **Use in Pregnancy**

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 Anti-inflammatory Lozenges are to be used in these patients.

#### Use in Children

Because of the lack of sufficient clinical experience, Difflam Anti-inflammatory Lozenges are not recommended in children under 6 years of age.

#### **Drug Interactions**

There are no known drug interactions with benzydamine.

### **ADVERSE REACTIONS**

Difflam in topical oral preparations 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%). Occasional burning or stinging sensation may occur and has been reported in 1.4% of treated cases. 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 very uncommonand never of a serious nature. They consisted mainly of nausea, vomiting, retching, gastro-intestinal 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**

Difflam Anti-inflammatory Lozenges should not be chewed. They should be slowly dissolved in the mouth. One lozenge should be sucked slowly every one to two hours as required up to a maximum of 12 lozenges per day. Uninterrupted treatment should not exceed seven days.

#### With Impaired Renal Function

Since absorbed benzydamine and its metabolites are excreted in the urine, the possibility of systemic effects should be considered in patients with severe renal impairment.

With Impaired Liver Function
Since absorbed benzydamine is highly metabolised in the liver the possibility or systemic effects should be considered in patients with severe hepatic impairment.

### **OVERDOSAGE**

There are no known cases of overdosage with Difflam Anti-inflammatory Lozenges. Adverse CNS effects have been reported following overdosage with high doses of benzydamine hydrochloride in solution form. There is no specific antidote for benzydamine and should excessive quantities be ingested, the treatment should be symptomatic. Excess consumption of products containing isomalt may have a laxative effect.

### **PRESENTATION**

Mint Fresh Flavour lozenges (green) blister pack, 16's.

Store below 30°C.

## SHELF LIFE

3 Years

# Manufactured by:

UNIQUE PHARMACEUTICAL LABS. (A Div. of J. B. Chemicals & Pharmaceuticals Ltd.)

101/2 & 102/1, Daman Industrial Estate, Kadaiya, Daman-396 210, India

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