SOBENZ LOZENGE

Anti-inflammatory Lozenges
(with antibacterial)

COMPOSITION
Actives: Benzydamine hydrochloride 3 mg, and Cetylpyridinium chloride 1.33 mg.

DESCRIPTION
Orange Flavour: A 16mm, round, flat, orange coloured tablet and beveled edge.
Melon Flavour: A 16mm, round, flat, green coloured tablet and bevelled edge.

This product containing ASPARTAME 7.8mg (Artificial sweetening substance) . UNSUITABLE FOR PHENYLKETONURICS.

PHARMACODYNAMICS

Benzydamine Hydrochloride
The mechanism of anti-inflammatory action 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 stabilizing effect on cellular membranes may also be involved in the mechanism of action.

Cetylpyridinium Chloride
Cetylpyridinium Chloride is a quarternary pyridinium antiseptic with actions and uses similar to those of other cationic surfactants. It is used chiefly as lozenges or solutions for the treatment of minor infections of the mouth and throat. It is a broad spectrum antimicrobial agent with a long history of use to promote gingival health.

PHARMACOKINETICS
Benzydamine Hydrochloride

Absorption - Benzydamine is well absorbed following oral administration. 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. 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.

Cetylpyridinium Chloride
Cetylpyridinium chloride is a quaternary pyridinium antiseptic with actions and uses similar to those of other cationic surfactants. It is used chiefly as lozenges or solutions for the treatment of minor infections of the mouth and throat. It is a broad spectrum antimicromial agent with long history of use to promote gingival health. As a cationic surfactant, cetylpyridinium chloride dissociate in aqueous solution into a relatively large and complex cation, which is responsible for the surface activity, and a smaller inactive anion. In addition to emulsifying and detergent properties, quaternary ammonium compounds have bactericidal activity against Gram-positive and, at a higher concentration, against some Gram-negative bacteria. They are ineffective against bacterial spores, have variable antifungal activity, and are effective against some viruses.

Quaternary ammonium compounds are most effective in natural or slightly alkaline solution and their bactericidal activity is appreciably reduced in acid media; their activity is enhanced by alcohols.

Reference: Martindale 33rd Edition page 1138 & 1137

CPC is a broad-spectrum antimicrobial agent with a long history of use to promote gingival health. It penetrates the cell membrane, causing leakage of cell components, disruption of bacterial metabolism, inhibition of cell growth, and ultimately cell death.

INDICATIONS
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 cetylpyridinium chloride or to any of the components of the vehicle.

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 Sobenz Anti-inflammatory Lozenges.

For use in patients with hepatic or renal impairment see Dosage and Administration section.

Size: 21cm (h) x 14.8cm (w)

Black 100%

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

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

Drug Interactions
These are no known drug interactions with benzydamine.

ADVERSE REACTIONS
The following adverse reactions have been reported after use of benzydamine hydrochloride.

Local Adverse Reactions: The most commonly reported reaction is oral numbness with occasional burning or stinging sensation. Other local adverse effects were less common and included dryness or thirst, tingling, warm feeling in mouth and altered sense of taste .

Systemic Adverse Reactions: These were very uncommon and never of a serious nature. They consisted mainly of nausea, vomiting, retching, gastro-intestinal disorders, dizziness, headache and drowsiness.

Hypersensitivity reactions occur very rarely but may be associated with pruritis, rash, urticaria, photo dermatitis and occasionally laryngospasm.

DOSAGE AND ADMINISTRATION
Sobenz 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 are 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 metabolized in the liver the possibility of systemic effects should be considered in patients with severe hepatic impairment.

OVERDOSAGE
There are no known cases of overdosage with Sobenz lozenges. There is no specific antidote for benzydamine and should excessive quantities be ingested, the treatment should be symptomatic.

PRESENTATION
Orange Flavour: 2 x 8's, 10 x 8's
Melon Flavour: 2 x 8's, 10 x 8's

Not all pack sizes available locally.

STORAGE
Store in a dry place below 30°C.
Keep out of reach of children. Jauhi daripada kanak-kanak.

SHELF LIFE
Please refer to outer package.

Route of administration:Oral.

Product Registration Holder:

DUOPHARMA MARKETING SDN. BHD.
Lot No. 2, 4, 6, 8 & 10, Jalan P/7, Section 13,
Bangi Industrial Estate,
43650 Bandar Baru Bangi, Selangor. Malaysia.

Manufacturer:

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DUOPHARMA

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