SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Beechams Max Strength Sore Throat Blackberry Flavour Lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hexylresorcinol 2.5mg and Benzalkonium Chloride Solution 1.2mg

3 PHARMACEUTICAL FORM

Lozenge

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic relief of sore throat, the associated pain and pharyngitis.

4.2 Posology and method of administration

Adults (including the elderly) and children over the age of 12: One lozenge dissolved slowly in the mouth every three hours or as required. Do not take more than 8 lozenges in 24 hours.

Children aged 7 to 12 years: One lozenge dissolved slowly in the mouth every three hours or as required. Do not take more than 4 lozenges in 24 hours. Not to be given to children under 7 years.

4.3 Contraindications

Hypersensitivity to any of the active ingredients or excipients.

Patients with metabolic disorders relating to glucose/sucrose ingestion or fructose intolerance.

4.4 Special warnings and precautions for use

Keep out of the reach and sight of children.

If symptoms persist consult your doctor.

Do not exceed the stated dose

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Contains 2.5g of total glucose and sucrose per lozenge. This should be taken into account in patients with diabetes mellitus.

4.5 Interaction with other medicinal products and other forms of interaction

None

4.6 Fertility, Pregnancy and lactation

There is a lack of evidence of safety of the product in human pregnancy and in animals, but both hexylresorcinol and benzalkonium chloride have been used widely in lozenges for many years without apparent ill consequence. However, as with all medicines, caution should be exercised during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Gastrointestinal Disorders: Local irritations or inflammations in the mouth and throat.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at:www.mhra.gov.uk/yellowcard.

4.9 Overdose

The oral toxic dose of benzalkonium chloride is between 1 and 3g, symptoms of overdose are unlikely with a product containing such a low level.

An overdose of hexylresorcinol may cause minor gastrointestinal irritation.

After withdrawal of the product, treatment is symptomatic.

Theoretically symptoms are possible in children if at least 50 lozenges are consumed in a short space of time. In such extreme overdose related to menthol ingestion, symptoms may include nausea, vomiting, diarrhoea, profuse sweating and intense thirst.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Hexylresorcinol is a local anaesthetic effective for topical use on the mucous membranes of the mouth and throat. Mild antiseptic activity has also been demonstrated.

Benzalkonium chloride is a quaternary ammonium compound with antiseptic activity typical of this group.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

There are no preclinical data of any relevance additional to that already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid monohydrate, sucrose, liquid glucose, propylene glycol, blackberry flavour, levomenthol, Ponceau Red E124, Brilliant Black E151

6.2 Incompatibilities

Benzalkonium chloride is incompatible with other anionic surfactants, citrates, iodides, nitrates, permanganates, salicylates, tartrates and alkalis. Incompatibilities have also been reported with other substances including aluminium, hydrogen peroxide, kaolin and some sulphonamides.

Hexylresorcinol is also incompatible with alkalis and oxidising agents.

6.3 Shelf life

Two years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Blisters (PVC 250 microns/PVdC 60 microns/Aluminium 20 microns)

Pack sizes 10, 12, 20

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Haleon UK Trading Limited
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Weybridge
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KT13 0NY
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8 MARKETING AUTHORISATION NUMBER(S)

PL 44673/0027

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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