Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Merocaine Lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cetylpyridinium chloride 1.4 mg/lozenge
Benzocaine 10.0 mg/lozenge

Excipients with a known effect: also includes sucrose 1.137g per lozenge and glucose 1.0496g per lozenge.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lozenge
Clear green, slightly domed shaped, disc lozenge with a lemon-lime flavour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Merocaine Lozenges provide rapid and profound local anaesthetic action and topical antibacterial effects for the temporary relief of pain and discomfort in sore throat and superficial mouth infections. Indicated for relief of minor throat irritations and adjunctively, for symptomatic relief of pain and discomfort in more serious throat infections, such as tonsillitis and pharyngitis.

4.2 Posology and method of administration

Adults and children over 12 years
Allow to dissolve slowly in the mouth. One lozenge every 2 hours as needed but not more than 8 lozenges in 24 hours.

Children under 12 years
Merocaine lozenges are not recommended for use in children under 12 years (see section 4.4).

4.3 Contraindications

Hypersensitivity to the active ingredients or any of the excipients.

4.4 Special warnings and precautions for use

Consult your doctor in case of severe irritation of your throat with high fever or if symptoms persist for more than 3 days.

Merocaine Lozenges contain sucrose and glucose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

This should be taken into account in patients with diabetes mellitus.

Cases of methaemoglobinaemia have been reported with Merocaine Lozenges (see section 4.8). If patients present with signs or symptoms of methemoglobinemia such as pale, grey or blue coloured skin, lips and nail beds; headache; tachycardia; shortness of breath; dizziness or lightheadedness; confusion; fatigue or lack of energy, treatment should be discontinued immediately and patients should be treated appropriately.

Paediatric population are at increased risk for the development of benzocaine-induced methemoglobinemia, even when appropriate dosing guidelines are followed. This is due to their increased body surface area to body mass ratio compared to adults, resulting in a greater proportion of drug absorbed per kilogram of body weight. Merocaine lozenges are not recommended for use in childrenunder 12 years of age (see section 4.2).

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, pregnancy and lactation

There are no or limited amount of data from the use of Cetylpyridinium chloride and benzocaine in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).
Medical advice is required for use in pregnancy.

It is unknown whether Cetylpyridinium chloride and benzocaine are excreted in human milk. A risk to the newborns/infants cannot be excluded.
Medical advice is required for use in lactation.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Adverse reactions have been ranked under headings of frequency using the following convention:	
Very common	≥ 1/10
Common	≥ 1/100 to < 1/10
Uncommon	≥ 1/1,000 to < 1/100
Rare	≥ 1/10,000 to < 1/1,000
Very rare	< 1/10,000
Not known: frequency cannot be estimated from the available data	

Skin and subcutaneous tissue disorders
Not known: urticaria.

Gastrointestinal disorders
Not known: oral discomfort.

Immune system disorders
Not known: hypersensitivity, sensitisation.

Blood and lymphatic system disorders
Not known: methaemoglobinaemia.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

There is no experience of overdosage but normal procedures of gastric lavage and maintenance of respiration and circulation (using vasopressor drugs if necessary) should apply.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Cetylpyridinium chloride – topical antibacterial agent.
Benzocaine – local anaesthetic.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lime oil
Lemon oil
Sucrose (granular)
Glucose liquid 80 %
Quinoline yellow (E104)
Indigo carmine (E132)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

PVC/aluminium foil laminate blister in cardboard cartons in packs of 24.
There are 3 strips of 8 lozenges per carton.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Sanofi-Aventis Ireland Limited T/A SANOFI
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0540/178/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 March 1982

Date of last renewal: 10 March 2012

10 DATE OF REVISION OF THE TEXT

October 2019