Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Merocets 1.4mg Lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains: Cetylpyridinium chloride 1.4mg.

Excipients: Also contains sucrose 1139.2mg, glucose liquid 1314.5mg and sunset yellow (E110) 0.0036mg.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lozenge
Round, yellow, plain, convex lozenges.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an antiseptic for the symptomatic relief of sore throat. Also indicated for the minor irritations of the mouth and throat.

4.2 Posology and method of administration

For oral administration

Adults, the elderly and children over 6 years:
One lozenge every 3 hours. Allow the lozenge to dissolve slowly in the mouth.

Children under 6 years: not recommended

4.3 Contraindications

Hypersensitivity to the active ingredient cetylpyridinium chloride or to any other excipients in this product listed in section 6.1.

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.

Advice for diabetic patients: Take into account the carbohydrate content.

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

Sunset yellow (E110) may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

There is no or inadequate evidence of safety of cetylpyridinium chloride in human pregnancy but it has been in wide use for many years without apparent ill-consequences. No data are available on the use of Merocets lozenges in pregnancy.

As with all medicines, if pregnant or breast feeding, seek medical advice before taking this product.

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:
Very rare: urticaria.

Gastrointestinal disorders:
Not known: oral discomfort.

Reporting of suspected adverse reactions
Reporting of 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

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

ATC Code: R02AA06
Cetylpyridinium chloride is a surface active quaternary ammonium compound with antiseptic properties.

5.2 Pharmacokinetic properties

Cetylpyridinium chloride exerts its antimicrobial activity topically in the mouth and throat as it dissolves from the lozenge. Pharmacokinetic data are not available.

5.3 Preclinical safety data

None of relevance.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Glucose liquid
Peppermint oil
Sunset yellow (E110)
Quinoline yellow (E104)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container in order to protect from moisture.

6.5 Nature and contents of container

PVC/PVdC/aluminium foil laminate blister in cardboard carton containing 8 or 24 lozenges.

Not all pack sizes may be marketed.

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 Ltd
T/A SANOFI
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0540/176/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 July 1988

Date of last renewal: 25 July 2008

10 DATE OF REVISION OF THE TEXT

September 2017