Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Merocets Plus Lozenges
Cetylpyridinium chloride 1.4 mg
Menthol 5.0 mg
Eucalyptus oil 3.0 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains

Cetylpyridinium chloride	1.4mg
Menthol	5.0mg
Eucalyptus oil	3.0mg

Excipient with known effect:
Sucrose 1.13g per lozenge and glucose 1.31 g per lozenge.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lozenges.
Off-white, round, plain lozenge with a menthol/eucalyptus flavour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Symptomatic relief of sore throats and nasal congestion.

4.2 Posology and method of administration

Oral

Adults and children 6 years or over:

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 any of the active ingredients or 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.

Exercise caution if you suffer from diabetes mellitus.

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

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

There is no adequate 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 Plus in pregnancy

As with all medicines, caution should be exercised during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None known.

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.

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 overdose, but normal procedure of gastric lavage and maintenance of respiration and circulation should apply.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: R02AA06

Cetylpyridinium chloride is a surface active quarternary ammonium compound with antibacterial properties.

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Glucose liquid

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.

Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Container: PVC/PPdC/aluminium foil laminate blister in cardboard carton.

Pack size: 24 lozenges.

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

PA0540/177/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first renewal: 19th April 1998

Date of last renewal: 19th April 2008

10 DATE OF REVISION OF THE TEXT

September 2017