Summary of Product Characteristics

Product Summary

1 Trade Name of the Medicinal Product

MACKENZIES SMELLING SALTS

2 Qualitative and Quantitative Composition

Contains not less than 8.820g Ammonia Liquor 880/890 and 0.539g Eucalyptus Oil.

For a full list of excipients, see section 6.1.

3 Pharmaceutical Form

White granules.

Clinical Particulars

4.1 Therapeutic Indications

1) Traditionally used for the symptomatic relief of catarrh and head colds.

4.2 Posology and Method of Administration

Posology
Inhale vapour through nostrils as required.
Do not use for children under 3 months of age.

Method of Administration
Inhalant.

4.3 Contraindications

Do not use for children under 3 months of age.

4.4 Special Warnings and Precautions for Use

None known.
The product labelling includes the following statements:
Not to be taken.
If symptoms persist consult your doctor.
Keep out of the reach and sight of children.

4.5 Interactions with other Medicaments and other forms of Interaction

None known.

4.6 Pregnancy and Lactation

No special precautions are considered necessary.

4.7 Effects on Ability to Drive and Use Machines

None known.

4.8 Undesirable Effects

None known.

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; website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

No special requirements are anticipated.

Pharmacological Properties

5.1 Pharmacodynamic properties

*ATC code:*R01A X
Ammonia is employed in the product as a reflex stimulant.
Eucalyptus oil is an essential oil.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

Pharmaceutical Particulars

6.1 List of excipients

Also contains glycerol, soft soap, tapioca, water.

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life
Three years from the date of manufacture.

Shelf-life after dilution/reconstitution
Not applicable.

Shelf-life after first opening
Not applicable.

6.4 Special precautions for storage

Store in a cool place.

6.5 Nature and contents of container

The product container is a uniquely-shaped amber glass bottle with black HDPE cap with LDPE liner.

Pack size: 17ml

6.6 Instructions for use/handling

Not applicable.

Administrative Data

7 MARKETING AUTHORISATION HOLDER

Teva UK Limited
Ridings Point,
Whistler Drive,
Castleford,
WF10 5HX,
United Kingdom

8 Marketing Authorisation Number

PL 00289/2207

9 Date of First Authorisation/Renewal of Authorisation

16.10.86 (Product Licence of Right issued: 27.7.73)
Renewed: 14.5.92; 11.7.97

10 DATE OF REVISION OF THE TEXT

29/01/2021