

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Meggezones 16mg Pastilles

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pastille contains levomenthol 16.0 mg.
Excipients also includes sucrose, 761mg per pastille and liquid glucose 140mg per pastille.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pastille.

Round, brown to dark brown, sugar coated pastille.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the symptomatic relief of oropharyngeal irritation.

4.2 Posology and method of administration

Adults only: Allow one pastille to dissolve slowly in the mouth as required.

4.3 Contraindications

None known.

4.4 Special warnings and precautions for use

If sensitivity or undue irritation develops, discontinue use immediately.
If symptoms persist, consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

No special warnings.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

None stated.

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

Systemic effects due to overdosage are most unlikely.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Menthol in pastille formulation relieves catarrh and other symptoms associated with colds.

5.2 Pharmacokinetic properties

Menthol is excreted in the urine and bile as a glucuronide.

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Modified starch
Silicone antifoam emulsion
Sucrose
Liquorice extract powder
Liquid glucose
Peppermint oil
Benzoin sumatra
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

PVC blister packs with aluminium seal in a cardboard box. Packs contain 24, 36 or 48 pastilles.
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

Bayer Limited
The Atrium
Blackthorn Road
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1410/079/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th October 1992

Date of last renewal: 4th April 2007

10 DATE OF REVISION OF THE TEXT

April 2015