SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

NAZINETTE DU DOCTEUR GILBERT, ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Essential oil of wild thyme ……..…….. 0,2571 g
Essential oil of scotch pine ……..…….. 0,2571 g
Essential oil of eucalyptus ……..……..…….. 1,0284 g
Essential oil of myrtle ……...……...…….. 0,4285 g
Essential oil of clove ……...……..……. 0,1714 g
Essential oil of thyme ……..……..……. 0,3428 g
Terpineol ……..…….……. 0,2571 g

For 100 g of ointment

Excipients with known effect: lanolin (wool fat).
For the complete list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Local adjunctive treatment of disorders of the nasopharyngeal mucosa.

4.2 Posology and method of administration

Dosage

Children over 30 months of age : one application per day of a small amount of ointment in each nostril.
Adult : 1 to 3 applications per day of a small amount of ointment in each nostril.

Method of administration

Nasal application after blowing your nose.

4.3 Contraindications

- Due to the presence of terpene derivatives:
o child under 30 months of age.
o child with a history of seizures (febrile or not).
- Hypersensitivity to one of the components, particularly to wool fat (lanolin).

4.4 Special warnings and precautions for use

Warnings

This specialty contains terpene derivatives (eucalyptus, thyme, terpineol) which can cause at excessive doses:
- accidents involving convulsions, in infants and children,
- breathing breaks and collapses in infants.

The patient should be informed of the recommended use and dosage and never exceed the recommended doses.

Precautions for use

- In case of a history of epilepsy, take into account the presence of terpene derivatives.

- The indication does not justify prolonged treatment.

4.5 Interactions with other medicinal products and other forms of interactions

Medicinal products that may lower seizure threshold

The combined use of pro-convulsant drugs, or drugs that lower the epileptogenic threshold, should be carefully considered, due to the severity of the risk involved. These drugs are represented by the most of the antidepressants (imipraminics, selective serotonin reuptake inhibitors), neuroleptics (phenothiazines and butyrophenones), mefloquine, chloroquine, bupropion, tramadol, terpenic derivatives (camphor, eucalyptol or cineole, menthol, levomenthol; essential oils of eucalyptus, niaouli, cajeput, and mint, terpineol, terpinol, thymol, alpha-pinene, beta-pinene, eugenol, linalol and carvacrol; essential oils of pine, fir, turpentine, anise, star anise, serpolet, clove and cedar (see section 4.4).

4.6 Pregnancy and breast-feeding

In case of breastfeeding, it is preferable not to use this medication due to:
- the absence of kinetic data on the passage of terpene derivatives in milk,
- and their potential neurological toxicity in infants.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

- Hypersensitivity reactions.
- In case of non-compliance with the recommended doses:
o risk of seizures in infants and children,
o possibility of agitation and confusion in the elderly.

4.9 Overdose

This specialty contains terpene derivatives, which can lower the epileptogenic threshold and cause neurological accidents in children (with seizure type) and elderly subjects (with agitation and confusion type).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic class :
NASAL PREPARATION FOR LOCAL USE
(R: Respiratory system)

The essential oil of eucalyptus and thyme, as well as terpineol are terpene derivatives. They can lower the epileptogenic threshold.
Vaseline and paraffin are mineral oils composed of saturated long-chain aliphatic hydrocarbons that are neither resorbable nor metabolizable.

5.2 Pharmacokinetic properties

Not documented.

5.3 Preclinical safety data

Not documented.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Basil essential oil, cypress essential oil, cedar essential oil, palmarosa essential oil, lavender essential oil, rosemary essential oil, purified water, wool grease, macrogol 400, macrogol 4000.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
1 year.

6.4 Special precautions for storage
Store at a temperature below 25°C.

6.5 Nature and contents of container
Aluminium cannula tube, 12 g epoxyphenolic varnish, rubber gasket and polyethylene cap.

6.6 Special precautions for disposal and handling
No special requirements.

7. MARKETING AUTHORISATION HOLDER
PHARMA DEVELOPPEMENT SAS
CHEMIN DE MARCY
58800 CORBIGNY
FRANCE

8. MARKETING AUTHORISATION NUMBER (S)
- 307 037-2 : 12 g in cannula tube (aluminium, epoxyphenolic varnish).

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION
16/10/1996

10. DATE OF REVISION OF THE TEXT
(to be completed by the holder)

11. DOSIMETRY
Not relevant.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS
Not relevant.

PRESCRIPTION AND SUPPLY CONDITIONS
Medicinal product not subject to medical prescription.