SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Plantago lanceolata siroop, stroop

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml (corresponding to 1.15 g) of the syrup contains 23.3 mg of extract (as dry extract) from *Plantago lanceolata* L., folium (Ribwort plantain) (DER 3-6:1)
Extraction solvent: water

Excipient(s) with known effect
- Sodium benzoate (E-211): 3 mg per 1 ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup
Brown viscous liquid

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Traditional herbal medicinal product used as a demulcent for the symptomatic treatment of oral or pharyngeal irritations and associated dry cough.

The product is a traditional herbal medicinal product for use in the specific indication exclusively based upon long-standing use.

Plantago lanceolata syrup is indicated in adults, adolescents and children from 3 years of age.

4.2 Posology and method of administration

Posology
Adolescents from 12 years of age, adults and elderly:
10 ml syrup 3 times daily
(single dose 233 mg extract, daily dose: 699 mg extract).

Pediatric population:
Children from 5-11 years of age:
10 ml syrup 2-3 times daily
(single dose 233 mg extract, daily dose: 466-699 mg extract).

Children from 3-4 years of age:
5 ml syrup 3 times daily.
(single dose 117 mg extract, daily dose: 351 mg extract).

The use in children at 2 years of age is not recommended because of concerns requiring medical advice and due to the lack of adequate data (see section 4.4 'Special warnings and precautions for use').

The use in children under 2 years of age is contraindicated due to menthol content in Plantago lanceolata syrup (see section 4.3 'Contraindications').

Patients with renal and/or hepatic impairment
No pharmacokinetic data are available concerning patients with renal and/or hepatic impairment. Therefore, a dose recommendation is not possible.

Method of administration
For oral use.
For correct dosing of Plantago lanceolata syrup, the enclosed measuring cup should be used, applying the suitable graduation marks 5 ml and 10 ml.

Shake the bottle before use.

Duration of use
If the symptoms persist longer than 7 days during the use of the medicinal product, a doctor should be consulted.

4.3 Contraindications

Hypersensitivity to the active substance, menthol or to any of the excipients listed in section 6.1.

Children under 2 years of age, because menthol may induce reflex apnoea and laryngospasm.

4.4 Special warnings and precautions for use

If dyspnoea, fever, or purulent sputum occurs during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Paediatric population
The use in children at 2 years of age is not recommended because of concerns requiring medical advice and due to the lack of adequate data.

The use in children under 2 years of age is contraindicated due to menthol content in Plantago lanceolata syrup (see section 4.3 'Contraindications').

This medicine contains 15 mg of sodium benzoate in each 5 ml dose and 30 mg sodium benzoate in each 10 ml dose which is equivalent to 3 mg/1 ml of Plantago lanceolata syrup.

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

No drug interactions are known. No studies on drug interactions have been performed with Plantago lanceolata syrup.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of ribwort plantain dry extract in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).
Plantago lanceolata syrup is not recommended during pregnancy.

Breast-feeding
It is unknown whether constituents or metabolites of ribwort plantain dry extract are excreted in human breast milk. A risk to the newborns/infants cannot be excluded. Plantago lanceolata syrup is not recommended during breast-feeding.

Fertility
There are no data on the effects of ribwort plantain dry extract on fertility available.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Menthol may induce reflex apnoea and laryngospasm in children under 2 years of age.

If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after registration of the traditional herbal medicinal product is important. It allows continued monitoring of the benefit/risk balance of the traditional herbal medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V

4.9 Overdose

No specific overdose symptoms in humans are reported to date.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: respiratory system, cough and cold preparations.
ATC code: R05 D

Plantago lanceolata syrup is a traditional herbal medicinal product.

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data

Preclinical data are incomplete and therefore of limited informative value. Based on the long standing clinical use there is a sufficiently established safety of the usage in the given posology in humans.

The genotoxicity potential of ribwort plantain dry extract was investigated in an in vitro mutagenicity study (Ames test) and revealed no mutagenic activity.

Tests on reproductive toxicity and carcinogenicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maltodextrin
Silica, colloidal anhydrous
Glycerol
Hydroxyethylcellulose (containing phosphate buffer)
Citric acid monohydrate
Potassium sorbate
Sodium benzoate (E-211)
Menthol flavour (containing natural menthol flavour, propylene glycol (E 1520))
Lemon flavour (containing natural flavours)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

After first opening: 6 months.

6.4 Special precautions for storage

Unopened medicinal product does not require any special storage conditions.

After first opening of bottle: Do not store above 25°C.

6.5 Nature and contents of container

The syrup is available in glass bottles of 150 ml (brown hydrolytic class III). The bottles are closed with child resistant caps (PE/PP).
The bottles are further packed into cartons with a patient information leaflet and a polypropylene (PP) graduated measuring cup.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. REGISTRATION HOLDER

Opella Healthcare France S.A.S.
157 Avenue Charles De Gaulle
92200 Neuilly-sur-Seine
Frankrijk

8. REGISTRATION NUMBER(S)

RVG 132962

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Datum van eerste verlening van de vergunning: 30 september 2024
Datum van laatste verlenging: 16 september 2025

10. DATE OF REVISION OF THE TEXT

Laatste gedeeltelijke wijziging betreft rubriek 9: 3 april 2025