

## Package leaflet: Information for the patient

Plantago lanceolata siroop, stroop

<Plantago lanceolata L., folium (Ribwort plantain) dry extract>

### **Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

### **What is in this leaflet**

1. What <Invented name> syrup is and what it is used for
2. What you need to know before you take <Invented name> syrup
3. How to take <Invented name> syrup
4. Possible side effects
5. How to store <Invented name> syrup
6. Contents of the pack and other information

#### **1. What <Invented name> syrup is and what it is used for**

<Invented name> syrup is a traditional herbal medicinal product used as a relief of symptoms of irritations of mouth or throat and associated dry cough.

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

<Invented name> syrup is indicated in adults, adolescents and children from 3 years of age.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

#### **2. What you need to know before you take <Invented name> syrup**

##### **Do not take <Invented name> syrup:**

- if you are allergic to ribwort plantain, menthol or any of the other ingredients of this medicine (listed in section 6).
- in children under 2 years of age, because menthol may induce choking and sudden blockage of the airway by uncontrolled spasm of the vocal chords (laryngospasm).

##### **Warnings and precautions**

<Talk to your doctor or pharmacist before taking <Invented name> syrup. >

Contact your doctor immediately if the symptoms worsen during the use of the medicinal product or if you develop fever, shortness of breath or purulent mucus (yellowish greenish phlegm).

## **Children**

The use of <Invented name> syrup in children at 2 years of age is not recommended because of concerns requiring medical advice and due to the lack of adequate data.

Do not use in children under 2 years of age due to menthol content in <Invented name> syrup (see under 'Do not take <Invented name> syrup').

## **Other medicines and <Invented name> syrup**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

No drug interactions are known. No studies on drug interactions have been performed with <Invented name> syrup.

## **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Safety during pregnancy and lactation has not been established. Due to the lack of sufficient data, the use of this medicine during pregnancy and lactation is not recommended.

## **Driving and using machines**

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

## **<Invented name> syrup contains sodium benzoate and sodium**

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 <Invented name> syrup.

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

## **3. How to take <Invented name> syrup**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is

*Adolescents from 12 years of age, adults and elderly:*  
10 ml three times a day.

### **Use in children:**

*Children from 5 to 11 years:*  
10 ml two to three times a day.

*Children from 3 to 4 years:*  
5 ml three times a day.

The use of <Invented name> syrup in children at 2 years of age is not recommended because of concerns requiring medical advice and due to the lack of adequate data.

Do not use in children under 2 years of age due to menthol content in <Invented name> syrup (see under 'Do not take <Invented name> syrup' in section 2).

*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 <Invented name> 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

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

**If you take more <Invented name> than you should**

No specific overdose symptoms in humans are reported to date.

**If you forget to take <Invented name> syrup**

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

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

If adverse reactions occur, a doctor should be consulted.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#).

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store <Invented name> syrup**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

This medicine must not be used for more than 6 months after first opening of the bottle. Do not store above 25°C after first opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What <Invented name> syrup contains

#### The active substance is:

- 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

#### The other ingredients are:

- 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

### What <Invented name> syrup looks like and contents of the pack

<Invented name> is a brown syrup 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.

### Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:

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

Fabrikant:

A. Nattermann & Cie. GmbH  
Nattermannallee 1  
50829 Köln  
Duitsland

### In het register ingeschreven onder:

RVG 132962

### This medicinal product is registered in the Member States of the EEA under the following names:

Belgium: Bisolnatural syrup

France: Plantuxil sirop

Italy: Bisol Tosse e Gola sciroppo

Luxembourg: Bisolnatural syrup  
Spain: Bisolherb Plantago lanceolata jarabe

**This leaflet was last revised in September 2024.**