

## **Package leaflet: Information for the user**

### **Buttercup Bronchostop Day & Night oral solution**

Marshmallow root dry extract  
Lime flower dry extract  
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 has 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 Buttercup Bronchostop Day & Night oral solution is and what it is used for
2. What you need to know before you take Buttercup Bronchostop Day & Night oral solution
3. How to take Buttercup Bronchostop Day & Night oral solution
4. Possible side effects
5. How to store Buttercup Bronchostop Day & Night oral solution
6. Contents of the pack and other information

#### **1. What Buttercup Bronchostop Day & Night oral solution is and what it is used for**

Buttercup Bronchostop Day & Night oral solution contains the active substances marshmallow root, lime flower and ribwort plantain extracts.

Traditional herbal medicinal product used in adults and adolescents aged 12 years and older for the symptomatic treatment of throat irritation and dry cough, associated with common cold.

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

If the symptoms worsen, persist or do not improve after 7 days, a doctor should be consulted.

#### **2. What you need to know before you take Buttercup Bronchostop Day & Night oral solution**

##### **Do not take Buttercup Bronchostop Day & Night oral solution**

- if you are allergic to marshmallow root, lime flower or ribwort plantain or any of the other ingredients of this medicine (listed in section 6)

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Buttercup Bronchostop Day & Night oral solution if:

- you are short of breath (dyspnoea)
- you have a high temperature (fever)
- your phlegm is yellow-green or brown in color (purulent sputum)

Tell your doctor if your symptoms worsen or persist after you have taken Buttercup Bronchostop Day & Night oral solution for 7 days.

Theoretically, this medicine may delay the absorption of other medicines taken at the same time. As a precautionary measure, do not take this medicinal product for 30 minutes to 1 hour before or after taking other medicines.

### **Children**

The use in children under 12 years of age has not been established due to lack of adequate data.

### **Other medicines and Buttercup Bronchostop Day & Night oral solution**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The lime flower active ingredient can cause drowsiness. Therefore, this medicine may increase the drowsiness caused by other medicines such as antihistamines (drugs that block the action of histamine and are used to treat allergic reactions and colds), antidepressants (drugs that are used in the treatment of depression) or other sedatives (drugs to calm or reduce anxiety).

Theoretically, the substances present in all three active ingredients may delay the absorption of other medicines taken at the same time.

### **Buttercup Bronchostop Day & Night oral solution with food, drink and alcohol**

Due to the way in which this medicine works (partly physical and local), avoid drinking for 30 minutes to 1 hour after administration.

The effects of this traditional herbal medicine may be increased by alcohol. Use of alcohol should therefore be avoided with this product.

### **Pregnancy and breast-feeding**

The safety of taking this medicine during pregnancy and breast-feeding is not known. Therefore, it is not recommended to take this medicine if you are pregnant or 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.

### **Driving and using machines**

This traditional herbal medicine may cause drowsiness. If affected, do not drive or operate machinery.

### **Buttercup Bronchostop Day & Night oral solution contains xylitol**

This medicine contains 11.04 g xylitol (calorific value is 2.4 kcal/g xylitol, corresponding to 26.5 kcal) in the maximum daily dose (60 ml). It may therefore have a laxative effect.

**Buttercup Bronchostop Day & Night oral solution contains methyl parahydroxybenzoate and propyl parahydroxybenzoate**

This medicine contains methyl parahydroxybenzoate and propyl parahydroxybenzoate. These preservatives may cause hypersensitivity (allergic) reactions, possibly delayed.

**Buttercup Bronchostop Day & Night oral solution contains propylene-glycol**

This medicine contains 13.6 mg of propylene-glycol in each 15 ml.

**Buttercup Bronchostop Day & Night oral solution contains benzyl-alcohol**

This medicine contains 0.0018 mg benzyl alcohol in each 15 ml dose. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl-alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

**3. How to take Buttercup Bronchostop Day & Night oral solution**

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.

For oral use (undiluted).

Due to the way in which this medicine works (partly physical and local), avoid drinking for 30 minutes to 1 hour after administration.

**The recommended dose is:**

Adults and adolescents aged 12 years and above:

Using the measuring cup provided, 15 ml of oral solution should be taken as required up to four times daily (the maximum recommended dose is 60 ml in 24 hours). The last dose should be taken directly before bedtime.

Children under 12 years:

The use in children under 12 years of age is not recommended.

For oral short-term use only.

**DO NOT EXCEED THE STATED DOSE.**

If the symptoms worsen, persist or do not improve after 7 days, a doctor should be consulted.

**If you take more Buttercup Bronchostop Day & Night oral solution than you should**

No cases of overdose have been reported. However, known effects may occur more intensely if you have taken considerable overdose of this medicine. In this case, speak to your doctor or pharmacist immediately and take this leaflet and bottle with you.

**If you forget to take Buttercup Bronchostop Day & Night oral solution**

Do not take a double dose to make up for a forgotten dose. Take the next recommended dose as required.

**If you stop taking Buttercup Bronchostop Day & Night oral solution**

No special precautions needed.

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

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

None known. If adverse reactions occur, a doctor or pharmacist 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

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

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

#### **5. How to store Buttercup Bronchostop Day & Night oral solution**

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

Do not store above 25 °C. After opening, use within 4 weeks.

Keep the container tightly closed after use.

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

Do not throw away any medicines via wastewater or household waste. Ask your qualified healthcare professional 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 Buttercup Bronchostop Day & Night oral solution contains**

- The active substances are:

Each 15 ml (= 16.3 g) of oral solution contains:

- 187.5 mg of extract (as dry extract) from *Althaea officinalis* L., radix (Marshmallow root) (7-9:1). Extraction solvent: water
- 136.4 mg of extract (as dry extract) from *Tilia cordata* Miller, *Tilia platyphyllos* Scop., *Tilia x europaea* L. or their mixtures, flos (Lime flower) (3-8:1). Extraction solvent: water
- 150.0 mg of extract (as dry extract) from *Plantago lanceolata* L., folium (Ribwort plantain leaf) (4-6:1). Extraction solvent: water

- The other ingredients are:

- Xylitol (E967)
- Maltodextrin
- Glycerol
- Xanthan gum
- Citric acid monohydrate
- Strawberry flavour (containing propylene-glycol (E1520) and benzyl-alcohol),
- Methyl-parahydroxybenzoate (E218)
- Silica colloidal anhydrous
- Propyl-parahydroxybenzoate (E216)
- Purified water

### **What Buttercup Bronchostop Day & Night oral solution looks like and contents of the pack**

Buttercup Bronchostop Day & Night oral solution is a brown, opaque oral solution contained in a brown glass bottle with a nozzle and plastic screw cap packed in a carton box. It is provided with a plastic cup with a scale from 2.5 ml to 20 ml for measuring the recommended dose.

Buttercup Bronchostop Day & Night oral solution is available in 120 ml, 200 ml and 240 ml pack sizes. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

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