

PACKAGE LEAFLET: INFORMATION FOR THE USER

Buttercup Bronchostop Cough Syrup

Thyme herb dry extract, Marshmallow root liquid extract

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

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or qualified Healthcare Professional 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 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® Cough Syrup is and what it is used for
2. What you need to know before you take Buttercup Bronchostop® Cough Syrup
3. How to take Buttercup Bronchostop® Cough Syrup
4. Possible side effects
5. How to store Buttercup Bronchostop® Cough Syrup
6. Contents of the pack and other information

1. WHAT BUTTERCUP BRONCHOSTOP® COUGH SYRUP IS AND WHAT IT IS USED FOR

Buttercup Bronchostop® Cough Syrup is a traditional herbal medicinal product used for the relief of coughs, such as chesty, dry, tickly, irritating coughs and catarrh exclusively based on long standing use.

Buttercup Bronchostop® Cough Syrup is for use in adults and adolescents over 12 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 BUTTERCUP BRONCHOSTOP® COUGH SYRUP

Do not take Buttercup Bronchostop® Cough Syrup

- If you are allergic to Marshmallow root, Thyme or other members of the Lamiaceae family (e.g. Basil, Rosemary, Sage), or to any of the other ingredients of this medicine (listed in section 6).
- If you are pregnant or breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking Buttercup Bronchostop® Cough Syrup

- If you are short of breath, have a high temperature (fever), or your phlegm is yellow-green or brown in colour (purulent sputum).
- If you have asthma or are prone to develop allergic reactions, as Buttercup Bronchostop® Cough Syrup may make asthma symptoms worse. There is a possible risk that this medicine may trigger allergic reactions, in very rare cases anaphylaxis including anaphylactic shock, in patients who have a tendency to develop allergic reactions.

Children

The use in children under 12 years of age is not recommended due to lack of sufficient data and because medical advice should be sought.

Other medicines and Buttercup Bronchostop® Cough Syrup

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including herbal medicines or medicines obtained without a prescription.

Absorption of concomitantly administered medicines may be delayed. As a precautionary measure, the product should not be taken ½ to 1 hour before or after intake of other medicinal products.

Pregnancy and breast-feeding

There are no data on the effects of this medicine on fertility, during pregnancy and lactation. In the absence of adequate data, use of this medicine during pregnancy and breast-feeding is not recommended.

If you are pregnant or breastfeeding, 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

No studies on the effects on the ability to drive and to use machines have been performed. Buttercup Bronchostop® Cough Syrup contains no ingredients that are known to cause drowsiness.

Buttercup Bronchostop® Cough Syrup contains the preservatives Methyl parahydroxybenzoate and Propyl parahydroxybenzoate.

These may cause acute hypersensitivity (allergic) reactions, including mouth/ facial swelling, breathing difficulty, rash, anaphylactic shock and delayed reactions (see “Do not take Buttercup Bronchostop® Cough Syrup”).

Buttercup Bronchostop® Cough Syrup contains raspberry juice concentrate which contains sucrose, glucose and fructose

This medicine contains 66 mg fructose in each 15 ml dose.

If you have been told by your doctor that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, contact your doctor before you (or your child) take this medicinal product.

Buttercup Bronchostop® Cough Syrup contains Propylene glycol (E1520).

This medicine contains 38.9 mg of propylene glycol (E1520), from raspberry aroma flavour, in each 15 ml dose.

Buttercup Bronchostop® Cough Syrup contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per 15 ml dose that is to say essentially 'sodium-free'.

3. HOW TO TAKE BUTTERCUP BRONCHOSTOP® COUGH SYRUP

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

If you are short of breath, have a high temperature (fever), your phlegm is yellow-green or brown in colour (purulent sputum), you must consult your doctor or qualified Healthcare Professional.

Always use the enclosed measuring cup.

Buttercup Bronchostop Cough Syrup® can be taken undiluted or can be diluted in water or warm tea.

Dosage

For oral short-term use only.

Adults, the elderly and children over 12 years:

Using the measuring cup provided, 15 ml of syrup to be taken every 4 hours, 4 times per day. If required, up to a maximum of 6 doses (90 ml) can be taken per day.

Do not give to children under 12 years.

DO NOT EXCEED THE STATED DOSE.

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

If you take more Buttercup Bronchostop® Cough Syrup than you should

Talk to a doctor straight away, or contact your nearest hospital casualty department. Take the carton and this leaflet with you.

If you forget to take Buttercup Bronchostop® Cough Syrup

Take the next dose when it is due. Do not take a double dose to make up for a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Buttercup BRONCHOSTOP® Cough Syrup can cause side effects, although not everybody gets them.

The frequency of the following side effects occurring is not known.

This medicine may cause the following serious allergic reactions. If you experience any of the following effects, stop taking the medicine and seek urgent medical advice:

- symptoms that may include feeling lightheaded or faint, breathing difficulties or wheezing, a fast heartbeat, skin rash, confusion and anxiety, or loss of consciousness (anaphylactic reaction)
- swelling of the face, lips, tongue, mouth or throat (angioedema),
- blistering of the mouth and throat
- difficulty breathing (including shortness of breath)

Other possible side effects

If any of the following side effects get serious or concern you, or you notice any other side effect, stop taking the medicine and seek medical advice as soon as possible:

Allergic skin reactions including urticaria (red bumps on the skin), and itching.

Gastrointestinal disorders such as pain or discomfort in the abdomen, diarrhoea, vomiting, and nausea.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Website: www.hpra.ie

5. HOW TO STORE BUTTERCUP BRONCHOSTOP® COUGH SYRUP

Do not store above 25°C.

Store in the original package in order to protect the contents from light.

Keep out of the sight and reach of children.

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

Close tightly after use. After opening, use within 4 weeks.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Buttercup Bronchostop® Cough Syrup contains

15 ml of the syrup (15.45 g) contains the active ingredients:

0.12 g of dry extract from *Thymus vulgaris* L. and *Thymus zygis* L. herba (thyme herb) (7-13:1).
Extraction solvent: water.

0.83 g liquid extract from *Althaea officinalis* L. (marshmallow root) (DER 1:12-14). Extraction solvent: water.

The other ingredients are:

Maltodextrin, Acacia (E414), Xylitol (E967), Methyl parahydroxybenzoate (E218), Raspberry juice concentrate (containing sucrose, glucose and fructose), Xanthan gum, Citric acid monohydrate, Propyl parahydroxybenzoate (E216), Raspberry aroma flavour (containing synthetic and natural flavourings and propylene glycol (E1520)), Glycerol (E422), Saccharin-sodium (E954), Neohesperidin-dihydrochalcone, Purified water.

What Buttercup Bronchostop® Cough Syrup looks like and contents of the package

Buttercup Bronchostop® Cough Syrup is a brown-red, viscous liquid. The syrup is contained in brown glass bottles with a sealed screw cap in 120 ml, 200 ml, 240 ml and 290 ml sizes. Not all pack sizes may be marketed.

The package includes a measuring cup with a scale from 2.5 ml to 20 ml which allows precise measuring of the recommended dose.

TR Holder and manufacturer

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