

FRONT

PACKAGE LEAFLET: INFORMATION FOR THE USER

Buttercup Bronchostop® Berry Flavour Cough Pastilles



Thyme herb dry 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 practitioner has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist or qualified Healthcare Professional 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 or qualified Healthcare Professional if you do not feel better or if you feel worse after 7 days.

What is in this leaflet:

- 1. What Buttercup Bronchostop® Berry Flavour Cough Pastilles are and what they are used for**
- 2. What you need to know before you take Buttercup Bronchostop® Berry Flavour Cough Pastilles**
- 3. How to take Buttercup Bronchostop® Berry Flavour Cough Pastilles**
- 4. Possible side effects**
- 5. How to store Buttercup Bronchostop® Berry Flavour Cough Pastilles**
- 6. Contents of the pack and other information**

1. WHAT BUTTERCUP BRONCHOSTOP® BERRY FLAVOUR COUGH PASTILLES ARE AND WHAT THEY ARE USED FOR

Buttercup Bronchostop® Berry Flavour Cough Pastilles are 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BUTTERCUP BRONCHOSTOP® BERRY FLAVOUR COUGH PASTILLES

Do not take Buttercup Bronchostop® Berry Flavour Cough Pastilles

- If you are allergic to 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

Children

Do not give this medicine to children under 12 years.

Other medicines and Buttercup Bronchostop® Berry Flavour Cough Pastilles

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.

Pregnancy and breast-feeding

Do not take this medicine if you are pregnant or breast-feeding.

Driving and using machines

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

Buttercup Bronchostop® Berry Flavour Cough Pastilles contain fructose and sorbitol.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. Contains 0.6 g of fructose per maximum single dose (2 pastilles). This should be taken into account in patients with diabetes mellitus.

3. HOW TO TAKE BUTTERCUP BRONCHOSTOP® BERRY FLAVOUR COUGH PASTILLES

Always take Buttercup Bronchostop® Berry Flavour Cough Pastilles 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.

For oral short-term use only.

Dosage

Adults, the elderly and children over 12 years:

1 – 2 pastilles to be taken every 4 hours, 4 times a day. If required, up to a maximum of 12 pastilles can be taken per day.

REVERSE

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 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.

If you take more Buttercup Bronchostop® Berry Flavour Cough Pastilles 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® Berry Flavour Cough Pastilles

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® Berry Flavour Cough Pastilles can cause side effects, although not everybody gets them. Allergic reactions including Quincke's oedema and anaphylactic shock have been reported.

Stop taking the pastilles and tell your doctor immediately if:

- you get any swelling of the face, lips, tongue or throat
- you have any difficulty in swallowing or breathing (including shortness of breath)
- you get a skin rash after taking the pastilles

The above symptoms may mean you are having a very rare, serious allergic reaction to this medicine.

Other possible side effects:

If any of the following side effects get serious or concerns you, or you notice any other side effect, stop taking the pastilles.

- Stomach disorders (frequency unknown)

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: <http://www.hpra.ie>; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE BUTTERCUP BRONCHOSTOP® BERRY FLAVOUR COUGH PASTILLES

Do not store above 30°C. Store the blister in the original package in order to protect 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 blister and carton. The expiry date refers to the last day of that month. 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® Berry Flavour Cough Pastilles contain

Each pastille contains the active ingredient 59.5 mg of dry extract from Thymus vulgaris (L.) and Thymus zygis (L.) herba (thyme herb) (7-13:1). Extraction solvent: water.

Each pastille also contains 300 mg of fructose and 523 mg of sorbitol.

The other ingredients are:

Maltodextrin, Acacia (E414), Fructose, Sorbitol (E420), Anhydrous citric acid (E330), Saccharin sodium (E954), Aronia (chokeberry) aroma flavour, Fruit of the forest (berry) aroma flavour, Light liquid paraffin, White beeswax, Purified water.

What Buttercup Bronchostop® Berry Flavour Cough Pastilles look like and contents of the package

Buttercup Bronchostop® Berry Flavour Cough Pastilles are hexagonal, brown pastilles. Buttercup Bronchostop® Berry Flavour Cough Pastilles are available in blister packs containing 10, 20 or 40 pastilles. Not all pack sizes may be marketed.

TR Holder and Manufacturer:

Kwizda Pharma GmbH, Effingergasse 21, A-1160 Vienna, Austria.

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TR 2006/1/2

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Process Black Cutter

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Marketing Approval:

Sign:..... Date:.....

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Regulatory Approval:

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