Package leaflet: Information for the patient

Butamirate 7.5mg/5ml Syrup

butamirate citrate

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 4 to 5 days.
- The full name of this medicine is Butamirate 7.5mg/5ml Syrup but within the leaflet it will be referred to as Butamirate Syrup.

What is in this leaflet

- 1. What Butamirate Syrup is and what it is used for
- 2. What you need to know before you take Butamirate Syrup
- 3. How to take Butamirate Syrup
- 4. Possible side effects
- 5. How to store Butamirate Syrup
- 6. Contents of the pack and other information

1. What Butamirate Syrup is and what it is used for

Butamirate Syrup contains the active ingredient butamirate citrate, which belongs to a group of medicines called antitussives.

Butamirate Syrup is used for the symptomatic treatment of non-productive (dry) cough.

2. What you need to know before you take Butamirate Syrup

Do not take Butamirate Syrup if you are allergic to butamirate citrate or any of the other ingredients of this medicine (listed in section 6).

Butamirate Syrup must not be used in children or adolescents under 18 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Butamirate Syrup.

Before you begin using this cough medicine, consult your doctor or pharmacist so that they can decide whether this medicine is suitable for you.

If your cough persists after taking this medicine at the recommended dose, consult your doctor or pharmacist.

This cough medicine should not be used for prolonged periods of time.

Do not use this cough medicine for longer than your doctor or pharmacist has told you to.

This medicinal product suppresses the coughing reflex. You should avoid taking it at the same time as some other cough medicines called 'expectorants' since this could lead to the build-up of mucus in your lungs, possibly causing breathing difficulty and/or lung infection.

Other medicines and Butamirate Syrup

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

It is not known whether Butamirate Syrup affects the way other medicines work, or whether Butamirate Syrup is affected by other medicines.

You should not take Butexio if you are taking medicines known as 'strong enzyme inhibitors' or medicines known to have 'a narrow therapeutic index'. Your doctor or pharmacist will be able to confirm whether this applies to you.

Pregnancy and lactation

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.

You should not take Butamirate Syrup during the first trimester of pregnancy.

You shoul only take Butamirate Syrup during the second or third trimester of pregnancy if your doctor has advised you to do so.

You should not take Butamirate Syrup if you are breastfeeding.

Driving and using machines

Butamirate Syrup may cause drowsiness and dizziness. Butamirate Syrup should be used with caution if you drive or use machines.

Butamirate Syrup contains sorbitol

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

May have a mild laxative effect.

3. How to take Butamirate 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:

Adults: 15 ml up to 4 times daily

Use the enclosed measuring cup for proper dosing. Clean and dry the measuring cup after use.

You should stop taking this medicine when symptoms disappear.

Talk to a doctor if your cough lasts longer than 4 to 5 days or if you develop a fever, shortness of breath or chest pain.

If you have kidney or liver problems, talk to your doctor or pharmacist before taking this medicine because you may be more likely to get side effects.

If you take more Butamirate Syrup than you should

If you have taken more Butamirate Syrup than you should, talk to your doctor immediately.

If you forget to take Butamirate 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

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

The following side effects may occur in rare cases (they may affect 1 to 10 patients in 10,000):

- drowsiness
- dizziness
- nausea
- diarrhoea
- itchy skin rash

Allergic reactions have also been reported (frequency not known).

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard

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

5. How to store Butamirate Syrup

Do not store above 25°C.

Shelf life after first opening the bottle: 6 months.

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 label and carton. The expiry date refers to the last day of that month.

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 Butamirate Syrup contains

- The active substance is butamirate citrate. 1ml of syrup contains 1.5mg butamirate citrate. 5ml of syrup contains 7.5mg butamirate citrate.
- The other ingredients are: sorbitol (E420), glycerol, sucralose (E955), sodium benzoate (E211), citric acid monohydrate, caramel flavour 12788 (containing: flavouring substances, flavouring preparations, natural flavouring substances, propylene glycol (E1520)), bitter chocolate flavour F2428 (containing: flavouring substances, flavouring preparation, quinine hydrochloride, natural flavouring substances, propylene glycol (E1520), water, quassin), purified water.

What Butamirate Syrup looks like and contents of the pack

Butamirate Syrup is a colourless or pale yellow liquid.

Butamirate Syrup is supplied in a 100ml or 200ml glass or plastic bottle with a child-resistant plastic screw cap. Each pack contains a plastic measuring cup with graduations for dosing.

Marketing Authorisation Holder and

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Manufacturer

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If you would like a leaflet with larger text, please contact 01271 385257.