

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### SINECOD

7.5mg/5ml Syrup

BUTAMIRATE CITRATE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What SINECOD is and what it is used for
2. Before you take SINECOD
3. How to take SINECOD
4. Possible side effects
5. How to store SINECOD

#### 1. WHAT SINECOD IS AND WHAT IS IT USED FOR

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

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

#### 2. BEFORE YOU TAKE SINECOD

##### **Do not take SINECOD Syrup**

- if you are allergic to butamirate citrate or any of the other ingredients of this medicine.

SINECOD 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 SINECOD 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 SINECOD Syrup***

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

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

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

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

You should not take SINECOD Syrup if you are breastfeeding.

### ***Driving and using machines***

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

### ***SINECOD 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 SINECOD***

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 SINECOD Syrup than you should***

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

### ***If you forget to take SINECOD 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.

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

#### *5. HOW TO STORE SINECOD*

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.