

PACKAGE LEAFLET: INFORMATION FOR THE USER

SINECOD 7.5 mg/5 ml syrup

Butamirate citrate

Read all of this leaflet carefully because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must talk to a doctor if your signs of illness worsen or do not improve.
- If of the side effects gets serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

What is in this leaflet

1. What Sinecod is and what it is used for
2. What you need to know before you use Sinecod
3. How to use Sinecod
4. Possible side effects
5. How to store Sinecod
6. Other information

1. WHAT SINECOD IS AND WHAT IT IS USED FOR

Sinecod is an antitussive administered for the treatment of dry non-productive cough. Unlike other antitussives, it suppresses the cough without causing an addiction. Unlike narcotic antitussives, Sinecod lacks the risk of their side effects without lacking the antitussive action.

2. BEFORE YOU TAKE SINECOD

Do not take Sinecod

- If you are allergic to butamirate citrate or any of the other ingredients of Sinecod

Using - Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including those obtained without a prescription. Simultaneous use of other cough medicines should be avoided, because may lead to retention of mucus in the respiratory system, which can increase the risk of bronchospasm and airway infection.

Taking Sinecod with food and drinks

No interaction studies have been performed. If possible, Sinecod must be taken before meals.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Use during pregnancy:

As there are no sufficient studies in pregnant women, the use of Sinecod should be avoided during the first trimester of pregnancy. For the following month of pregnancy Sinecod may be used according to the doctor's judgement and instructions.

Use during breast-feeding:

Because there is insufficient information on the excretion of butamirate in human milk, for safety reasons Sinecod should be used during breast-feeding only after a careful evaluation of benefits compared with the potential risk.

Driving and using machines

Sinecod may cause drowsiness. Therefore it must be taken into account when driving or performing other activities requiring alertness (e.g. using machines).

Important information about some of the excipients of Sinecod

(E 420) 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.

Ethanol: This medicinal product contains small amounts of ethanol (alcohol), corresponding to less than 100 mg per dose.

3. HOW TO TAKE Sinecod

Always take **Sinecod** exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Package includes a measuring cup.

The usual dose is

Adults:

Adolescents over 12 years of age: 15 ml three times daily.

Adults: 15 ml four times daily

Children aged 4- 6 years: 5 ml three times daily

Children aged 6-12 years:: 10 ml three times daily

If you forget to take Sinecod

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.

4. POSSIBLE SIDE EFFECTS

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Generally, the following have been reported:

Nervous system disorders

Rare (>1/10,000, <1/1000): drowsiness

Gastrointestinal disorders

Rare (>1/10,000. <1/1000): nausea. Diarrhoea

Skin and subcutaneous tissue disorders

Rare (>1/10,000, <1/1000): hives

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effect n not listed in this leaflet. You can report any side effects directly via www.medicinesauthority.gov.mt/adrportal - Malta.

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

5. HOW TO STORE Sinecod

Do not use Sinecod after the expiry date which is stated on the label and the box after the Exp. Date. The expiry date refers to the last day of that month.

Store at 25°C or below.

Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer require. These measures will help to protect the environment.

6. OTHER INFORMATION

What Sinecod® contains

The active substance(s) is butamirate citrate 7.5 mg/5 ml.

The other ingredients are: sorbitol sol., glycerol, saccharin, sodium benzoic acidl, vanillin, ethanol sol., sodium hydroxide sol., water purified.

The syrup contains saccharin and sorbitol sweeteners; therefore, it may be used by diabetics.

What Sinecod looks like and contents of the pack

Glass bottle containing 200 ml or 250 ml of syrup

Package includes a measuring cup.

Marketing Authorisation Holder - Malta

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