

Sinecod



Syrup

0.15 % w/v Syrup

For Oral Administration Only

Composition:

Each 5 ml of Sinecod Syrup contains:

Active ingredient: 7.5 mg butamirate citrate

Excipients with known effect: Sorbitol solution(E-420) 70%, Ethanol 96%

Other excipients: Glycerol, Sodium saccharin, Benzoic acid (E210), Vanillin aroma, Sodium hydroxide (for pH adjustment), Purified water

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

Always use 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.

In this leaflet

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1. What is Sinecod syrup and what is it used for?

* It is used for Symptomatic treatment of cough of various origins

Sinecod Syrup relieves coughs, including non-productive cough, caused by common cold. On medical prescription Sinecod Syrup can also be used to treat acute coughing fits of various causes.

- The syrup can be used in children aged 3 years and older.

* Points to bear in mind:

- Smoking will make you cough, you can support the effect of Sinecod Syrup by not smoking.
- As the syrup is sweetened by saccharine and sorbitol, it can also be taken by diabetics.

2. What you need to know before you use Sinecod Syrup?

a. Do Not Use Sinecod Syrup in case:

- You are allergic to Butamirate citrate or to any of the excipients given according to the composition.
- You or your child suffer from a (rare) hereditary disease known as Fructose intolerance, which affects sugar metabolism. As a sweetener, the syrup contains Sorbitol, sugar which produces fructose when digested.

b. Warnings and precautions

- If your Cough or your child's cough is productive, i.e. produces a lot of mucus, you should consult your doctor before taking Sinecod Syrup. Sinecod Syrup inhibits the cough reflex, which promotes the build-up of mucus within the bronchial tubes. This increases the risk of airway infection (e.g. pneumonia) and can also lead to dangerous contraction of the bronchial tubes (bronchospasm). You should therefore not take any cough medicines that break up mucus in the bronchial tubes (expectorants and mucolytic agents) at the same time you are using Sinecod Syrup.
- A doctor or pharmacist must be consulted if the cough persists for more than 7 days or if the symptoms worsen and/or are accompanied by fever, rash or persistent headache, so that the underlying cause can be determined if necessary.
- Sinecod Syrup contains 284mg of sorbitol in each mL Sorbitol is a source of fructose. Patients suffering from rare hereditary fructose intolerance should not take this medicine. Sorbitol can cause gastrointestinal discomfort and have a mild laxative effect.
- Sinecod syrup contains ethanol (11.73 mg/5 ml).
- Sinecod Syrup contains less than 1 mmol sodium (23 mg) per dose, meaning that they are almost Sodium-free
- Tell your doctor or pharmacist if you or your child have any other diseases, or allergies or other medicines are being taken or externally applied (including those obtained without prescription)
- Your child should avoid riding a bike on the road

c. Taking other Medicines:

The concomitant administration of an expectorant or mucolytic agent should be avoided (see «Special warnings and precautions for use»).

There are no specific studies on interactions available. Based on fundamental considerations, it cannot be excluded that the effect of co-administered centrally depressing substances, including alcohol, may be increased, as the mechanism of action for cough suppression is thought to be central.

d. Pregnancy and breast-feeding

If you are pregnant or breast feeding, you should Not Take Sinecod Syrup without talking to your doctor first. Safety for use during pregnancy and lactation has not been evaluated in specific studies.

Pregnancy

The use of Sinecod Syrup should be avoided during the first three months of pregnancy.

Reproductive studies in animals have shown no foetal risk.

However, no controlled studies have been performed in pregnant women. Sinecod Syrup is therefore not

recommended for use during pregnancy unless it is clearly

necessary and on the advice of a medical practitioner.

Lactation

The passage of Sinecod into breast milk has not been studied and the product should not be used during

breast-feeding.

e. Driving and using machines

Sinecod can cause tiredness and can affect the ability to drive and operate machines. Your child should avoid

riding a bike on the road.

3. How to use Sinecod Syrup?

Unless otherwise prescribed by the doctor:

Sinecod Syrup is to be used from the age of 3 years and older

Age Group	Recommended Dose
Children 3 to 6 years of age	5 ml 3 times daily
Children 6 to 12 years of age	10 ml 3 times daily
Adolescents aged 12 to 18 years	15 ml 3 times daily
Adults	15 ml 4 times daily

- Measure the syrup using the graduated cup supplied.
- Rinse and dry the graduated cup after each use and before use by a different person.
- For Oral Administration ONLY
- Do not exceed the recommended Dose
- Maximum duration of treatment without doctor's prescription is 7 days
- Should preferably be taken before meals.
- If your child has taken too much Sinecod Syrup, tell your doctor immediately
- The lowest effective dose should always be used for the shortest possible time.
- Always keep to the dosage given to this leaflet or as prescribed by your doctor. If you think that the effect of this medicine is too weak or too strong. Talk to your doctor or pharmacist.

Overdose

An accidental overdosage with Sinecod Syrup may cause the following symptoms: somnolence, nausea, vomiting, diarrhea, loss of balance and hypotension.

The usual emergency assistance must be undertaken:

gastric lavage, activated charcoal, monitoring and treatment of the vital functions required. There is no

known specific antidote. Overdose is treated according

to the clinical situation, if necessary after consultation with national poison centre, where available.

4. Possible side effects:

The use of Sinecod Syrup can cause the following

undesirable side effects: Nervous system disorders:

Uncommon (0.1 to 1.0%): vertigo, somnolence and

light-headedness.

Gastrointestinal disorders: Uncommon (0.1 to 1.0%):

nausea, diarrhoea.

Skin: Rare (0.01 to 0.1%): exanthema, urticaria.

If you notice side effects not described here, you should

inform your doctor or pharmacist.

5. How to store Sinecod Syrup?

- Keep out of reach and sight of children.
- Do not store above 30° C. Protect from heat.
- Do not use this medicine after the expiry date, which is stated on the carton, inner label. The expiry date refers to the last day of that month.

6. Pack and other Information:

Sinecod Syrup is a clear, colourless sweet syrup with vanilla aroma

Pack 200 ml

Please consult your doctor or pharmacist for further information

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THIS IS A MEDICAMENT

- a. Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- b. Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament.
- c. The doctor and the pharmacist are experts in medicine, its benefits and risks.
- d. Do not by yourself interrupt the period of treatment prescribed.
- e. Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach and sight of children

Council of Arab Health Ministers
Union of Arab Pharmacists