

Sinecod

Drops

0.5% w/v Oral drops Solution (For Children)

For Oral Administration Only

Composition:

Each 1ml (=22drops) of Sinecod Drops contain:

Active Ingredient: 5mg butamirate citrate

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

Other excipients: Glycerol, Sodium saccharin, E210 (benzoic acid), 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.

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

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

Sinecod Drops relieves coughs, including non-productive cough, caused by common cold. On a medical prescription only, Sinecod Drops can also be used to treat acute coughing fits of various causes. Sinecod Drops can be used on medical prescription in children aged 2 months and older. Due to their low active substance content, they are not suitable for adolescents over 12 years of age.

* Points to bear in mind:

The oral drops are sweetened with saccharine and sorbitol and can also be given to children with diabetes

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

a. Do Not Use Sinecod Drops in case:

- Your child is allergic to Butamirate citrate or to any of the excipients given according to the composition
- Your child suffer from Fructose intolerance (due to the Sorbitol content, a sugar that produces fructose during its metabolic conversion)

b. Warnings and precautions

- If your child's cough is productive, i.e. produces a lot of mucus, you should consult your doctor before giving Sinecod Drops to your child. Sinecod Drops 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 give your child any cough medicines that break up mucus in the bronchial tubes (expectorants and mucolytic agents) at the same time you are using Sinecod Drops
- For Children under 2 years of age, use only with a Doctor's prescription
- 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.
- 5 drops of this medicine contain 71mg of sorbitol. 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 Drops contains Ethanol (2.81 mg/ml).
- Sinecod Drops contains less than 1 mmol sodium (23 mg) per dose, meaning that they are almost Sodium-free
- Tell your doctor or pharmacist if your child has 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, breast-feeding, and Fertility

Sinecod Drops is not suitable for the treatment of cough in adults. If you are pregnant or breast feeding and you have taken this medicine by mistake, you should inform your doctor as a precaution

e. Driving and using machines

Sinecod Drops 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 Drops?

Unless otherwise prescribed by the doctor:

Sinecod Drops should be administered to children below 2 years of age on medical prescription only.

Age Group	Recommended Dose
Babies from 2 months to 1 year old	10 drops 4 times daily
Toddlers from 1 to 3 years	15 drops 4 times daily
Above 3 years	25 drops 4 times daily

– 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 Drops, 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 Drops may cause the following symptoms: somnolence, nausea, vomiting, diarrhoea, 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 Drops 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 Drops?

- Keep out of reach and sight of children.
- Do not store above 30 °C. Protect from heat
- The medication must not be used after the date printed on the packaging after the term "EXP"

6. Pack and other Information:

Sinecod Drops is a clear, colourless sweet solution with vanilla aroma

Pack of 20ml

Please consult your doctor or pharmacist for further information

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MAH: GSK Consumer Healthcare Schweiz AG, Switzerland.

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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