

Patient information

Read carefully the package leaflet. You will find all the important information concerning the medicine.

This medicine was prescribed for you by your doctor or was delivered without prescription by the pharmacist or dispensing chemist.

To get the best benefit from it, please use the medicine exactly as it is described in the package leaflet, or when applicable, as it is indicated by your doctor, pharmacist or dispensing chemist.

Keep this leaflet to read it again later if necessary.

Sinecod®

Syrup

Depot tablets 50 mg

What is Sinecod and what is it used for?

Sinecod calms coughing and irritant coughs during colds. On medical prescription, Sinecod can also be used to treat acute coughs of other origins. The syrup can be used in children from the age of 3 years, and the 50 mg depot tablets from the age of 12 years.

What should be taken into account apart from the treatment?

Smoking reinforces coughing. You should support the action of Sinecod by refraining from smoking. The syrup is sweetened with saccharine and sorbitol and thus can be used by diabetics. The 50 mg depot tablet contains 93 mg of lactose and their use by diabetics can be considered to be without danger.

When should Sinecod not be used?

You should not use Sinecod if you are allergic to its active principle or to one of the excipients. Furthermore, you should not take the syrup or give it to your child if you or your child suffer from a (rare) hereditary disease of sugar metabolism called fructose intolerance. The syrup contains sorbitol as a sweetener. During digestion, this sugar gives rise to the formation of fructose.

The 50 mg depot tablets are not suitable for children of less than 12 years due to their increased content of the active principle.

Your doctor or pharmacist knows what should be done in these situations.

What precautions should be taken during the use of Sinecod?

If the cough lasts for more than 7 days, medical advice is necessary. If your cough or your child's cough is productive, namely it is accompanied by abundant expectoration, you should consult your doctor before starting to use Sinecod. Suppression of the cough reflex by Sinecod favours the accumulation of secretions in the bronchi, which increases the risk of respiratory tract infection (e.g. pneumonia) and can also induce a dangerous cramping of the bronchi called bronchospasm. Thus you should refrain from using medication which loosens bronchial secretions (expectorants, mucolytics) at the same time as using Sinecod. This medication can affect reactions, the ability to drive and the ability to use tools or machinery.

Please inform your doctor, pharmacist or dispensing chemist if you or your child suffer from another disease, are allergic, or are already taking other medicine whether internally or externally (even self-medication!).

Can Sinecod be used during pregnancy or breast-feeding?

You should only use Sinecod during pregnancy or breast-feeding if advised to do so by the doctor.

How should Sinecod be used?

Unless otherwise advised by the doctor:

Syrup (from the age of 3 years)

Children from 3 to 6 years: 5 ml 3 times per day; *from 6 to 12 years:* 10 ml 3 times per day.

Adolescents from 12 years: 15 ml 3 times per day.

Adults: 15 ml 4 times per day.

Use the graduated measuring cup that comes with the pack. Wash and dry the measuring cup after use and after each user.

Depot tablets 50 mg

Adolescents from 12 years: 1 or 2 tablets per day.

Adults: 2 or 3 tablets per day, at intervals of 8 to 12 hours.

Swallow without chewing.

The syrup and 50 mg depot tablets should, if possible, be taken before meals.

If the cough lasts more than 7 days, medical advice is necessary.

Please observe the dosage shown on the package leaflet or prescribed by your doctor.

If you think that the efficacy of the medicine is too weak, or too strong, please consult your doctor, pharmacist or dispensing chemist.

What side effects can Sinecod cause?

The use of Sinecod can cause the following side effects: skin rashes in rare cases, occasionally nausea, diarrhoea, dizziness or drowsiness.

If you notice other side effects, please inform your doctor, pharmacist or dispensing chemist.

What else needs to be known?

Medicines must be kept out of the reach of children.

Syrup: do not store above 30° C.

Depot tablets 50 mg: protect from moisture, do not store above 25° C. The medication must not be used after the date printed on the packaging after the term "EXP".

Please consult your doctor, pharmacist or dispensing chemist for further information, since they have detailed information prepared for professionals.

What does Sinecod contain?

Syrup: 10 ml contains: 15 mg butamirate citrate as the active principle and saccharine, sorbitol, vanillin as excipients; the preservative benzoic acid (E 210) and other excipients.

Depot tablets 50 mg: 1 tablet contains: 50 mg butamirate citrate as the active substance and the colourings erythrosine (E 127) and iron oxide (E 172) as excipients together with other excipients.

Where can Sinecod be obtained?

What packs are available on the market?

In a pharmacy or chemists, without a prescription.

Syrup: pack of 200 ml.

Depot tablets 50 mg: pack of 10 tablets.

Novartis Consumer Health SA, Nyon, Switzerland.

Information updated: October 2006.

(THIS IS A MEDICAMENT)

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

Keep medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists