
Global Labelling & Compliance

Sinecod

Oral drops

Butamirate citrate

Core Summary of Product Characteristics (SmPC)

1 NAME OF THE MEDICINAL PRODUCT

Sinecod

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: Butamirate citrate (INN).

For a full list of excipients, see section 6.

3 PHARMACEUTICAL FORM

Sinecod oral drops: packs of 20 ml

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of dry cough of various origins

4.2 Posology and method of administration

For oral use only.

For children under 2 years of age: only with a doctor's prescription (see 4.4. Special warnings and precautions for use).

Children 2 months to 1 year old: 10 drops 4 times daily

1 to 3 years: 15 drops 4 times daily;

over 3 years: 25 drops 4 times daily.

The maximum duration of treatment without a doctor's prescription is 1 week.

The smallest dose should be used to achieve necessary effect in the shortest period of treatment.

4.3 Contraindications

Known hypersensitivity to any of the ingredients. Do not take Sinecod if you have allergy to butamirate citrate or any other ingredient.

4.4 Special warnings and precautions for use

Due to inhibition of the cough reflex by butamirate, the simultaneous administration of expectorants has to be avoided, because it may lead to the stagnation of mucus in the respiratory tract, which increases the risk of bronchospasm and airways infection.

For patients whose symptoms worsen or do not improve within 7 days and / or develop a fever, rash, or persistent headache, additional investigations of the underlying cause should be done.

The paediatric drops may only be used with a doctor's prescription in children aged less than 2 years.

Keep out of the reach of children.

5 drops of the drug contain 71 mg of sorbitol, which is a source of fructose. **Drops should not be taken to patients with rare hereditary disorders associated with intolerance to fructose.**

This drug contains a small amount of ethanol (alcohol), less than 100 mg per dose.

This drug contains less than 1 mmol sodium (23 mg) per dose, that is, almost "sodium free".

4.5 Interaction with other medicinal products and other forms of interaction

Avoid simultaneous use with expectorants (see information under "Special warnings and precautions for use").

4.6 Pregnancy and lactation

Pregnancy:

There is insufficient data on the use of this product in pregnant women. During pregnancy the drug should be used only with doctor's prescription.

The use of Sinecod should be avoided during the first three months of pregnancy. During the rest of pregnancy, Sinecod should be used only if drug therapy is essential.

Lactation: It is not known whether the active substance and/or its metabolites pass into breast milk. During lactation the drug should be used only with doctor's prescription. For safety reasons, as a general rule, the benefits and risks of taking Sinecod during lactation should be carefully considered.

4.7 Effects on ability to drive and use machines

In rare cases the drug can cause somnolence and affect engaging in activities that require increased concentration of attention and speed of psychomotor reactions.

4.8 Undesirable effects

The adverse reactions are listed below according to system class and frequency. The frequencies are defined as follows:

Very common ($\geq 1/10$), common ($< 1/10$, $\geq 1/100$), uncommon ($< 1/100$, $\geq 1/1,000$), rare ($< 1/1,000$, $\geq 1/10,000$), very rare ($< 1/10,000$), frequency is unknown (based on available data it is impossible to estimate).

Body system	Undesirable effect	Frequency
Nervous system disorders	somnolence	Rare
Gastrointestinal disorders	nausea, diarrhoea	Rare
Skin and subcutaneous disorders	urticaria	Rare

4.9 Overdose

Overdosage with Sinecod[®] may cause the following symptoms: somnolence, nausea, vomiting, diarrhoea, dizziness and hypotension.

Treatment: There is no known specific antidote. In case of overdose the patient must undergo treatment with appropriate supervision. Further guidance should be prescribed on an outpatient basis or as recommended by the national poison control center, if available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group

Other cough suppressants R05D B13

Mechanism of action and pharmacodynamic effects

Butamirate citrate, the sole active ingredient of Sinecod, is a cough suppressant non-narcotic drug.

The substance is thought to have central effect. However the exact mechanism of action is unknown. Butamirate citrate possesses non-specific anticholinergic and bronchospasmolytic effects, which facilitate the respiratory function. Sinecod does not induce habit forming effects or dependence.

Butamirate citrate has a broad therapeutic margin; Sinecod is thus well tolerated in therapeutic doses, and well suited for cough relief in children.

5.2 Pharmacokinetic properties

Based on available data, it can be assumed that butamirate is well and rapidly absorbed and that it is hydrolysed completely into phenyl-2-butyric acid and diethylaminoethoxyethanol. The influence of food ingestion has not been investigated. The effects of 2-phenylbutyric acid and diethylaminoethoxyethanol are fully proportional in the dose range of 22.5 mg - 90 mg. Both metabolites are thought to have antitussive activity. 2-phenylbutyric acid undergoes further metabolism. It is not known whether butamirate citrate passes through the placenta or is secreted into breast milk. All metabolites are excreted mainly through the kidneys. It is not known whether abnormal liver or kidney function affects the pharmacokinetic parameters of butamirate.

5.3 Preclinical safety data

Neither animal trials nor in vitro experiments on the acute and chronic toxicity, reproductive toxicity and mutagenicity of butamirate have provided any evidence of safety risks which would be of relevance to the therapeutic use of the product.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sinecod 0.5% oral drops solution

Sorbitol solution 70 % w/w
Glycerol
Saccharin sodium
Benzoic acid
Vanillin
Sodium hydroxide 30 % w/w
Ethanol 96 % v/v
Purified water

6.2 Shelf life

3 years. Do not use after expiry date.

6.3 Special precautions for storage

Do not store below 30°C , protect from high temperature.
Keep out of the reach of children

6.4 Nature and contents of container

**6.5 20 ml in a vial made of dark glass with a dropper dispenser and a lid equipped with a first opening control system. The bottle, along with instructions for use, is placed in a cardboard box
Special precautions for disposal <and other handling>**

No special requirements.

7 MARKETING AUTHORISATION HOLDER

GSK Consumer Healthcare SARL, Route de l'Etraz, 1260 Nyon, Switzerland.

8 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION