Novartis Consumer Health SA
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Global Regulatory Affairs

Global Labelling & Compliance

Sinecod®

syrup

Butamirate citrate

Core Summary of Product Characteristics (SmPC)

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1 NAME OF THE MEDICINAL PRODUCT

Sinecod

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: Butamirate citrate (INN).

Chemical designation: 2-(2-diethylamino-ethoxy)-ethyl-2-phenylbutyrate citrate.

One Sinecod teaspoonful (5 ml) of syrup contains 7.5 mg of Butamirate citrate

For a full list of excipients, see section 6.

3 PHARMACEUTICAL FORM

Sinecod syrup: packs of 200 ml

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of cough of various origins

4.2 Posology and method of administration

The following dosing directions are based on experience. There are no data from corresponding dose-finding studies.

The maximum duration of treatment without a doctor's prescription is 1 week (see 4.4. Special warnings and precautions for use).

Syrup 0.15% with measuring cup

Children 3 to 6 years of age: 5 ml 3 times daily; 6 to 12 years: 10 ml 3 times daily.

Adolescents: 15 ml 3 times daily. Adults: 15 ml 4 times daily.

Wash and dry the graduated cup after each use and between different users.

4.3 Contraindications

Known hypersensitivity to any of the ingredients, children under the age of 3 years.

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.

Syrup contains saccharin and sorbitol as sweeteners, so it can be prescribed to patients with diabetes mellitus.

Due to the presence of sorbitol, the drug should not be taken to patients with rare hereditary disorders associated with intolerance to fructose.

The maximum duration of treatment should not exceed 7 days. If symptoms persist for more than 7 days, or the condition worsens, you should consult your doctor.

This drug contains a small amount of ethanol (11.73 mg / 5ml).

Special studies have not been conducted among patients with impaired renal and / or liver function.

In patients with impaired renal and / or liver function, there is a greater risk of side effects due to accumulation of butamirate or its metabolites.

4.5 Interaction with other medicinal products and other forms of interaction

Because of the proposed mechanism of action on the central nervous system, it is impossible to exclude the possible increase in the effect of drugs depressing the central nervous system, including ethanol-containing drugs. It is necessary to avoid simultaneous use of other drugs containing ethyl alcohol. Avoid simultaneous use with expectorants (see information under "Special warnings and precautions for use").

4.6 Pregnancy and lactation

The use of the drug during pregnancy and breastfeeding is not recommended.

4.7 Effects on ability to drive and use machines

Sinecod may cause somnolence. Caution should therefore be observed while driving or performing other tasks requiring alertness (e.g. operating machines).

4.8 Undesirable effects

Nervous system disorders:

Uncommon (>1/1,000 to < 1/100): dizziness, somnolence

Gastrointestinal disorders:

Uncommon (>1/1,000, <1/1,000): nausea, diarrhoea

Skin and subcutaneous disorders:

Rare (>1/10,000, <1/1,000): rash, urticaria

4.9 Overdose

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

The usual emergency assistance must be undertaken: activated charcoal, Salt laxatives, monitoring and treatment of the vital functions if required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group

Other cough suppressants R05D B13

Mechanism of action and pharmacodynamic effects

Butamirate citrate, the active ingredient of Sinecod, is a cough suppressant which is neither chemically, nor pharmacologically related to opium alkaloids.

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, even at high doses, and well suited for cough relief in adults and children.

5.2 Pharmacokinetic properties

Butamirate citrate is rapidly absorbed after oral administration, with measurable concentrations in the blood being detected within 5-10 minutes after application of the doses at the level of 22.5 mg-90 mg. The maximum concentration in the plasma is reached within 1 hour. The effect of food on absorption has not been studied.

Butamirate is hydrolyzed to 2-phenylbutyric acid and diethylaminoethoxyethanol. These metabolites of butamirate have antitussive activity.

2-phenylbutyric acid undergoes further metabolism. All metabolites are excreted mainly through the kidneys.

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 0.15% syrup
Sorbitol solution 70 % w/w
Glycerol
Saccharin sodium

Sinecod 0.15% syrup
Benzoic acid
Vanillin
Ethanol 96 % v/v
Sodium hydroxide 30 % w/w
Purified water

6.2 Shelf life

3 years

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

Sinecod® syrup: Amber glass bottle with a child proof cap made with polyethylene and polypropylene, with a polypropylene measuring device.

6.5 Special precautions for disposal <and other handling>

No special requirements.

7 MARKETING AUTHORISATION HOLDER

GSK Consumer Healthcare S.A., Route de l`Etraz, 1260 Nyon, Switzerland.

8 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION