

Kofarest[®] BT SYRUP

1. Generic name : Butamirate citrate

2. Qualitative and Quantitative composition

Each 5ml contains:

- Butamirate citrate - 7.5mg
- In flavoured syrupy base

3. Dosage form and strength

Kofarest BT syrup is available in a bottle of 100ml

Strength – 7.5mg/5ml

4. Clinical particulars

4.1 Therapeutic indication

Symptomatic treatment of dry cough of various origins

4.2 Posology and method of administration

Recommended dose - 15 ml up to 4 times daily

Children 4 -6 years of age - 5ml (7.5mg) 3 times daily

Children 6 -12 years of age - 5ml (7.5mg) 3 times daily

Adolescence 12 years of age - 15 ml (22.5mg) 3 times daily

Adults - 15 ml (22.5mg) 3 times daily

Treatment is limited to the symptomatic period. Medical advice should be sought if the cough lasts longer than 4-5 days or if fever, dyspnoea or chest pain develops.

Patients with renal or hepatic impairment : Data is lacking in patients with impaired renal or hepatic function. Patients with renal and/or liver disease may be at greater risk for adverse effects from butamirate due to drug and metabolite accumulation.

Method of administration

Kofarest-BT syrup should be taken orally.

4.3 Contraindication

Kofarest BT syrup is contraindicated in patients with a history of hypersensitivity to Butamirate citrate or any of the ingredients of the formulation

4.4 Special warnings and precautions for use

Before prescribing an antitussive treatment, the causes of the cough should be investigated to assess the need for aetiological treatment. If the cough persists after taking the antitussive treatment at the usual dose, the dose should not be increased; instead, the clinical situation should be reviewed. Antitussives should not be used for prolonged periods. Due to inhibition of the cough reflex by butamirate, the concomitant administration of expectorants must be avoided because this can lead to the stagnation of mucus in the respiratory tract, increasing the risk of bronchospasm and respiratory tract infections. This medicinal product contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Drug interactions

None known. The effects of other medicinal products on butamirate pharmacokinetics have not been investigated. Butamirate should not be used together with strong enzyme inhibitors, due to the possible risk of increased exposure of butamirate. There is no knowledge about the potential of butamirate to affect plasma concentrations of other drugs. Therefore, medicinal products with a narrow therapeutic index should not be used together with butamirate, due to the possible risk of altered exposure to these drugs.

4.6 Use in special population

Pregnancy: No studies have been conducted in pregnant women; therefore butamirate should not be used in the first trimester of pregnancy. During the second and third trimesters of pregnancy, butamirate should be administered with caution and only if absolutely necessary, taking into consideration the benefit for the mother and the potential risk for the foetus.

Breastfeeding: Since there are no data available on the excretion of the active substance or its metabolites in breast milk, the use of butamirate during breast-feeding is not recommended.

Fertility: No data available.

4.7 Effects on ability to drive and use machine

Kofarest-BT may cause drowsiness and dizziness. Therefore, this medicinal product should be used with caution in drivers and individuals using machines.

4.8 Undesirable effects

Nervous system disorders

Rare ($\geq 1/10,000, < 1/1,000$): drowsiness, dizziness

Gastrointestinal disorders

Rare ($\geq 1/10,000, < 1/1,000$): nausea, diarrhoea

Skin and subcutaneous tissue disorders

Rare ($\geq 1/10,000, < 1/1,000$): urticaria

Immune system disorders:

Frequency not known: hypersensitivity reactions

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

Symptoms

Butamirate overdose may lead to the following symptoms: drowsiness, nausea, vomiting, diarrhoea, dizziness, hypotension.

Measures

The following standard treatment is recommended: gastric lavage, administration of activated charcoal and, if necessary, the monitoring and treatment of vital signs. There is no known specific antidote.

5. Pharmacological properties

5.1 Mechanism of action

Pharmacotherapeutic group: Other cough suppressants, ATC code: R05DB13

Kofarest-BT syrup contains butamirate citrate which is a cough suppressant used for the symptomatic treatment of non-productive cough.

Butamirate acts centrally by diminishing the tussigenic reflex, and also acts peripherally via a bronchospasmolytic activity enhanced by an anti-inflammatory action.

Butamirate is a non-narcotic substance that is not chemically or pharmacologically related to the opioid alkaloids. It does not produce the undesirable effects caused by narcotic antitussives, such as sedation, constipation and addiction. Butamirate is well tolerated and suitable for cough relief in adults.

5.2 Pharmacokinetic properties

Butamirate administered orally is absorbed rapidly and completely. The peak plasma level of the principal metabolite, 2-phenylbutyric acid, is 6.4 µg/mL following administration of 150 mg butamirate citrate in syrup form, and is reached in approximately 1.5 hours. The apparent elimination half-life is approximately 6 hours. The behaviour is linear following repeat administration; no accumulation is observed.

Hydrolysis of butamirate, principally in 2-phenylbutyric acid and diethylaminoethoxyethanol, begins in the plasma. These two metabolites also have an antitussive action and are, like butamirate, extensively bound to plasma proteins (approximately 95%), which accounts for the long plasma half-life. 2-phenylbutyric acid is partially metabolised by hydroxylation in the para position. The three metabolites are mainly eliminated renally, with the acid metabolites being extensively linked to glucuronic acid.

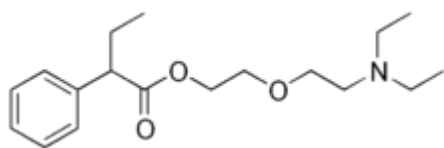
6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

Not required.

7. Description

Butamirate is a cough suppressant, with the empirical formula $C_{18}H_{29}NO_3$, a molecular weight of $307.434 \text{ g}\cdot\text{mol}^{-1}$, and the following structural formula:



8. Pharmaceutical particulars

8.1 Incompatibilities

Not applicable

8.2 Shelf-life

24 months.

8.3 Packaging Information

Kofarest-BT Syrup is available in a pack of 100ml

8.4 Storage and handling instructions

Do not store above 30°C .

8.5 Nature and contents of container

Kofarest-BT syrup contains Butamirate citrate of $7.5\text{mg}/5\text{ml}$.

8.6 Special precautions for disposal:

No special requirements. Any unused medicinal product or waste material from it should be disposed of in accordance with local requirements.

9. Patient Counselling Information

9.1 Adverse reactions

Refer part 4.8

9.2 Drug Interactions

Refer part 4.5

9.3 Dosage

Refer part 4.2

9.4 Storage

Refer part 8.4

9.5 Risk factors

Refer part 4.4

9.6 Self-monitoring information

NA

9.7 Information on when to contact a health care provider or seek emergency help

Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

9.8 Contraindications

Refer part 4.3

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