Turkey

BUTATEX SYRUP

Summary of Products Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Butatex Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:

Each 5 ml syrup contains 7.5 mg butamirate citrate (1.5 mg / ml).

Excipients:

Each 5ml syrup;

Sorbitol, liquid, non-crystalline (70%)	2500 mg
Fructose	400 mg
Sodium benzoate	5 mg
Azorubin (Carmoisine) (E122)	0.005 mg

See 6.1 for excipients.

3. PHARMACEUTICAL FORM

Syrup
Pink, clear solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BUTATEX is indicated in the following cases:

• Acute cough with different etiology

• Prevention of cough before and after surgery for surgical interventions and bronchoscopy.

4.2 Posology and method of administration

Posology / Application frequency and duration:

For children aged 6–12 years: 10 ml 3 times a day

Adolescents over the age of 12 (adolescents): 15 ml 3 times a day

In adults: 15 ml four times a day

The maximum duration of treatment is one week unless prescribed by the doctor (see section).
4.4 Special warnings and precautions for use).

Method of Application:

It is used orally.

The graduated scale should be washed and dried each time it is used.

Additional information on special populations:

Renal / Liver failure:
BUTATEX has not been studied in patients with renal or hepatic impairment.

Pediatric population:
BUTATEX Syrup is contraindicated in children under 3 years. Under 6 years use is not recommended.

Geriatric population:
The use of BUTATEX in the elderly has not been investigated.

4.3 Contraindications

BUTATEX is contraindicated in people who are known to have hypersensitivity to butamirate citrate or any of the components of the product.
Use under the age of 3 is contraindicated.

4.4 Special warnings and precautions for use

Due to the inhibition of the cough reflex by butamirate, simultaneous use of expectorants may cause mucus to accumulate in the respiratory tract, which increases the risk of bronchospasm and airway infection. Therefore, BUTATEX's simultaneous use with expectorants should be avoided.
Not recommended for use under 6 years of age.
If the cough lasts longer than 7 days, a doctor or pharmacist should be consulted.
BUTATEX contains sorbitol and fructose. Patients with rare hereditary fructose intolerance problems should not use this drug.

BUTATEX contains less than 1 mmol (23 mg) of sodium per 100 ml; that is essentially sodium-free.
This medicinal product contains azorubin as a coloring agent. May cause an allergic reaction.

4.5 Interaction with other medicinal products and other forms of interaction

Simultaneous expectorant administration should be avoided (see 4.4).

4.6 Pregnancy and lactation

General advice

Pregnancy category: B

Women with childbearing potential / Birth control (Contraception)

Animal studies, pregnancy / and-or / embryonal / fetal development / or / birth / and-or / birth is insufficient in terms of effects on post-development (see.Section 5.3). The potential risk for humans is unknown.
Since the fetus and newborn effects of butamirate citrate are not known, those who have to use the drug should be protected from pregnancy by an appropriate birth control method.

Pregnancy

For butamirate citrate, clinical data on exposure in pregnancy are not available.
BUTATEX should be avoided during the first 3 months of pregnancy. After the first 3 months of pregnancy, BUTATEX should be used only if it is absolutely necessary.

Lactation period

It is not known whether butamirate citrate and / or its metabolites are excreted in human milk.
When deciding whether to stop breastfeeding or whether BUTATEX treatment should be stopped / avoided, the benefit of breastfeeding for the child and the benefit of BUTATEX treatment for the breastfeeding mother should be taken into consideration.

Reproductive ability / Fertility

No risk of safety was observed in studies of reproductive toxicity (see section 5.3 Preclinical safety data).

4.7 Effects on ability to drive and use machines

In rare cases BUTATEX can cause drowsiness. Therefore, it may have a minor effect on the use of the vehicle or machine. Care must be taken when carrying out vehicles or other work requiring attention (eg machine operation).

4.8 Undesirable effects

The frequency order of adverse effects is as follows:

Very common (≥1 / 10);

common (≥1 / 100 to <1/10);

uncommon (≥1 / 1,000 to <1/100)

infrequently (≥1 / 10,000 to <1 / 1,000),

very sparse (<1 / 10,000),

unknown (cannot be estimated from the available data).

Diseases of the nervous system

Sparse: Sleepiness

Gastrointestinal diseases

Rarely: Nausea, diarrhea

Skin and subcutaneous tissue diseases

Sparse: Urticaria

4.9 Overdose and treatment

In the event of an overdose of BUTATEX, the following symptoms may occur: drowsiness, nausea, vomiting, diarrhea, dizziness and hypotension.

General emergency aid should be applied: gastric lavage, activated charcoal, monitoring vital functions and treatment if necessary. There is no known specific antidote.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other cough suppressants

ATC code: R05D B13

Butamirate citrate, an active ingredient of BUTATEX, is a cough suppressor that is chemically and pharmacologically unlike opium alkaloids.

Mechanism of action

The active substance is thought to be centrally acting. However, the mechanism of action is not fully known. Butamirate citrate, non-specific, facilitating respiratory functions anticholinergic and bronchospasmolytic effects.

BUTATEX has no habit-forming effects or is not addictive.

Butamirate citrate has a wide therapeutic range. BUTATEX is well tolerated even at high doses and is suitable for relieving cough in children and adults over 6 years of age.

5.2 Pharmacokinetic properties

Absorption:

Based on the available data, it can be assumed that the butamirate ester is well and rapidly absorbed and completely hydrolyzed to phenyl-2-butyric acid and diethylaminoethoxyethanol. The effect of food intake has not been investigated. Exposure to 2-phenylbutyric acid and diethylaminoethoxyethanol 22.5 mg-90 mg it is completely proportional to the dose range.

Following oral administration, butamirate is rapidly absorbed and administered in doses of 22.5 mg, 45 mg, 67.5 mg and 90 mg. Within minutes, blood is determined at measurable concentrations. Maximum plasma concentrations for all doses within 1 hour, 90 mg with an average value of 16.1 nanograms / ml.

Following administration of 90 mg (3052 nanograms / ml) of the major metabolite, phenyl-2-butyric acid, the average maximum plasma concentration is reached after about 1.5 hours. 90 mg (160 nanograms / ml) followed by administration of diethyl-aminoethoxyethanol to the mean plasma concentration within 0.67 hours.

Distribution:

Butamirate citrate has a wide dispersion volume of 81-112 L (relative to body weight in kg) as well as high binding to proteins.

2-phenylbutyric acid binds to plasma proteins at a high rate (89.3-91.6%) at all doses (22.5-90mg).

Diethylaminoethoxyethanol shows a degree of binding to proteins (28.8-45.7%). It is not known whether butamirate crosses the placenta or is discarded with milk.

Metabolism:

Hydrolysis of butamirate citrate, mainly to phenyl-2-butyric acid and diethylaminoethoxyethanol, takes place rapidly and completely. Based on studies on various species, it is assumed that both major metabolites have cough-relieving effects. There are no data on human alcoholic metabolites. Strong binding to plasma proteins (about 95%, only phenyl-2-butyric acid was shown for methodological reasons) was observed in human C-14 studies. Phenyl-2-butyric acid also undergoes partial biotransformation by hydroxylation at the para position.

Elimination:

The excretion of the three metabolites occurs mainly through the kidneys. Following conjugation in the liver, acid metabolites are broadly bound to glucuronic acid. Urinary 2-phenylbutyric acid conjugate levels are much higher than plasma. Butamirate citrate can be detected in urea for up to 48 hours and the amount of butamirate excreted in urea during the 96-hour sampling period is 0.02%, 0.02%, 0.03% and 0.03% at 22.5 mg, 45 mg, 67.5 mg and 90 mg, respectively.

A significant percentage of butamirate citrate compared to butamirate or unconjugated 2-phenylbutyric acid is excreted in urea as diethylaminoethoxyethanol. The measured elimination half-life for 2-phenylbutyric acid, butamirate and diethylaminoethoxyethanol is 23.26-24.42, 1.48-1.93 and 2.72-2.90 hours, respectively.

Characteristics of patients

The effect of liver or kidney dysfunction on the pharmacokinetic parameters of butamirate is not known.

5.3 Preclinical safety data

According to non-clinical data, there is no specific harm to human based on conventional safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, reproductive and developmental toxicity studies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol, liquid, non-crystalline (70%)
glycerol
Sodium benzoate
Raspberry Aroma
sucralose
fructose
Citric Acid Monohydrate
Sodium Citrate Dihydrate
Tutti Frutti Aroma
Azorubin (Carmoisine) (E122)
Purified water

6.2 Incompatibilities

It does not have any known incompatibilities.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at room temperature below 25°C.

6.5 Nature and contents of container

Primary packaging: Type II colored glass bottle with PE vistop lid.

Scale marked with 5, 10 and 15 ml of 15 ml

100 ml colored bottle.

6.6 Special precautions for disposal and other handling

Unused products or waste materials must be disposed of in accordance with the "Regulation on the Control of Medical Wastes" and the ve Packaging and Packaging Waste Control Regulations ".

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER (In Turkey)

23.11.2007 - 213/21

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First registration date: 23.11.2007

License renewal date:

10. DATE OF REVISION OF THE TEXT

13/06/2015