SUMMARY OF PRODUCT CHARACTERISTICS

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1. NAME OF THE MEDICINAL PRODUCT
Butagan 7.5mg/5ml Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
5 ml of syrup contains 7.5 mg butamirate citrate

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Syrup
Colourless or pale yellow liquid.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Symptomatic treatment of non-productive cough.

4.2 Posology and method of administration

Posology
Recommended dose - 15 ml up to 4 times daily

*Adolescence 12 years of age:*15 ml (22,5mg) 3 times daily

Adults: 15 ml (22,5mg) 4 times daily

Children 4 -6 years of age: 5ml (7,5mg) 3 times daily
Children 6 -12 years of age: 10ml (15mg) 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
Butamirate syrup should be taken orally.

4.3 Contraindications
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

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 Interaction with other medicinal products and other forms of interaction
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 Fertility, pregnancy and lactation
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 machines
Butamirate 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 (≥1/10,000,<1/1,000): drowsiness, dizziness

Gastrointestinal disorders
Rare (≥1/10,000,<1/1,000): nausea, diarrhoea

Skin and subcutaneous tissue disorders
Rare (≥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 Pharmacodynamic properties
Pharmacotherapeutic group: Other cough suppressants, ATC code: R05DB13

Butamirate 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.

5.3 Preclinical safety data
No data available.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Glycerol, sorbitol solution 70%, benzoic acid, saccharin sodium, vanillin, ethanol, sodium hydroxide, water purified

6.2 Incompatibilities
Not applicable

6.3 Shelf life
36 months

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container
Butamirate syrup is supplied in a 200 ml glass bottle.

6.6 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.

7. MARKETING AUTHORISATION HOLDER
ANFARM HELLAS S.A.
53-57, Perikleous St.
153 44, Gerakas
Athens, GREECE

8. MARKETING AUTHORISATION NUMBER(S)
46778/10-9-2009

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
10-09-2009

10. DATE OF REVISION OF THE TEXT
18/10/2016