

# PACKAGE LEAFLET: INFORMATION FOR THE USER

## Pintal 7.5mg/5ml syrup

### Butamirate Citrate

Read all of this leaflet carefully before you start using this medicine.

-Keep this leaflet. You may need to read it again.

-If you have any further questions, ask your doctor or pharmacist.

-This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

-If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### In this leaflet:

1. What Pintal is and what it is used for
2. Before you take Pintal
3. How to use Pintal
4. Possible side effects
5. How to store Pintal
6. Further information

#### 1. WHAT PINTAL IS AND WHAT IT IS USED FOR

Butamirate citrate is a non-narcotic antitussive agent acting in the center of cough. In contrary to the derivatives of morphine (antitussive narcotics), Pintal is free from their side effects without loss of their antitussive action. Pintal is indicated primarily for the treatment of irritant dry cough.

#### 2. BEFORE YOU TAKE PINTAL

##### Do not use Pintal

- if you are allergic (hypersensitive) to butamirate citrate or any of the other ingredients of Pintal.

##### Take special care with Pintal

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

##### Taking Pintal with food and drink

Pintal is preferable to be administered with meals.

##### Pregnancy and breast-feeding

Since there are not sufficient studies in pregnant women, the use of Pintal must be avoided in the first trimester of pregnancy. During the other months of pregnancy, Pintal can be administered according to the judgment and instruc-

tions of your physician.

Since there is no information concerning the excretion of butamirate citrate to the maternal milk, Pintal must be administered with care in nursing mothers and after careful evaluation of the benefits against the possible risk.

##### Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

#### 3. HOW TO USE PINTAL

The usual dose is 6 mg butamirate citrate 3-5 times a day. For the children is 8 - 12 mg / day in divided doses.

- Adults: 1 large measuring spoon or 5 ml of syrup, 3-4 times a day is administered.

- Children : 1 small measuring spoon or 2,5 ml syrup, 2-3 times a day or according to the physician's instructions.

##### If you use more Pintal than you should

If you take more than the prescribed dose, or in the event of an overdose, the following symptoms could be occurred: somnolence, nausea, diarrhea, unbalance and hypotension.

##### If you forget to take Pintal

If you miss a dose, take the missed dose as soon as you remember but do not take two doses in one day.

#### 4. POSSIBLE SIDE EFFECTS

Serious side effects have not been reported.

#### 5. HOW TO STORE PINTAL

Keep out of the reach and sight of children.

Store below 25°C.

Do not use Pintal after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not use Pintal if you notice visible changes in the appearance of the medicinal product.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### What Pintal contains

- The active substance is butamirata citrate.
- The other ingredients are sorbitol solution, glycerol, saccharin sodium, benzoic acid, vanillin, alcohol 95%, sodium hydroxide sol., water purified.

### What Pintal looks like and contents of the pack

Pintal syrup 7.5mg/5ml is a slightly viscous, clear and colourless syrup with odor of vanilla.

Contents of container: Pintal 7.5mg/5ml, packed in 200 ml transparent amber glass bottle.

### Marketing Authorisation Holder

ALET Pharmaceuticals S.A.  
121, M. Alexandrou str.  
Ag. Varvara 123 51  
Athens-Greece

### Manufacturer

Specifar S.A.  
1, 28 Octovriou str.  
Ag. Varvara 123 51  
Athens-Greece

### This leaflet was last approved on

The text was revised on 22.04.2008

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If you miss a dose, take the missed dose as soon as you remember but do not take two doses in one day.

### 4. POSSIBLE SIDE EFFECTS

Some side effects may occur:

### 5. HOW TO STORE PINTAL

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Do not use Pintal if you notice any side effects not listed in this leaflet and of the medicinal product.

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Pintal is indicated primarily for the treatment of infant dry cough.

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