

**APIZINE<sup>®</sup>**  
**0.25 mg/5 mL syrup**

**Dear patient,**

**Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.**

**Information about APIZINE**

Each 5 mL of APIZINE syrup contains pizotifen malate equivalent to 0.25 mg pizotifen with the following excipients: propyl paraben, methyl paraben, citric acid, disodium phosphate, ethanol, sorbitol, strawberry liquid, and purified water.

Pizotifen has an anti-migraine and an appetite stimulant property due to its inhibitory effect on serotonin, histamine, and tryptamine.

APIZINE is a sugar free syrup indicated in anorexia of somatic or psychogenic origin in underweight patients, as an adjuvant to treatment of the underlying condition, such as infectious or parasitic diseases, chronic diarrhea, anorexia nervosa, or depression in the elderly. The underlying condition should always be treated.

**The way to take APIZINE**

Take APIZINE as directed by your physician.

Children older than 2 years old and adolescents:

Initial low doses should gradually increase to a total average daily maintenance dose of 0.025 mg per kg body weight, which can be administered in 2 or 3 divided doses or as medically indicated.

Adults and adolescents more than 13 years of age (and weighing more than 40 Kg):

The starting dose is 0.5 mg (10 mL) per day, which is gradually increased as needed to 0.5 mg (10 mL) three times a day.

**In case of overdose**

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

**In case of missed dose**

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

**Contraindications**

This drug is contraindicated in case of hypersensitivity to any of the components.

**Precautions**

- Doseage adjustment is needed in patients with renal or hepatic impairment; the treatment with pizotifen should be discontinued in case of appearance of signs of liver dysfunction.
- Use caution in case of glaucoma, urinary retention or in case of patients suffering from epilepsy.
- Gradual withdrawal of pizotifen is recommended.
- This drug should not be used in patients less than 2 years of age.
- Consult your doctor before using this drug in case of pregnancy or lactation. This drug is not recommended during lactation.

-Caution should be taken when driving a car or operating dangerous machinery until you know how you respond to the drug.

**Adverse reactions**

The most commonly reported adverse reactions include: increased appetite, weight gain, drowsiness, dizziness, nausea, dry mouth, and fatigue.

Hypersensitivity reactions, facial edema, depression, central nervous system stimulation, hallucinations, insomnia, anxiety, paresthesia, epilepsy, constipation, increased liver enzyme, hepatitis, jaundice, urticaria, rash, myalgia, and muscle cramps have been rarely reported.

Please inform your doctor if any adverse reaction appears or becomes bothersome.

**Associations with other medications**

Please inform your doctor if other medicines are being taken or have been taken recently.

Use caution with cisapride, sedative hypnotics, antihistamines, alcohol, and drugs subject to N-glucuronidation.

**Storage**

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children. The expiry date is printed on the pack; don't use this medicine after this date.

**Pack Presentation**

APIZINE syrup, pizotifen 0.25 mg/ 5mL, bottle of 100 mL (with a dosing cup)

**Issue date:** 07/2017

APIS025/001