

FLUISEDAL, syrup

Meglumine benzoate plus Promethazine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. If you have any further questions, ask your doctor or pharmacist.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your pharmacist.
- If the symptoms get worse or persist, consult your doctor.
- 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.

1. WHAT FLUISEDAL, syrup, IS AND WHAT IT IS USED FOR ?

Systemic antihistamine (R: respiratory system)

This medicine contains an antihistamine, promethazine, and meglumine benzoate.

This medicine is recommended for the alleviation of unproductive cough and irritative cough in adults and children aged more than 2 years, in particular when coughing occurs in the evening or at night.

2. BEFORE YOU TAKE FLUISEDAL, syrup

If your doctor has informed you that you are intolerant to certain sugars, contact him/her before taking this medicine.

Do not take FLUISEDAL, syrup, in the following cases (contra-indications)

- Infants (aged less than 2 years) due to the risk of exacerbation of bronchial congestion.
- Known allergy to one of the constituents and, in particular, to antihistamines.
- Old or recent agranulocytosis (marked fall in the white blood cells in the blood).
- Difficulty urinating with a prostatic or other etiology.
- Certain forms of glaucoma (increase in the pressure in the eyes).

This medicine MUST GENERALLY NOT BE USED during pregnancy or in combination with sultopride unless your doctor tells you to do so.

Ask your doctor or pharmacist if you need more information or advice.

Take special care with FLUISEDAL, syrup (Special warnings)

Emergence of a cough in an infant necessitates consulting a doctor.

Do not use this medicine to treat a productive cough. In that case, the cough is a natural defense mechanism necessary to evacuate bronchial secretions.

If the cough becomes productive with congestion, expectoration and fever, ask your doctor for advice.

In the event of chronic (long-term) disease of the bronchi or lungs together with a cough with expectoration, a medical opinion is indispensable.

Do not combine with a medicine to make bronchial secretions fluid (expectorant, mucolytic). Treatment is not to be continued if the symptoms get worse. In that case, consult your doctor for a review of your treatment.

Use of this medicine is not advised for patients presenting with fructose intolerance, glucose and galactose malabsorption syndrome or sucrose/isomaltase deficiency (rare hereditary diseases).

This medicine contains sulfites that may induce or exacerbate allergic reactions.

Precautions for use

Use of this medicine by children aged less than 2 years is not advisable.

In the event of long-term disease of the liver or kidneys, CONSULT YOUR DOCTOR in order for him/her to adjust the dosage.

Use of this medicine requires a MEDICAL OPINION:

- in the event of serious heart disease or epilepsy,
- in children in the event of asthma or gastroesophageal reflux,
- in elderly patients:

- o predisposed to constipation,
- o predisposed to dizziness or drowsiness,
- o presenting with prostatic disorders.

INFORM YOUR DOCTOR before taking this antihistamine.

Refrain from alcoholic beverages and medicines containing alcohol throughout the duration of treatment.

It is preferable not to expose yourself to the sun during treatment.

This medicine is to be used with caution due to the risk of sedation. Combination with other sedative medicines is not advisable (see section "Taking or using other medicines").

In the event of diabetes or a low-sugar diet, take the sugar content of this medicine into account in the daily ration: 3.6 g per 5-mL measuring spoon and 10.8 g per soup spoon.

If you are in doubt, ask your doctor or pharmacist.

Taking or using other medicines

In order to prevent potential interactions between several medicines and, particularly, interactions with sultopride, always report all other ongoing treatments to your doctor or pharmacist.

This medicine contains an antihistamine, promethazine, and meglumine benzoate. Other medicines also contain those drugs. Do not combine medicines in order not to exceed the recommended maximum dose (see Dosage).

Combination with other sedative medicines is not advisable due to the risk of potentiation of the sedative effect of this medicine.

Pregnancy

This medicine SHOULD GENERALLY NOT BE USED during pregnancy unless your doctor tells you to do so. If you discover that you are pregnant during treatment, consult your doctor rapidly. Only your doctor can adapt the treatment to your condition.

Ask your doctor or pharmacist for advice before taking any medicine.

Breastfeeding

Since this medicine is excreted in breast milk, you should avoid taking it in the event of breastfeeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Effects on the ability to drive and use machines

Attention, particularly that of drivers and machine users, is drawn to the potential drowsiness related to use of this medicine, particularly at the start of treatment.

The drowsiness phenomenon is accentuated by the intake of alcoholic beverages or medicines containing alcohol.

List of excipients with a known effect: sodium metabisulfite (E223), sucrose (3.6 g per 5-mL measuring spoon and 10.8 g per soup spoon), propylene glycol.

3. HOW TO TAKE FLUISEDAL, syrup ?

Dosage: FOR ADULTS AND CHILDREN AGED MORE THAN 2 YEARS ONLY.

Adults: 3 to 4 soup spoons daily.

For children, use the 5-mL measuring spoon supplied with the syrup and comply with your doctor's prescription.

As an indication:

- Children aged 12 to 15 years: 6 to 9 measuring spoons (5 mL) daily,
- Children aged 6 to 12 years: 4 to 6 measuring spoons (5 mL) daily,
- Children aged 24 months to 6 years: 3 to 4 measuring spoons (5 mL) daily.

The emergence of a cough in infants necessitates a medical consultation.

Wash the measuring spoon after each use.

This medicine has been dispensed to you personally in a specific situation:

- it may not be suitable for other cases,
- do not advise anyone else to use it.

Administration route: oral route.

Treatment duration: the treatment is to be of short duration (a few days) and restricted to the times when coughing occurs.

If you take more FLUISEDAL, syrup, than you should: in the event of overdose or erroneous intake of an excessively high dose, CONSULT A DOCTOR IMMEDIATELY.

4. POSSIBLE SIDE EFFECTS

Like all medicines, FLUISEDAL, syrup, can cause side effects, although not everybody gets them.

- Risk of worsening of the bronchial congestion, particularly in infants and in patients unable to expectorate (spit) effectively.

Certain effects require IMMEDIATE DISCONTINUATION OF TREATMENT AND INFORMING A DOCTOR.

- Allergic reactions:
 - o of the skin rash type (erythema, eczema, purpura, urticaria),
 - o asthma attack,
 - o angioedema (urticaria with abrupt swelling of the face and neck liable to induce respiratory discomfort),
 - o anaphylactic shock,
 - o phenomena of skin sensitization on exposure to the sun,
- Marked fall in the white blood cells in the blood, which may give rise to emergence or resurgence of fever with or without signs of infection,
- Abnormal decrease in the platelets in the blood, which may give rise to bleeding from the nose or gums.

Other effects are more frequent:

- Drowsiness, impairment of alertness, which are more marked at the start of treatment,
- Memory or concentration disorders, dizziness (more frequent in the elderly),
- Motor incoordination, tremor,
- Confusion, hallucinations,
- Dry mouth, visual disorders, urine retention, constipation, palpitations, fall in blood pressure.

More rarely, signs of excitation: agitation, nervousness and insomnia may occur.

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.

5. HOW TO STORE FLUISEDAL, syrup ?

Keep out of the reach and sight of children.

Do not use FLUISEDAL, syrup, after the expiry date which is stated on the bottle.

Store at a temperature of less than 30°C.

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

6. FURTHER INFORMATIONS

The active substances are: per 100 mL of syrup

Meglumine benzoate (expressed as the anhydrous salt).....2.600 g

Polysorbate 20.....0.300 g

Promethazine hydrochloride.....0.050 g

1 measuring spoon (5 mL) contains 130 mg of meglumine benzoate, 15 mg of polysorbate

20, 2.5 mg of promethazine hydrochloride and 3.6 g of sucrose.

1 soup spoon (15 mL) contains 390 mg of meglumine benzoate, 45 mg of polysorbate 20,

7.5 mg of promethazine hydrochloride and 10.8 g of sucrose.

The other ingredients are: ascorbic acid, sodium metabisulfite (E 223), caramel color (E 150) (caramel obtained by heating sucrose or other dietary sugars), caramel flavor (solution of vanillin, piperonal, gamma-nonalactone, maltol and acetyl methylcarbinol in propylene glycol), sucrose, purified water.

This medicine is a syrup. 125-mL or 250-mL bottle.

Holder / Operator / Manufacturer: LABORATOIRES ELERTE

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This leaflet was last approved on 18 October 2010.

Detailed information on this medicine is available on the ANSM website (France).