TUSSISEDAL, syrup

Noscapine 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, if you are in doubt, ask your doctor or pharmacist.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your pharmacist.
- You must contact your doctor if your symptoms worsen or do not improve.
- 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 TUSSISEDAL, syrup, IS AND WHAT IT IS USED FOR

Antitussive and antihistamine for systemic use (R: respiratory system)

This medicine is indicated for the alleviation of unproductive cough and irritative cough in adults and children aged more than 30 months, in particular when the cough occurs in the evening or at night.

2. BEFORE YOU TAKE TUSSISEDAL, syrup

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

Contra-indications: do not take TUSSISEDAL, syrup, in the following cases:
- Infant aged less than 30 months;
- Known allergy to one of the constituents and, in particular, to morphine derivatives, antihistamines, sulfites and parabens;
- Respiratory insufficiency;
- Asthmatic cough;
- Old or recent agranulocytosis (marked fall in the white blood cells in the blood);
- Difficulty urinating of prostatic or other etiology;
- Certain forms of glaucoma (increased pressure in the eyes);
- In combination with buprenorphine and nalbuphine.

This medicine SHOULD GENERALLY NOT BE USED in combination with sultopride unless your doctor tells you to.

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

Special warnings

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 the bronchial secretions fluid (expectorant, mucolytic).

This medicine contains 'sulfite' and may induce severe allergic reactions and respiratory discomfort.

This medicine contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) and may induce allergic reactions.

This medicine contains an azo dye, sunset yellow FCF (E110), and may induce allergic reactions.

This medicine contains sucrose (sugar). Use of the medicine is not advised in patients presenting with sucrose intolerance (rare hereditary disease).

Precautions for use

In the event of long-term disease of the liver or kidneys, CONSULT YOUR DOCTOR so that he/she can adjust the dosage.

Use of this medicine requires a MEDICAL OPINION:
- in the event of excessive pressure inside the skull,
- in the event of serious heart disease or epilepsy,
- in children in the event of asthma or gastroesophageal reflux,
- in the elderly:

o predisposed to constipation, dizziness or drowsiness,

o presenting with prostate disorders.

TELL YOUR DOCTOR before taking this medicine.

If you are taking other medicines at the same time as this medicine, you should take them 2 hours before or after this one.

Do not drink alcoholic beverages or use medicines containing alcohol during treatment.

You should not expose yourself to the sun or UV A radiation during treatment.

This medicine contains 3.6 g of sucrose per 5-mL measuring spoon and 10.8 g of sucrose per soup spoon (15 mL). The sucrose is to be taken into account in the daily ration in the event of a low-sugar diet or diabetes.

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

Interactions with other medicines

In order to prevent potential interactions between several medicines and, particularly, morphine derivatives (buprenorphine, nalbuphine) and sultopride, always tell your doctor or pharmacist if you are taking other medicines.

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

Pregnancy

This medicine should not be taken during the first trimester of pregnancy.

If you discover that you are pregnant during treatment, you should discontinue treatment and ask your doctor for advice.

This medicine is only to be used during the second and third trimesters of pregnancy providing that treatment is of short duration (a few days) and at the recommended dosage. Abusive intake of this medicine toward the end of pregnancy may induce harmful effects on the neonate.

In consequence, always ask your doctor for advice before using this medicine and never exceed the recommended dosage and treatment duration.

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.

The drowsiness phenomenon is increased by intake of alcoholic beverages.

List of excipients with a known effect

Methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216).

Sodium metabisulfite (E223), orange yellow FCF (E110), sucrose:

1 half measuring spoon (2.5-mL graduation) contains 1.8 g of sucrose.

1 measuring spoon (5 mL) contains 3.6 g of sucrose.

1 soup spoon (15 mL) contains 10.8 g of sucrose.

3. HOW TO TAKE TUSSISEDAL, syrup

In the absence of efficacy, do not increase the dosage to above the recommended dosage. Do not take another antitussive at the same time. Consult your doctor.

FOR ADULTS AND CHILDREN AGED MORE THAN 30 MONTHS ONLY.

Shake before use
- Adults: 1 soup spoon per intake to be repeated if required after 6 hours without exceeding 4 soup spoons per day.

Elderly subjects or in the event of serious liver disease: consult your doctor.
- For children aged more than 30 months, **use the 2.5-mL and 5-mL graduated measuring spoon supplied with the syrup** and comply with the prescribed dosage.

Wash the measuring spoon after use.

Given the potential for pronounced drowsiness with this medicine, the highest dose is to be taken in the evening.

This medicine has been prescribed for 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.

Administration frequency

If you are taking other medicines, take them 2 hours before or after this medicine.

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 TUSSISEDAL, syrup, than you should:

In the event of overdose or erroneous intake of an excessively high dose, CONSULT A DOCTOR RAPIDLY.

4. POSSIBLE SIDE EFFECTS

Like all medicines, TUSSISEDAL, syrup, can cause side effects, although not everybody gets them.
- **Certain effects require IMMEDIATE DISCONTINUATION OF TREATMENT AND INFORMING A DOCTOR:**

o Allergic reactions:
- of the skin rash type (erythema, eczema, purpura, urticaria),
- angioedema (urticaria with abrupt swelling of the face and neck liable to induce respiratory discomfort),
- anaphylactic shock.

o Phenomena of skin sensitization on exposure to the sun.

o 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.

o Abnormal decrease in the platelet count in the blood, which may give rise to bleeding from the nose or gums.
- **Other effects are more frequent:**

o Drowsiness, impairment of alertness more marked at the start of treatment.

o Memory or concentration disorders, dizziness (more frequent in the elderly).

o Motor incoordination, tremor.

o Confusion, hallucinations.

o Dry mouth, visual disorders, urine retention, constipation, palpitations, fall in blood pressure.

o Nausea, vomiting.

o Respiratory discomfort (decreased caliber of the bronchi).
- More rarely, signs of excitation (agitation, nervousness, 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 TUSSISEDAL, syrup

Keep out of the reach and sight of children.

Do not use TUSSISEDAL, 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 INFORMATION

The active substances are (per 100 mL of syrup):

Noscapine resinate, quantity equivalent to noscapine base: 0.10 g

Promethazine resinate, quantity equivalent to promethazine base: 0.05 g

1 half measuring spoon (2.5-mL graduation) contains 2.5 mg of noscapine and 1.25 mg of promethazine.

1 measuring spoon (5 mL) contains 5 mg of noscapine and 2.5 mg of promethazine.

1 soup spoon (15 mL) contains 15 mg of noscapine and 7.5 mg of promethazine.

The other ingredients are: polysorbate 85, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium metabisulfite (E223), essential oil of orange, sunset yellow FCF (E110), tragacanth gum, sucrose and purified water.

The medicine is a syrup. 125-mL bottle with measuring spoon.

Holder / Operator / Manufacturer: Laboratoires ELERTE

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This leaflet was last approved on **8 December 1997.**

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

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