

1.6.2.PACKAGE LEAFLET: INFORMATION FOR THE USER

PAIDOTERIN DECONGESTANT

Liquid

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What PAIDOTERIN DECONGESTANT liquid is and what it is used for.
2. What you need to know before you take PAIDOTERIN DECONGESTANT liquid.
3. How to take PAIDOTERIN DECONGESTANT liquid.
4. Possible side effects.
5. How to store PAIDOTERIN DECONGESTANT liquid.
6. Contents of the pack and other information.

1. What PAIDOTERIN DECONGESTANT liquid is and what it is used for

PAIDOTERIN DECONGESTANT liquid is an association of phenylephrine, diphenhydramine and chlorpheniramine. Phenylephrine is a sympathomimetic amine that acts on alpha-adrenergic receptors of the mucosa of the respiratory tract causing vasoconstriction, which reduces, temporarily, the swelling associated with the inflammation of the mucous membranes that cover the nasal airways, acting as decongestant.

Diphenhydramine and chlorpheniramine are two antihistamines that prevent, although they do not revert, histamine-mediated responses. The antimuscarinic actions of antihistamines produce a drying effect on the nasal mucosa.

It relieves the symptoms of the congestion of the mucosa of the upper airways that occurs in perennial or seasonal allergic rhinitis.

2. What you need to know before you take PAIDOTERIN DECONGESTANT Liquid

Do not take PAIDOTERIN DECONGESTANT Liquid:

- If you are hypersensitive to the active substances or to any of the other ingredients of this medicine.

- Children under 2 years of age

Take special care with PAIDOTERIN DECONGESTANT liquid:

Administer with caution to patients with hypertension, severe cardiovascular conditions, glaucoma, prostatic hypertrophy, bladder neck obstruction and urinary retention.

Patients who are sensitive to a certain antihistamine can be also sensitive to others.

Taking other medicines:

Antihistamines can enhance the CNS depressant effects when they are administered together with CNS depressants, tricyclic antidepressants, maprotiline, monoamine-oxidase inhibitors (MAOIs) and alcohol. They can also enhance the anticholinergic effects of medicinal products with anticholinergic actions.

The pressor effects can also be reinforced by the simultaneous administration of phenylephrine with doxapram, methyldopa or trimethaphan. Phenylephrine used in combination with digitalic glucosides can increase the risk of cardiac arrhythmias and favour the vasoconstriction induced by hay ergot alkaloids or methysergide. It can also prolong or favour the cardiac and vasopressor stimulant effects of sympathomimetic amines. The pressor response to phenylephrine can be blocked by the previous administration of adrenergic alpha- blockers and phenylephrine can inhibit the therapeutic effects of adrenergic beta-blockers. The risk of severe ventricular arrhythmias can be increased when phenylephrine is administered simultaneously with inhaled halogenated hydrocarbon anesthetics.

PAIDOTERIN DECONGESTANT liquid is compatible with any therapy with sulfonamides or antibiotics.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription.

Use in children:

Do not give this medicine to children under 2 years.

Use in elderly patients:

In elderly patients anticholinergic effects and CNS-stimulating effects are likely to occur and there is risk of precipitation of undiagnosed glaucoma.

Pregnancy and breast-feeding:

The innocuousness of **PAIDOTERIN DECONGESTANT liquid** in pregnancy has not been established. Its use is not recommended in nursing women since there is risk of appearance of side effects in the baby, such as unusual excitement or irritability, as small quantities of antihistamines are excreted in milk.

Driving and using machines:

Due to the fact that this medicinal product can cause somnolence, it can have an effect on the ability to drive vehicles and use machines, as it could be dangerous.

Use in sportspeople:

This medicinal product contains phenylephrine, which may give a positive result in the analytical doping controls.

Important information about some of the ingredients of PAIDOTERIN DECONGESTANT liquid:

This medicinal product contains of sucrose. If your doctor has told you have an intolerance to certain sugars, ask him for advice before taking this medicine.

- It may cause dental decay.
- It may cause allergic reactions (possibly delayed) due to its content in methyl parahydroxybenzoate (E 129).
- It may cause allergic reactions due to its content in amaranth (E 123). It may cause asthma, especially in patients allergic to acetylsalicylic acid.

3. How to take PAIDOTERIN DECONGESTANT liquid

Instructions for proper use:

Always take **PAIDOTERIN DECONGESTANT liquid** exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

The recommended doses are the following:

Children aged 2 to 6 years: 5 ml every 6 or 8 hours.

Children aged 6 to 12 years: 10-15 ml every 6 or 8 hours.

Adults: 15-20 ml every 6 or 8 hours.

It should be administered preferably after meals.

The medicinal product can be dosed using the dosing cup (with marks at 2.5, 5, 10, 15 and 20 ml) included in the presentation or alternatively using 1 teaspoonful (equivalent to 5 ml).

Each of the doses should never be greater than twice the indicated dose.

If you take more PAIDOTERIN DECONGESTANT liquid than you should:

Should acute intoxication due to overdose occur, the treatment consists of the administration of an emetic or gastric lavage with solution of sodium bicarbonate at 5%, activated charcoal and catharsis. Should ventricular tachycardia occur lidocaine should be administered and if there is no response propranolol should be administered. In case of seizures diazepam should be administered. In case of severe hypertension nitroprusside or phentolamine should be administered. If the anticholinergic effects are intractable physostigmine should be administered. Electrocardiographic and vital signs monitoring should be carried out. In symptomatic patients urine controls and electrolytes in blood determinations should be carried out.

In case of overdose or accidental ingestion, consult your doctor or pharmacist or call the Toxicological Information Service immediately indicating the medicine and the amount administered.

If you forget to take PAIDOTERIN DECONGESTANT liquid:

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, **PAIDOTERIN DECONGESTANT liquid** can cause side effects, although not everybody gets them.

Exceptionally, somnolence can occur. Rarely, blood dyscrasias, increase in the skin's sensitivity to the sun, increase in sweating and loss of appetite can occur. Rarely, a paradoxical reaction can also occur (nightmares, excitement, nervousness, etc.), it is more likely to occur in children and in elderly patients; these patients are also more prone to suffer confusion, difficulty or pain during micturition and somnolence.

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 PAIDOTERIN DECONGESTANT liquid

Keep this medicine out of the reach and sight of children.

The bottle should be kept in its original packaging protected from light and excessively low temperatures.

Do not use **PAIDOTERIN DECONGESTANT liquid** after the expiry date which is stated on the label after the abbreviation Exp. Date. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Content of the pack and other information

What PAIDOTERIN DECONGESTANT liquid contains

-The active substances are phenylephrine, diphenhydramine hydrochloride, and chlorphenamine maleate.

-The other ingredients are saccharin sodium, saccharose, amaranth (E 123), methyl parahydroxybenzoate (E 219), glycerin, sodium citrate, citric acid, strawberry essence and deionised water.

What PAIDOTERIN DECONGESTANT liquid looks like and contents of the pack

PAIDOTERIN DECONGESTANT liquid is a red liquid with strawberry flavour, packaged in a 100 ml bottle, equipped with a dosing cup.

Marketing Authorisation Holder and Manufacturer

Laboratorio Aldo-Unión, S.L.

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