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DETIXOL®

DOXYLAMINE SUCCINATE
PYRIDOXINE HYDROCHLORIDE

EXTENDED RELEASE CAPSULES

PATIENT INFORMATION
- CONSULT YOUR DOCTOR -

Rx only
Argentine Industry

Read this patient information before taking DETIXOL and each time you repeat the recipe, as there may be new information. This information does not replace your conversation with your doctor about your illness or treatment.

Formula
Each extended-release capsule contains: Doxylamine Succinate 10.000 mg, Pyridoxine Hydrochloride 10.000 mg. Excipients: Microcrystalline cellulose 30.800 mg; Mannitol 20.880 mg; Croscarmellose Sodium 4.650 mg; Talc 5.630 mg; Magnesium stearate 1.580 mg; Tricalcium phosphate 34.200 mg; Sodium Glycolate Starch 3.250 mg; Methacrylic Acid Copolymer and Ethyl Acrylate (1:1) 13.607 mg; Polysorbate 80 0.332 mg; Triethylcitrate 2.620 mg; Titanium dioxide 1.694 mg; Copovidone 3.250 mg; Crospovidone 6.500 mg; Red Iron Oxide 0.006 mg; Sodium hydroxide q.s. pH 5.2;
Hard gelatin capsules (Titanium dioxide 0.478 mg; Gelatin 75.485 mg; Quinoline Yellow [C.I. 47005] 0.036 mg; Yellow Sunset [C.I. 15985] 0.001 mg) 1 unit.

What is DETIXOL and what is it used for?
This medicine belongs to the group of so-called antiemetics and anti-nauseous and is indicated for the symptomatic treatment of nausea and vomiting.

Before using DETIXOL
Do not take DETIXOL
- If you are allergic (hypersensitive) to doxylamine, pyridoxine or any of the other components of DETIXOL.
- If you are hypersensitive to any other antihistamine of the H1 group (histamine antagonists).
- If you have asthma attacks.
- If you have any type of porphyria: metabolic diseases caused by deficiency in enzymes involved in the biosynthesis of the heme group (hemoglobin component, essential part of blood red blood cells).

Do not use DETIXOL if
- you have glaucoma (increased eye pressure), intestinal disturbances such as intestinal obstruction or ulcers, urinary bladder obstruction, urine retention, prostate abnormalities, hyperthyroidism, increased blood pressure and cardiovascular disturbances, as DETIXOL can aggravate the disease.
- you have asthma, pulmonary emphysema or chronic obstructive pulmonary disease (COPD), as DETIXOL may aggravate the disease;
- you have kidney disease;
- you have liver disease;
- you have epilepsy, as it can aggravate the disease.

Take special care with DETIXOL
- may cause sensitivity reactions to light, so sunbathing is not recommended during treatment;
- may interfere with the diagnosis of appendicitis;
- you can mask symptoms that may affect your ears (such as vertigo), so you should consult your doctor if you are taking other medicines that might have the same effects.

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Simultaneous taking of other medicines
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including over-the-counter medications.
DETIXOL should not be administered together with drugs called anticholinergics (e.g. some antidepressant drugs) as toxicity may be enhanced. It should also not be administered together with sedative drugs as its hypnotic action can be enhanced.
This medicine may alter the following analytical determinations: false negative skin tests using allergenic extracts. It is advised to stop treatment at least 72 hours before starting the test.

How to use DETIXOL?
Follow exactly the DETIXOL administration instructions indicated by your doctor. Consult your doctor or pharmacist if you have any questions.
DETIXOL is for oral use.
In adults and children over 12 years of age, a dose of 1 capsule is recommended every 8 hours up to a maximum of 70 mg per day (equivalent to 7 capsules).
In pregnant women: initially, two DETIXOL extended release capsules orally should be taken at bedtime (Day 1). If this dose adequately control symptoms the next day, continue taking two capsules daily at bedtime. However, if symptoms persist in the afternoon of Day 2, the normal dose of two capsules should be taken at bedtime that night and then take three capsules from Day 3 (one capsule in the morning and two capsules at bedtime). If these three capsules adequately control symptoms on Day 4, you should continue taking three capsules daily. Otherwise, four capsules should be taken from Day 4 (one capsule in the morning, one mid-afternoon and two capsules at bedtime). The maximum recommended dose is four capsules daily (one in the morning, one mid-afternoon and two at bedtime). They should be taken on a daily basis and not as needed. Your doctor should examine you to see the need to continue treatment with DETIXOL as your pregnancy progresses.
DETIXOL is for oral use. The capsules should be swallowed whole, without chewing.

Pregnancy and lactation
Consult to your doctor or pharmacist before using any medicine. Your doctor will assess the convenience or not of this medicine.

Use in children
The child may be more sensitive to the sedative and anticholinergic effects of this medicine. Do not use in children under 12 years of age.

Use in the elderly
The anticholinergic effects of DETIXOL may aggravate pre-existing conditions in elderly patients. Before using this product, you should consult your doctor or pharmacist.

Effects on vehicle driving ability
DETIXOL may cause drowsiness in some patients, so situations that require a state of alertness, such as driving vehicles or operating machinery, should be avoided.

Joint take of DETIXOL with food and drink
It is not advisable to drink alcoholic beverages during treatment with DETIXOL because they may enhance the toxicity of the medicine.

Appropriate use of DETIXOL
If you forgot to take DETIXOL
Do not take a double dose to compensate for forgotten doses.
If you have any further questions about the use of this product, ask your doctor or pharmacist.
Undesirable effects (adverse)
Like all medicines, DETIXOL can cause side effects, although not everyone suffers them.
The following definitions apply to the incidence of side effects: very frequent (>/=1/10); frequent (>/=1/100, <1/10); uncommon (>/=1/1000, <1/100); rare (>/=1/10000, <1/1000); very rare (<1/10000).
-Frequent side effects (at least 1 in 100 patients): dry mouth, constipation, drowsiness especially at the start of treatment, urinary retention (difficulty urinating), bronchial hypersecretion, blurred vision.
-Uncommon side effects (at least 1 in 1000 patients): asthenia (feeling weak and lack of vitality), peripheral edema (accumulation of fluids in the ankles, feet and legs), orthostatic hypotension

(reduction of blood pressure after a postural change), nausea, vomiting, diarrhea, confusion, tinnitus (feeling beeping in the ears), diplopia (double vision), glaucoma (increased eye pressure), exanthematic rashes, photosensitivity reactions.
-Rare side effects (at least 1 in 10000 patients): hemolytic anemia (red blood cell disorders), tremor, seizures, paradoxical excitement especially in children and the elderly.
If you think any of the side effects that you suffer is serious or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

How to store DETIXOL?
- Store between 15°C and 30°C
- Keep out of reach of children.

Presentation
Boxes with 30 extended release capsules.

If you take higher doses of DETIXOL than you should
If you have taken more DETIXOL than you should, talk to your doctor or pharmacist immediately.
Possible intoxication would be recognized by neurological alterations such as agitation, hallucinations or intermittent seizures, which may lead in extreme cases to decreased vital activity and coma. If any of these symptoms occur, appropriate treatment will be instituted.
In the event of overdose, go to the nearest hospital or communicate with the Toxicology Centers:
- Hospital A. Posadas: (011) 4654-6648/4658-7777.
- Hospital of Pediatrics Ricardo Gutiérrez: (011) 4962-6666/2247.
Optionally other Toxicology Centers.

"This medication has been prescribed only for your current medical problem.
Do not recommend it to other people."
"If any inconvenience with the product, the patient may fill in the
form that is on the website of ANMAT
http://anmat.gov.ar/farmacovigilancia/Notificar.asp or call
ANMAT responds 0800-333-1234"

Technical Director: Dr. Luis M. Radici – Pharmacist.
MEDICAL SPECIALTY AUTHORIZED BY THE MINISTRY OF HEALTH OF THE NATION
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