Package Leaflet: Information for the patient

Destoxican 50 mg tablets
cloridrato de naltrexona

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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, 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 Destoxican is and what it is used for

Destoxican is used for its opiate antagonist effects, as an adjunct to the behavioural modification programme in maintaining non-dependence on opiates in physically dependent individuals who have undergone successful detoxification.

Destoxican is indicated as supportive treatment in the setting of opiate addiction, after weaning cure and in tertiary prevention to prevent relapse.

Destoxican is used effectively in reducing the need to drink alcoholic beverages for use as part of a comprehensive treatment programme for alcohol dependence with the aim of reducing the risk of relapse, maintaining abstinence and reducing the desire to drink alcohol.

2. What you need to know before you take Destoxican

Do not take Destoxican:
- If you are allergic to the active substance (naltrexone) or any of the other ingredients of this medicine;
- If you have an acute liver infection;
- If you have severe hepatocellular insufficiency;

- If you are dependent on opiates, before the detox cure, due to the possibility of acute withdrawal syndrome;
- If you are a patient who has abruptly stopped opioids;
- If you are taking opioid agonists;
- If opiates are detected in your urine.

Warnings and precautions
If you have impaired liver and kidney function, a particular vigilance should be done as naltrexone is largely metabolised in the liver and excreted mainly in the urine.

It is not uncommon for alcohol abusers or drug addicts to have altered liver function. Before starting treatment, and periodically throughout, it is recommended that liver function tests be carried out.

In opioid-dependent patients, the administration of naltrexone hydrochloride can cause a severe and long-lasting withdrawal syndrome (48 hours). Administering a high dose of opiates (heroin) in order to cancel out the effect produced by naltrexone can lead to acute intoxication with potentially fatal consequences. If symptoms and/or signs of withdrawal appear, close monitoring should be carried out and naltrexone hydrochloride therapy adjusted according to need and response.

For this reason, treatment with Destoxican should be started only when opioid treatment has been suspended for a sufficiently long period of time (about 5-7 days for heroin and at least 10 days for methadone) and after confirmation of the absence of elimination of morphine derivatives in the patient's urine.

Confirmation of non-dependence on opiates can possibly be achieved through a provocation test with naloxone (morphine antagonist).

The simultaneous use of Destoxican with other opioid-containing products should be avoided. In the event of an emergency situation requiring analgesia only possible with these products, a higher dose may be required and the patient should be closely monitored. Before elective surgery, in which analgesia can only be achieved with opiate agonists, naltrexone hydrochloride therapy should be discontinued at least 48 hours beforehand.

Regular monitoring of liver function is recommended in order to detect early liver damage or disease that may arise during the course of therapy.

Other medicines and Destoxican
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Destoxican should not be administered with preparations that may contain opiate derivatives, such as antipyretics, antitussives, antidiarrhoeals and opiate analgesics.

Since naltrexone is mainly metabolised in the liver, other medicines that alter hepatic metabolism can increase or decrease the serum concentration of naltrexone.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, thinking you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The studies in animals do not suggest teratogenic effects, even at doses higher than therapeutic doses. However, the safety of Destoxican during pregnancy and breastfeeding has not been established, so in these cases its administration should only be carried out when, according to medical judgement, the potential benefits justify the possible risks.

Driving vehicles and using machines:
The effects of Destoxican on the ability to drive and use machines are considerable. Naltrexone may impair mental and/or psychic capacity needed to perform potentially dangerous tasks such as driving vehicles or operating machinery.

Dextoxican contains sucrose
If you have been told by your doctor that you have an intolerance to some sugars you should contact your doctor before taking this medicine.

Tablets contain yellow-orange colouring (E110)
It may cause allergic reactions.

3. How to take Destoxican

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Initial treatment:
The recommended dose to initiate the treatment is 25 mg.

The patient should remain under medical observation for 1 hour, after which a new dose of 25 mg can be administered if no withdrawal symptoms are observed.

Maintenance treatment:
The recommended dose is 50 mg a day.

Considering that antagonist activity is reduced by administering high doses at spaced intervals, various therapeutic regimens are recommended.

One of the most widely used regimens, which allows patients to adhere better to the therapy, consists of thrice-weekly administration:
- 100 mg on Mondays and Wednesdays;

- 150 mg on Fridays.

An initial treatment period of around 3 months is recommended, which can be extended depending on the state of psychological dependence.

In the treatment of alcoholism, the recommended dosage regimen is 50 mg/day, with trials demonstrating the efficacy of naltrexone as part of the treatment of alcoholism when administered in daily doses of 50 mg/day for up to three months. Dosage regimens similar to those used in the maintenance therapy of opiate antagonists can be used.

It is administered orally.

Destoxican can only be administered after a weaning period of 7 to 10 days.

An oral dose of 50 mg has an antagonizing and preventive action for around 24 hours.

If you notice that the effect of Destoxican is too strong or not strong enough, consult your doctor or pharmacist.

If you take more Destoxican than you should
If you take more Destoxican than you should, symptomatic treatment in hospital is recommended. Data on naltrexone overdose in human is limited.

If you forget to take Destoxican
If you forget to take a dose of Destoxican, follow the procedure below according to the dosage indicated:

Dosage 50 mg (1 tablet) per day:
Take the missed dose as soon as possible. However, if you don't remember until the next day, skip the missed dose and follow the usual procedure.

Three-weekly doses of 100 mg (2 tablets) on Mondays and Wednesdays and 150 mg (3 tablets) on Fridays:
If you forget on Monday or Wednesday, take the missing 100 mg (2 tablets) as soon as possible. However, if you don't remember until the next day, take 50 mg (1 tablet) the next day and follow the usual dosage.

If you forgot your dose on Friday, take the missing 150 mg (3 tablets) as soon as possible on the same day. However, if you don't remember on the same day, take 100 mg (2 tablets) on Saturday and if you don't remember until Sunday, take only 50 mg (1 tablet) and follow the usual dosage on Monday.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In patients who have not completely detoxified from external opiates, Destoxican can precipitate or exacerbate opiate withdrawal syndrome.

Gastrointestinal effects
Very common (> 10%): Abdominal pain, cramps, nausea and vomiting. These effects can be serious enough to lead to discontinuation of therapy.
Common (1-10%): constipation and anorexia
Uncommon (< 1%): diarrhoea, flatulence, sneezing, haemorrhoids, epigastric pain or heartburn and ulcers.

Effects on the Nervous System
Very common (> 10%): headache, asthenia, insomnia, anxiety and nervousness.
Common (1-10%): increased energy, irritability, dizziness, headaches
Uncommon (< 1%): paranoia, fatigue, restlessness, confusion, dysphoria, disorientation, hallucinations, nightmares, drowsiness and malaise.

Musculoskeletal effects
Very common (> 10%): muscle and joint pain.
Uncommon (< 1%): tremors, muscle twitches and pain in the shoulders, legs and knees.

Dermatological effects
Common (1-10%): rash
Uncommon (< 1%): oily skin, itching, acne, athlete's foot and alopecia.

Respiratory and cardiovascular effects
Uncommon (< 1%): nasal congestion, rhinorrhoea, sternutatory crises, odynophagia (sore throat), mucorrhoea (excessive mucus production), hoarseness, cough, epistaxis and dyspnoea, phlebitis, oedema, increased systolic and diastolic blood pressures, non-specific changes in the electrocardiogram, palpitation and tachycardia. Systolic pressures returned to their pre-treatment values after the first week of treatment in some patients.

Other effects
Common (1-10%): chills, thirst.
Uncommon (< 1%): urinary frequency and dysuria; blurred vision, sensitivity to light, burning, oedema and itchy eyes; otalgia (earache); lymphocytosis, decreased haematocrit, increased appetite, weight loss or weight gain, fever, xerostomia, inguinal pain, increased gland volume, cooling of the feet and hot flushes.

There was idiopathic thrombocytopenic purpura in a patient taking naltrexone: the patient recovered after stopping therapy and starting corticosteroid therapy.

A hypersensitivity reaction characterised by an allergic rash was observed in one patient, which disappeared after 5 days following discontinuation of therapy.

If you notice any undesirable effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get any side effects, including any possible side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to INFARMED, I.P. through the contacts below. By reporting side effects, you will help provide more information on the safety of this medicine.

Website: http://www.infarmed.pt/web/infarmed/submissaoram
(preferentially) or via the following contacts:
Direção de Gestão do Risco de Medicamentos
Parque da Saúde de Lisboa, Av. Brasil 53
1749-004 Lisboa
Phone: +351 21 798 73 73
Medicines line: 800222444 (free)
E-mail: farmacovigilancia@infarmed.pt

5. How to store Destoxican

Do not store above 25ºC.

Store in original packaging.

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

Do not use this medicine after the expiry date printed on the outer carton after EXP. 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. Contents of the pack and other information

What Destoxican contains
The active substance is naltrexone (in the form of hydrochloride). Each tablet contains 50 mg of Naltrexone hydrochloride;
The other components are: sucrose, microcrystalline cellulose, yellow-orange colouring (E110), alginic acid and magnesium stearate.

What Destoxican looks like and contents of the pack

Destoxican comes in the form of tablets with breakline and is dosed at 50 mg. The tablets are packed in an HDPE bottle with a tamper-evident white HDPE cap, containing a desiccant agent.

Destoxican is available in packs of 14, 20, 50 and 60 tablets. Destoxican is also available as a 50 mg/20 ml oral solution.

Not all packs sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Pentafarma - Sociedade Tecnico-Medicinal, S.A.
Rua da Tapada Grande, nº 2, Abrunheira
2710-228 Sintra
Portugal

Manufacturer
Atlantic Pharma – Produções Farmacêuticas, S.A.
Rua da Tapada Grande n.º2, Abrunheira,
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Iberfar - Indústria Farmacêutica S.A.
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