

PACKAGE LEAFLET

Package leaflet: Information for the user

Naltrexone 50 mg film-coated tablets (Naltrexone hydrochloride)

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

1. What Naltrexone is and what it is used for

Naltrexone is used as part of a treatment programme to help you stop taking opiates and remain off of them.

Naltrexone belongs to a group of medicines called opiate antagonists. It blocks the euphoric feelings (highs) that you may experience after taking opiates. In treatment for withdrawal from opiates it will reduce the craving.

Naltrexone tablets do not cause dependency.

2. What you need to know before you take Naltrexone

Do not take Naltrexone if:

- you are allergic to naltrexone hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- you have severe liver problems or acute hepatitis
- you have severe kidney problems
- you are taking opioid-containing drugs
- you are taking methadone
- you are opioid-addicted (without successful withdrawal)
- you experience acute symptoms of opioid withdrawal
- you experience withdrawal symptoms after a naloxone injection or your urine tests positive for opiates.

Warnings and precautions

Your treatment should be started by a physician experienced in treatment of addictions.

- **Don't** take opiates whilst taking Naltrexone tablets. Although Naltrexone will normally block some of the effects (i.e. the highs), if you take high doses of opiates, you may experience breathing difficulties and problems with your circulation (opiate poisoning).
- You should not use Naltrexone if you are still addicted to opiates as Naltrexone will cause severe withdrawal symptoms in this situation.
- You must inform every doctor that treats you that you are taking Naltrexone. Non-opiate based anaesthetics should be used if you require an anaesthetic in an emergency situation. If you have to

use opiate containing anaesthetics, you may need higher doses than usual. You may also be more sensitive to the side-effects (breathing difficulties and circulatory problems).

- You **must not** try to overcome the blocking effect of Naltrexone with high doses of opiates. There is a risk that the opiates could still be in your body after the effects of Naltrexone have passed. If this occurs, you could unintentionally overdose with serious consequences.
- Naltrexone is removed from the body by the liver and kidney. Liver problems are common in opiate-dependant individuals. Your doctor will carry out liver function tests before and during treatment.

Other medicines and Naltrexone

Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Some common medicines contain opiates and these may not work when you are taking Naltrexone. You should inform your doctor if you need cough-mixtures or medicines against diarrhoea or pain since these may contain opiates.

If, despite the contraindication to use in conjunction, opioid containing drugs are needed in emergency cases the suitable dose for pain relief can be higher as usual. Close monitoring through the doctor is absolutely necessary because occurring respiratory depression and other symptoms may be stronger and longer-lasting.

Naltrexone with food and drink

Food and drink do not interfere with the effects of Naltrexone.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Naltrexone should only be used in pregnancy if the benefit to the mother is greater than the possible risk.

Breastfeeding is not recommended if you are taking Naltrexone.

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

Driving and using machines

Naltrexone may make you feel less alert or drowsy. You should not drive or operate machines if you are affected.

Naltrexone contain lactose

Naltrexone contains lactose (a kind of sugar). If you have ever been told that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Naltrexone

Use in adults

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

The initial dose of Naltrexone is half a tablet (25 mg) on the first day of treatment. After that the usual dose is one tablet per day (50 mg). Your doctor may prescribe a different dosage depending on your individual needs.

The amount of time you should take Naltrexone for will be decided by your doctor. The usual length of treatment is three months. However, in certain cases, a longer period of treatment may be beneficial.

Use in children and adolescents

Naltrexone should not be used in children and adolescents under 18 years.

Use in elderly

There are insufficient data on the safety and efficacy for this indication in elderly patients.

If you take more Naltrexone than you should

If you take more Naltrexone than you should, tell your Doctor or Pharmacist or contact your nearest hospital emergency department immediately.

If you forget to take Naltrexone

Do not take a double dose to make up for a forgotten dose. Never take more than your prescribed dose at one time.

If you stop taking Naltrexone

After stopping treatment with Naltrexone you may be more sensitive to the effects of opiates. You could unintentionally overdose, even if you take the same dose as you previously used. This is because you build up tolerance whilst taking opiates and once you stop, this tolerance is lost. If you take a high dose, this could have severe consequences or in extreme cases may even be fatal.

4. Possible side effects

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

The most serious side effects occurring in people taking Naltrexone include feeling depressed, feeling suicidal, attempted suicide and hallucinations. Although these effects are rare or uncommon, if you do experience any of these, then you must contact your Doctor or Pharmacist immediately for help and support.

The following side effects to Naltrexone are sorted according to their frequency:

Very common (may affect more than 1 in 10 patients)

Anxiety, sleeplessness, headache, restlessness, nervousness, abdominal pain, nausea, vomiting, joint and muscle pain, weakness

Common (may affect up to 1 in 10 patients)

Decreased appetite, heart palpitations, increased heart rate, anomalies in ECG, libido disorders, thirst, dizziness, increased tear secretion, chest pains, diarrhoea, constipation, rash, delayed ejaculation, erectile dysfunction, increased energy, irritability, increased sweating, affective disorders

Uncommon (may affect up to 1 in 100 patients)

Oral herpes, athlete's foot, enlarged lymph nodes, hallucination, confusion, depression, paranoia, disorientation, nightmares, agitation, abnormal dreams, shaking, drowsiness, vision disorders, irritation and swelling of the eye, photophobia, eye pain or tiredness, eye strain, blood pressure changes, hot flushes, nasal congestion, nasal discomfort, rhinorrhoea (runny nose), sneezing, disorders of the mouth and throat, increased sputum, sinus disorders, disorders of the voice, coughing, breathlessness, yawning, flatulence, haemorrhoids, ulcer, mouth dryness, hepatic disorders, increased bilirubin levels, hepatitis, seborrhea (mild dermatitis), acne, hair loss, itching, groin pain, abnormally frequent urination, painful urination, tinnitus, vertigo, ear pain, ear discomfort, increased appetite, weight loss, weight gain, fever, pain, sensation of cold in extremities

Rare (may affect up to 1 in 1,000 patients)

Decreased number of blood platelets, thoughts of suicide, attempted suicide

Very rare (may affect up to 1 in 10,000 patients)

Breakdown of skeletal muscle tissue

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Naltrexone

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

Do not use this medicine after the expiry date which is stated on the carton and blister after “Exp”. The expiry date refers to the last day of that month.

Do not store above 25 °C. Store in the original package in order to protect from moisture.

If you notice any defects in the tablets such as chipped or broken tablets, ask your pharmacist for advice before taking them.

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 Naltrexone contains

Each tablet contains 50 mg of the active substance naltrexone hydrochloride.

The other ingredients are:

Lactose monohydrate, powdered cellulose, microcrystalline cellulose, silica colloidal anhydrous, crospovidone, magnesium stearate, hypromellose, titanium dioxide (E 171), macrogol 4000, black ferric oxide (E172), red ferric oxide (E 172), yellow ferric oxide (E 172).

What Naltrexone looks like and contents of the pack

Naltrexone film-coated tablets are beige and capsule-shaped, with a break-line across the middle. The film-coated tablet can be divided in to equal halves.

Naltrexone is available in packs of 7, 14, 28, 30 and 56 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

AOP Orphan Pharmaceuticals AG, Vienna, Austria

Manufacturer

Haupt Pharma GmbH, Wolfratshausen, Germany.

Amomed Pharma GmbH, 1150 Vienna, Austria

This medicinal product is authorised in the Member States of the EEA under the following names:

Czech Republic Naltrexone AOP 50 mg potahované tablety

Denmark Naltrexon AOP filmovertrukne tabletter

Germany	Naltrexon HCl aop 50 mg Filmtabletten
Hungary	Naltrexone aop 50 mg filmtabletta
Ireland	Naltrexone 50 mg film-coated tablets
Latvia	Naltrexone aop 50 mg apvalkotās tablets
Lithuania	Naltrexone aop 50 mg plėvele dengtos tabletės
Netherlands	Naltrexon HCl aop 50 mg, filmomhulde tabletten
Slovenia	Naltrekson aop 50 mg filmsko obložene tablet
United Kingdom	Naltrexone hydrochloride 50 mg film-coated tablet

The leaflet was last revised in September 2020