

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ethylex 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 onto 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.

In this leaflet:

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

1. What Ethylex is and what they are used for

Ethylex is used as an additional therapy for alcohol dependence within a comprehensive treatment program including psychological guidance to support abstinence.

The effect of Ethylex-therapy is that alcohol-intake is extensively diminished because the desire for alcohol is reduced. More patients are able to maintain their abstinence and stay relapse-free.

Ethylex does not cause dependency.

2. What you need to know before you take Ethylex

Do not take Ethylex if:

- You are allergic to Naltrexone hydrochloride or any of the other ingredients (See Section 6)
- You are taking opiates (including opioid containing medication)
- Your urine tests positive for opiates
- You experience withdrawal symptoms after a naloxone injection
- You have severe liver problems
- You have severe kidney problems

Warnings and precautions

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

- You must inform every doctor that treats you that you are taking Ethylex.
- You should not use Ethylex if you are still addicted to opiates as Naltrexone will cause severe withdrawal symptoms in this situation.
- Ethylex is removed from the body by the liver and kidney. Your doctor will carry out liver function tests before and during treatment.
- If you go for any blood tests, inform the doctor carrying out the test that you are taking Ethylex as these tablets can affect the results of liver function tests.
- Non-opiate based anaesthetics should be used if you require an anaesthetic in an emergency situation.
- If you become pregnant you have to inform your doctor.

Other medicines and Ethylex:

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

You should inform your doctor if you need cough-mixtures or medicines against diarrhoea or pain since these may contain opiates and the use in conjunction with an opioid-containing medication is contraindicated

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.

Pregnancy and breast-feeding

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

The doctor has to decide whether Ethylex 50 mg film-coated tablets can be taken during pregnancy and lactation considering the risk for the mother and the child.

Driving and using machines:

Ethylex can cause dizziness and feebleness and therefore may impair the mental and/or physical abilities required for performance of potentially hazardous tasks such as driving a car or using machines.

Important information about some of the ingredients of Ethylex:

Ethylex contains lactose (a kind of sugar). If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take EthylexUse in adults:

Always take Ethylex exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is 1 tablet per day.

Duration of treatment:

The duration of Ethylex-treatment is determined by your doctor. Usually Ethylex should be taken for 3 months, in certain cases prolonged administration may be necessary.

Use in children and adolescents:

Ethylex should not be used in children and adolescents below 18.

Use in elderly:

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

If you take more Ethylex than you should

In case of overdose treatment should be symptomatic. Effects related to overdose of Ethylex are not known.

4. Possible side effects

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

The following side effects may appear:

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 the ECG, thirst, dizziness, increased tear secretion, pain in the chest, 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, libido disorders, 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 uicide, attempted suicide

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

Breakdown of skeletal muscle tissue

If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

5. How to store Ethylex

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

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

Store below 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.

Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Ethylex 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 Ethylex looks like and contents of the pack

Ethylex 50 mg tablets are beige and capsule-shaped, with a break-line across the middle. The tablet can be divided into equal halves.

Ethylex 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

Walter Ritter GmbH + Co. KG
Spaldingstraße 110 B
20097 Hamburg
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Manufacturer

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AOP Orphan Pharmaceuticals GmbH

Leopold-Ungar-Platz 2
1190 Vienna
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This medicinal product is authorised in the Member States of the EEA under the following names:

Finland	Naltrexon Walter Ritter 50 mg tabletti
France	Naltrexone Viatrix 50 mg, comprimé pelliculé sécable
Ireland	Ethylex 50 mg film-coated tablets
Netherlands	Naltrexonhydrochloride 50 PCH, filmomhulde tabletten 50 mg
Sweden	Naltrexon Walter Ritter 50 mg filmdragerade tablett

The leaflet was last approved in