

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Adepend 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 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.

In this leaflet:

1. What Adepend 50 mg film-coated tablets are and what they are used for
2. What you need to know before you take Adepend 50 mg film-coated tablets
3. How to take Adepend 50 mg film-coated tablets
4. Possible side effects
5. How to store Adepend 50 mg film-coated tablets
6. Contents of the pack and other information

1. What Adepend 50 mg film-coated tablets are and what they are used for

Adepend is used as part of a comprehensive programme of treatment against alcoholism to reduce the risk of relapse, as support treatment in abstinence and to reduce the craving for alcohol.

Adepend 50 mg film-coated tablets diminish alcohol-intake extensively because the desire for alcohol is reduced. More patients are able to maintain their abstinence and stay relapse-free.

Adepend 50 mg film-coated tablets do not cause dependency.

2. What you need to know before you take Adepend 50 mg film-coated tablets

Do not take Adepend 50 mg film-coated tablets

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

Warnings and precautions

- Your treatment should be started and supervised by a physician experienced in treatment of alcohol addiction.
- You must inform every doctor treating you that you are taking Adepend 50 mg film-coated tablets.
- Adepend 50 mg film-coated tablets may cause life-threatening withdrawal symptoms to opioid-addicted patients
- Please inform your doctor if you are suffering from liver or kidney diseases. Liver function tests should be conducted before and during therapy.

- If you go for any blood tests, inform your doctor that you are taking Adepend 50 mg film-coated tablets as these tablets can affect the results of liver function tests.
- During treatment with Adepend 50 mg film-coated tablets painful conditions should not be treated with opioids.
- After treatment with Adepend 50 mg film-coated tablets you might be more sensitive to opioid containing medicines. (e.g. opioid containing cough medication, opioid containing medication for symptomatic treatment of common cold or opioid containing medication for diarrhea etc.).
- Please inform your doctor if you become pregnant.
- For patients with additional opioid-addiction:
Do not take opioids after use of Adepend 50 mg film-coated tablets.
Although Adepend 50 mg film-coated tablets inhibit the opioid-effect there might be opioids in your body when efficacy of Adepend 50 mg film-coated tablets has already decreased. Accidentally overdoes might have severe or fatal consequences (respiratory depression).

Other medicines and Adepend 50 mg film-coated tablets

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

During treatment with Adepend 50 mg film-coated tablets opioid containing medicines should be avoided as the effect might be decreased. Please inform your doctor if you take drugs against cough, common cold, diarrhoea or pain. He will prescribe non-opioid containing medicines.

If you need opioid analgesia in emergency situations the dose needed may be higher than normal.

In this situation a close attention by an experienced physician is **strictly** required because respiratory depression, circulatory disturbance and other symptoms (itching and other skin manifestations) might be stronger and longer lasting.

Pregnancy, breast-feeding and fertility

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.

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

Driving and using machines

Driving vehicles should be avoided.

Do not use any tools or machines since Adepend 50 mg film-coated tablets may impair the mental and physical abilities.

Adepend 50 mg film-coated tablets contain lactose. If you have been told by your doctor that you have intolerance to some sugars, please contact your doctor before taking this medicinal product.

3. How to take Adepend 50 mg film-coated tablets

Use in adults and elderly

Always take Adepend 50 mg film-coated tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Unless prescribed by your doctor, the usual dose is 1 tablet per day.

Use in children and adolescents (below 18 years).

Adepend 50 mg film-coated tablets should not be used in children and adolescents below 18 years.

Use in patients with liver or kidney diseases

Please inform your doctor if you are suffering from liver or kidney diseases. He has to decide whether the dosage of Adepend 50 mg film-coated tablets will be adjusted or the treatment discontinued.

Method of administration

Adepend 50 mg film-coated tablets are taken with a liquid under fasting conditions.

Duration of treatment

The duration of treatment with Adepend 50 mg film-coated tablets is determined by your doctor. Usually Adepend 50 mg film-coated tablets should be taken for at least 3 months, in certain cases prolonged administration may be necessary.

If you take more Adepend 50 mg film-coated tablets than you should

In case of overdosage please inform your doctor. Other side effects as mentioned below are not known.

If you forget to take Adepend 50 mg film-coated tablets

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

If you stop taking Adepend 50 mg film-coated tablets

Do not stop the treatment without consulting your doctor.

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

4. Possible side effects

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

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.

The following side effects may appear:

Very common (affects more than 1 in 10 users):

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

Common (may affect 1 to 10 users in 100):

Decreased appetite, heart palpitations, increased heart rate, anomalies in the ECG, libido disorders, 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 1 to 10 users in 1.000):

Oral herpes, athlete's foot, disease of the lymph nodes, hallucination, confusion, despondency, depression, paranoia, disorientation, nightmares, agitation, abnormal dreams, shaking, drowsiness, vision disorders, irritation and swelling of the eye, photophobia, eye pain or tiredness, colour asthenopia, blood pressure changes, hot flushes, nasal congestion, nasal discomfort, rinorrhoea, 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, 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 arms and legs

Rare (may affect 1 to 10 users in 10.000):

Decreased number of blood platelets, suicidal ideation, attempted suicide

Very rare (may affect less than 1 user in 10.000):

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Adepend 50 mg film-coated tablets

Keep out of the sight and reach of children.

Do not use Adepend 50 mg film-coated tablets after the expiry date which is stated on the blister and carton.

Do not store above 25 °C.

Store in the original package in order to protect from light.

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

Do not be 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 Adepend 50 mg film-coated tablets contain

The active substance is naltrexone hydrochloride.
Each tablet contains 50 mg naltrexone hydrochloride.

The other ingredients are

Tablet core

Lactose monohydrate, powdered cellulose, microcrystalline cellulose, silica colloidal anhydrous, crospovidone, magnesium stearate

Film-coat

Lactose-monohydrate, hypromellose, titanium dioxide (E 171), macrogol 4000, black ferric oxide (E 172), red ferric oxide (E 172), yellow ferric oxide (E 172)

What Adepend 50 mg film-coated tablets look like and contents of the pack

Beige film-coated tablets with a break-score on each side.
The tablet can be divided into equal doses.

Adepend 50 mg film-coated tablets are available in packs of 7, 10, 14, 28, 30 and 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Orpha-Devel Handels und Vertriebs GmbH
Wintergasse 85/1B
3002 Purkersdorf

Manufacturer:

AOP Orphan Pharmaceuticals GmbH,
Leopold-Ungar-Platz 2
1190 Vienna
Austria

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

Austria	Ethylex 50 mg Filmtabletten
Czech Republic	Adepend 50 mg potahované tablety
Denmark	Adepend 50 mg filmovertrukket tablet
Germany	Adepend 50 mg Filmtabletten
Hungary	Adepend 50 mg filmtabletta
Poland	Adepend, 50 mg, tabletki powlekana
Slovakia	Adepend 50 mg filmom obalené tablety
Slovenia	Adepend 50 mg filmsko obložene tablete
United Kingdom	Adepend 50 mg film-coated tablets

The leaflet was last approved in 12/2021.

The following information is intended for medical or healthcare professionals only:

In case of overdose patients should be supervised permanently and treated symptomatically.