Package leaflet: Information for the user
Naltrexone Hydrochloride 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.

What is in this leaflet:
1. What Naltrexone Hydrochloride film-coated tablets is and what it is used for
2. What you need to know before you take Naltrexone Hydrochloride film-coated tablets
3. How to take Naltrexone Hydrochloride film-coated tablets
4. Possible side effects
5. How to store Naltrexone Hydrochloride film-coated tablets
6. Contents of the pack and other information

1. What Naltrexone Hydrochloride film-coated tablets is and what it is used for

The active ingredient, naltrexone hydrochloride, belongs to a group of medicines other nervous system drugs; drugs used in addictive disorders

What is Naltrexone Hydrochloride film-coated tablets used for
Naltrexone hydrochloride is used in combination with other medicines or therapy to help those who are dependent on opioids drugs overcome their addiction

Naltrexone acts by blocking receptors in the brain to block the action of opioids. Individuals will no longer experience the euphoria previously experienced after taking opioids.

Naltrexone hydrochloride is used with a comprehensive treatment program to help those who are dependent on alcohol maintain abstinence (self denial).

Naltrexone Hydrochloride film-coated tablets does not cause dependency.

2. What you need to know before you take Naltrexone Hydrochloride film-coated tablets

Do not take Naltrexone Hydrochloride 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 have severe kidney problems
- if you have severe liver problems
- if you have an acute liver infection
- if you are dependent on opiates
- if your urine tests positive for opiates
- if you experience withdrawal symptoms after a naloxone injection

- if you are using a medicinal product containing an opioid, for example certain cough medicines, medicines to treat diarrhoea (such as kaolin and morphine) and analgesics (pain killers). Note: Naltrexone hydrochloride does not have a blocking effect on analgesics which do not contain any opioids (such as ibuprofen, paracetamol and acetylsalicylic acid).
- if you take methadone.

If you think any of these apply to you, do not take the tablets. Talk to your doctor first and follow his advice.

Warnings and precautions
Talk to your doctor or pharmacist before taking Naltrexone Hydrochloride film-coated tablets

- **Do not** take opiates whilst taking Naltrexone Hydrochloride film-coated tablets. Although Naltrexone Hydrochloride film-coated tablets 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 Hydrochloride film-coated tablets if you are still addicted to opiates as Naltrexone Hydrochloride film-coated tablets will cause severe withdrawal symptoms in this situation.
- You must inform every doctor that treats you that you are taking Naltrexone Hydrochloride film-coated tablets. 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 Hydrochloride film-coated tablets with high doses of opiates. There is a risk that the opiates could still be in your body after the effects of Naltrexone Hydrochloride film-coated tablets 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.

Consult your doctor if one of the above warnings applies to you, or has done so in the past.

Children and adolescents
Naltrexone should not be used in children and adolescents under 18 years of age, since clinical data in this age-group are lacking. Safe use in children has not been established.

Use in older people
There are insufficient data on the safety and efficacy of naltrexone for this indication in elderly patients.

Other medicines and Naltrexone Hydrochloride film-coated tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Some common medicines contain opiates and these may not work when you are taking Naltrexone Hydrochloride film-coated tablets. 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 Hydrochloride film-coated tablets with food and drink
Taking food and drink has no influence on your treatment with Naltrexone Hydrochloride film-coated tablets.

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.
The safety of using Naltrexone Hydrochloride film-coated tablets during pregnancy has not been demonstrated.

It is not known whether naltrexone is excreted in breast milk. Because the safety of using naltrexone in neonates and children has not been demonstrated, breast-feeding is not advised while using Naltrexone Hydrochloride film-coated tablets.

Driving and using machines
Naltrexone may impair the mental and/or physical abilities required for performance of potentially hazardous tasks such as driving a car or operating machinery.

Naltrexone Hydrochloride film-coated tablets contains lactose monohydrate
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Naltrexone Hydrochloride film-coated tablets

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

The recommended dose is 1 tablet per day unless a different dose has been prescribed by your doctor.

- Naltrexone Hydrochloride film-coated tablets taken orally with small amount of liquid.
- Before starting to take Naltrexone Hydrochloride film-coated tablets, you must not have used any other opiates for at least 7-10 days. Your doctor can use a test to establish whether you are clear of these drugs before you start the treatment. Generally speaking, treatment begins at a dose of 1/2 tablet per day (25 mg), later increased to 1 tablet per day (50 mg).
- Naltrexone Hydrochloride film-coated tablets must be used exclusively for the disorder for which your doctor has prescribed this medicine.
- It is important to follow your doctor's instructions closely with respect to the dosage.
- It is important that you take Naltrexone Hydrochloride film-coated tablets for the period of time prescribed by your doctor. The treatment can last for three months or longer, according to the judgment of your doctor. Naltrexone Hydrochloride film-coated tablets should be combined with other forms of treatment.

If you notice that the effect of Naltrexone Hydrochloride film-coated tablets is too strong or not strong enough, consult your doctor or pharmacist.

If you take more Naltrexone Hydrochloride film-coated tablets than you should
If you have taken more than the prescribed number of tablets, you should inform your doctor immediately.

If you forget to take Naltrexone Hydrochloride film-coated tablets
You can still take the Naltrexone Hydrochloride film-coated tablets when you remember.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Naltrexone Hydrochloride film-coated tablets
If you consider stopping before the end of the agreed period of treatment, always discuss this with your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Naltrexone Hydrochloride film-coated tablets can affect your liver function. Your doctor may carry out blood test before you start treatment and at various times during treatment to monitor your liver function.

If you notice any of the following, **stop taking** Naltrexone Hydrochloride film-coated tablets and contact your doctor **immediately:**

- Abdominal pain lasting more than a few days
- White bowel movements
- Dark urine
- Yellowing of your eyes

As these may be signs that your liver isn't working well.

If you notice any of the following, tell your doctor immediately:

- Swelling of the face, lips, or tongue
- Skin rash
- Difficulty breathing

As these may be signs of an allergic reaction

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

- Difficulty sleeping
- Anxiety or nervousness
- Abdominal cramps and pain
- Feeling sick and/or being sick
- Lack of energy or strength
- Joint and/or muscle pain
- Headaches
- Fast or irregular heartbeat
- Restlessness

Common (may affect up to 1 in 10 people)

- Irritability
- Mood swings
- Increased energy
- Despodency
- Dizziness
- Shivering
- Increased or excessive sweating
- Vertigo
- Increased lacrimation
- Increased heart beat
- Palpitations
- Change in ECG readings
- Pain in the chest
- Diarrhoea
- Constipation
- Rash
- Urine retention
- Delayed ejaculation
- Erectile dysfunction
- Lack of appetite
- Thirst

- Energy increased
- Chills

Uncommon (may affect up to 1 in 100 people)
- Some infections (e.g. Oral herpes, tinea pedis)
- Swollen/enlarged lymph nodes
- Hallucinations
- Confusional state
- Depression
- Paranoia
- Disorientation
- Nightmare
- Agitation
- Reduced libido
- Abnormal dreams
- Tremor
- Drowsiness
- Blurred vision
- Irritation in eye
- Abnormal intolerance to visual perception of light
- Swelling of eyes
- Eye pain
- Strain in eye
- Ear discomfort
- Ear pain
- Ringing of ear
- Vertigo
- Blood pressure fluctuation
- Flushing
- Nasal congestion & discomfort
- Sneezing
- Sputum increased
- Sinus problems
- Voice disorders
- Shortness of breath/difficulty in breathing
- Cough
- Yawning
- Runny nose
- Flatulence
- Piles
- Ulcer
- Dry mouth
- Liver disorders (including inflammation of liver)
- Increase in liver enzymes
- Greasy skin
- Pruritus
- Acne
- Hair loss
- Groin pain
- Increased urination
- Inflammation of urinary bladder
- Increased appetite

- Weight loss
- Weight gain
- Fever
- Pain
- Coldness in hands or feet
- Feeling hot

Rare (may affect up to 1 in 1,000 people)
- Suicidal thoughts
- Attempt to suicide
- Bleeding disorder
- Speech disorder

Very rare (may affect up to 1 in 10,000 people)
- Euphoria
- Skin rash/ eruptions
- Skeletal muscle damage

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 Hydrochloride film-coated tablets

- 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 label after 'EXP'. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- 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 Hydrochloride film-coated tablets contains

The active substance is Naltrexone hydrochloride.

Each film-coated tablet contains 50 mg Naltrexone Hydrochloride.

The other ingredients are:
Core Tablet: lactose monohydrate, cellulose microcrystalline, crospovidone, colloidal anhydrous silica, magnesium stearate

Film-coating: hypromellose (E464), macrogol 400, polysorbate 80 (E433), iron oxide yellow (E172), iron oxide red (E172), titanium dioxide (E171)

What Naltrexone Hydrochloride film-coated tablets looks like and contents of the pack

Naltrexone Hydrochloride film-coated tablets are available as yellow coloured, oval, biconvex, film coated tablets with breakline on one side and plain on other side.
The tablet can be divided into equal halves.

Naltrexone Hydrochloride film-coated tablets are available in white opaque PVC/PE/Aclar-Alu blister and Alu – Alu blister packs containing 7, 14, 28, 30, 50 and 56 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation holder & Manufacturer:

Marketing Authorisation holder
Accord Healthcare Ireland Limited,
Euro House, Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer:
Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

Accord Healthcare B.V.,
Winthontlaan 200,
3526 KV Utrecht,
The Netherlands

Accord Healthcare Single Member S.A.
64th Km National Road Athens, Lamia, 32009, Greece

This medicinal product is authorised in the Member States of the European Economic Area and the United Kingdom (Northern Ireland) under the following names:

Name of the Member State	**Name of the medicine**
Netherland	Naltrexon Hydrochloride Accord 50 mg filmomhulde tabletten
Belgium	Naltrexone Accord 50 mg filmomhuldetablet
Denmark	Naltrexon Accord
Estonia	Naltrexone Accord
Spain	Naltrexona Accord 50 mg comprimidos recubiertos con película
Finland	Naltreksonihydrokloridi Accord 50 mg Kalvopäävysteinen Tabletti
Germany	Naltrexonhydrochlorid Accord 50 mg Filmtabletten
Ireland	Naltrexone Hydrochloride 50 mg Film coated Tablets
Italy	Naltrexone Accord Healthcare 50 mg compresse rivestite con film
Lithuania	Naltrexone Hydrochloride Accord 50 mg plėvele dengtos tabletės
Latvia	Naltrexone Hydrochloride Accord 50 mg Film coated Tablets
Norway	Naltrexon Accord 50 mg Filmdrasjert tablett
Portugal	Naltrexona Hydrochloride Accord
Poland	Naltrexona Hydrochloride Accord
United Kingdom (Northern Ireland)	Naltrexone Hydrochloride 50 mg Film coated Tablets

Austria	Naltrexone Accord 50 mg Filmtabletten
Bulgaria	Naltrexone Акорд 50 мг филмирани таблетки
Cyprus	Naltrexone Hydrochloride Accord 50 mg Film coated Tablets
Sweden	Naltrexone Accord 50 mg filmdragerad tablet

This leaflet was last revised in November 2024.