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

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 drugs such as heroin (opioids), overcome their addiction
It is indicated as supportive therapy in maintaining abstinence (self denial) in alcohol-dependent patients.
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.

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 are dependent on opiates or are undergoing treatment involving abstinence (self denial), since abstinence syndrome or an exacerbation of abstinence syndrome can occur.
- if you are continuously 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 have an acute liver infection or if your liver function is poor.
- if patients have withdrawal symptoms after naloxone hydrochloride administration.
- 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

- If you have liver or kidney diseases. Patients who have used Naltrexone Hydrochloride film-coated tablets can still have hypersensitivity reactions when taking medicines containing opiates, even in the period after use.
- Before starting the treatment. Your doctor may carry out a blood test. Blood tests are also necessary during treatment, because Naltrexone Hydrochloride film-coated tablets is processed by the liver and these tests show how well your liver is working.
- If patient needs opioid treatment e.g. opioid analgesic or anaesthesia in emergency situation, opioid dose is higher to achieve the therapeutic effect. In these cases respiratory depression and circulatory effect will be more profound and longer lasting.
- Naltrexone treatment must begin only when the opioid has been discontinued for a sufficiently long period (about 5 to 7 days for heroin and at least 10 days for methadone).
- Liver function test abnormalities have been reported in obese and elderly patients taking naltrexone who have no history of drug abuse.
- It is important to stop taking Naltrexone Hydrochloride film-coated tablets immediately and to tell your doctor in the event of the following symptoms: persistent abdominal pain, white stools, dark urine or if your eyes and/or skin turn yellow.

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.
- Simultaneous use of Naltrexone Hydrochloride film-coated tablets and medicines containing opiates must be avoided. If you try to overcome the blocking action of Naltrexone Hydrochloride film-coated tablets with large quantities of opioids, you will find yourself in great difficulties. Such action can lead to breathlessness, coma and can even be fatal.
- Simultaneous use of Naltrexone Hydrochloride film-coated tablets and thioridazine can cause drowsiness. No other harmful affects due to interaction between Naltrexone Hydrochloride film-coated tablets and other medicines are known.
- Medicines can have a reciprocal effect on one another.

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
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.
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.

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
This medicinal product contains 192.85 mg of lactose. According to dosage recommendations each dose supplies up to 192.85 mg of lactose. If you have been told by your doctor that you have an intolerance to some

sugars, contact your doctor before taking this medicinal product.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

For United Kingdom: Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard
For Ireland - Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address:
FREEPOST
Pharmacovigilance Section
Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie (http://www.imb.ie)
e-mail: imbpharmacovigilance@imb.ie

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 Limited,

Sage House, 319, Pinner Road,
North Harrow, Middlesex, HA1 4HF,
United Kingdom.

Manufacturer:
Accord Healthcare Limited,
Sage House, 319, Pinner Road,
North Harrow, Middlesex, HA1 4HF,
United Kingdom.

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

This leaflet was last revised in 11/2019.