**Package leaflet: Information for the user**

# Naltrexone hydrochloride 50mg film-coated tablets

**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.

The name of your medicine is Naltrexone hydrochloride 50mg film-coated tablets but will be referred to as Naltrexone hydrochloride throughout this leaflet.

**What is in this leaflet:**


## 1. What Naltrexone hydrochloride 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 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 does not cause dependency.

## 2. What you need to know before you take Naltrexone hydrochloride

**Do not take Naltrexone hydrochloride:**
- 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.
- **Do not** take opiates whilst taking Naltrexone hydrochloride. Although Naltrexone hydrochloride 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 if you are still addicted to opiates as Naltrexone hydrochloride will cause severe withdrawal symptoms in this situation.
- You must inform every doctor that treats you that you are taking Naltrexone hydrochloride. 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 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 hydrochloride 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 hydrochloride for this indication in elderly patients.

**Other medicines and Naltrexone hydrochloride**
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. 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 with food and drink**
Taking food and drink has no influence on your treatment with Naltrexone hydrochloride.

**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 hydrochloride 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 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

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 taken orally with small amount of liquid.
- Before starting to take Naltrexone hydrochloride, 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 (25mg), later increased to 1 tablet per day (50mg).
- Naltrexone hydrochloride 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 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 should be combined with other forms of treatment.

If you notice that the effect of Naltrexone hydrochloride is too strong or not strong enough, consult your doctor or pharmacist.

**If you take more Naltrexone hydrochloride 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**
You can still take the Naltrexone hydrochloride when you remember.
Do not take a double dose to make up for a forgotten dose.

**If you stop taking Naltrexone hydrochloride**
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 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 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
- Despondency
- 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 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 Naltrexone hydrochloride

Keep out of the sight and reach of children.
This medicine does not require any special storage conditions.
Do not take the tablets after the expiry date which is stated on the carton and blister labels after 'Exp'. The expiry date refers to the last day of that month.

If the tablet becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.
Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
Medicines should not be disposed of 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 Naltrexone hydrochloride contains**
The active ingredient is naltrexone hydrochloride.
Each film-coated tablet contains 50mg naltrexone hydrochloride.
The other ingredients are:
Tablet core: lactose monohydrate, microcrystalline cellulose, crospovidone, colloidal anhydrous silica and magnesium stearate.

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

**What Naltrexone hydrochloride looks like and contents of the pack**
Naltrexone hydrochloride is yellow coloured, oval, biconvex, film coated tablets with breakline on one side and plain on the other side. The tablet can be divided into equal halves.

It is available in pack size of 28 tablets.

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

**Procured from within the EU and repackaged by the Product Licence holder:** B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

**Naltrexone hydrochloride 50mg film-coated tablets; PL 18799/4085**

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