Package leaflet: Information for the patient
NALOREX®
50 mg Film Coated Tablets
(Naltrexone Hydrochloride)

Read all of this leaflet carefully before you start taking using 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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Nalorex is and what it is used for

The name of your medicine is Nalorex. Nalorex contains the active ingredient naltrexone hydrochloride. Naltrexone hydrochloride belongs to a group of medicines called opioid antagonists.
NALOREX is used together with other forms of treatment such as counselling to help you to remain free from your dependence on heroin, methadone and other similar opiate drugs of addiction.

2. What you need to know before you take Nalorex

Do not take Nalorex if you:

- Have liver failure or hepatitis (inflammation of the liver)
- Are currently dependent on opiate drugs or going through withdrawal
- Are currently taking any medicines which contain any opioids which include certain cough medicines (e.g. mixtures containing dextromethorphan), analgesic pain killers (e.g. morphine, codeine) and some medicines used to treat diarrhoea (e.g. kaolin)
- If you are taking methadone
- If your urine tests are positive for opiates
- Are allergic (hypersensitive) to naltrexone hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- If you have kidney failure

Warnings and precautions
Talk to your doctor or pharmacist or nurse before taking Nalorex:

- If you have any liver or kidney problems
- If you are still taking opiates as Nalorex will cause severe withdrawal symptoms in this situation
- If you have been told you have a problem digesting some sugars (lactose intolerance).

Nalorex is removed from the body by the liver and kidney. Liver problems are common in opiate and alcohol dependant individuals. Your doctor will carry out liver function tests both before and during treatment. Nalorex may cause liver damage in patients with liver disease. Stop taking Nalorex and seek medical attention if you experience symptoms such as stomach pain, dark urine or yellowing of the skin and eyes.

If you are not completely free of opiates, taking Nalorex can cause withdrawal symptoms to start or become worse. Your doctor will only start treatment if you are free from opiates and will perform tests to ensure you do not have any opiates in your body.

If you attempt to overcome the effects of Nalorex with high doses of opioids it may result in life-threatening poisoning by stopping your breathing and blood circulation from working properly.

Medicines containing opioids for pain relief, coughs, colds or diarrhoea will not work whilst you are having treatment with Nalorex. Ask your doctor about an alternative medicine you can use if you need one for this.

After treatment with Nalorex you may be more sensitive to the effects of opiates and at doses lower than you previously tolerated. If you decide to take opiates again, this could lead to life-threatening poisoning or fatal overdose.

If you need pain relief in an emergency situation in hospital tell the doctor you are taking Nalorex so they will know which medicines to use.

People dependent on opioids or other substances of addiction have an increased risk of depression, suicidal thoughts and attempted suicide. Please tell your doctor if you are affected.

Children and adolescent
Nalorex is not recommended in patients below 18 years old.

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

Some common medicines contain opiates. These should not be taken and may not work when you are taking Nalorex. You should inform your doctor if you need medicines to relieve a cough, cold, pain or diarrhoea since these may contain opiates.
If you need to be given opiate containing medicine for pain relief in an emergency situation, you may need higher doses than usual. You may also be more sensitive to the side effects (breathing difficulties and circulatory problems) so this will be done by trained professionals in hospital.

Please tell your doctor if you are taking:

- Medicines used to treat pain (analgesics)
- Medicines to treat coughs (antitussives)
- Methadone or another substitution medicine
- Medicines to manage mental illness e.g droperiol (neuroleptics)
- Sedative medicines e.g. barbiturates, benzodiazepines, hypnotics
- Medicines to relieve anxiety (i.e meprobamate)
- Sedative antidepressants (amitiptyline, doxepin, mianserin, trimipramine)
- Sedative antihistamines
- Medicines to treat high blood pressure (alpha methyldopa)
- Acamprosate
- Thioridazine

Pregnancy, breast-feeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
Breastfeeding is not recommended during naltrexone treatment.

Driving and using machines
Nalorex may make you feel tired or dizzy. Do not drive or operate machinery until you know how this medicine affects you.

Nalorex contains Lactose
This medicine contains lactose. If you have been told that you have an intolerance to some sugars, you should not take Nalorex. Contact your doctor before taking this medicine.

3. How to take NALOREX
Always take Nalorex exactly as your doctor has told you. You should check with your doctor if you are not sure.

You must have stopped taking any opiate drugs for at least 7-10 days before starting Nalorex and must not be showing any signs of withdrawal such as goosebumps, runny nose, excessive tears or sweating and vomiting.

Your doctor will carry out tests which will show that you are free from these drugs before starting your treatment. This will include a urine test and an injection of a small dose of a substance similar to Nalorex through the skin or in a vein. Your doctor will look for any signs of withdrawal before continuing.

The initial dose is usually half a tablet (25 mg) once a day.

This may be increased to one tablet (50 mg) once a day.

Your doctor may decide to use a different dosing regimen such as a higher dose every other day, if this helps you to take your medicine regularly.

You should not take more than 150 mg a day because the chance of having side effects increases.

The tablets should be swallowed with a glass of water.

If you take more Nalorex than you should
If you take too many tablets go to your nearest hospital emergency department or contact your doctor **immediately.**

If you forget to take Nalorex
If you forget to take a tablet, do not worry. Miss out this dose completely and take the next dose as usual. Do not take a double dose to make up for the forgotten dose.

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

4. Possible side effects

Like all medicines, Nalorex can cause side effects although not everybody gets them. Nalorex can affect your liver function. Your doctor may carry out blood tests before you start treatment and at various times during treatment to monitor your liver function.

Tell your doctor immediately if you or your family notice any symptoms listed below:

Allergic reaction may include swelling of the face, lips and tongue; skin rash; difficulty breathing

Liver symptoms may include white bowel movements; dark urine; yellowing of the eyes.

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
• Joint and muscle pain
• Headaches
• Restlessness

Common: may affect up to 1 in 10 people
• Loss of appetite
• Diarrhoea or constipation
• Increased thirst
• Increased energy
• Feeling down
• Irritability and mood changes
• Dizziness
• Skin rash
• Delayed ejaculation, problems getting or maintaining an erection
• Chills
• Chest pain
• Increased sweating and increased flow of tears

• Abnormal heart beats (too fast or too slow)

Uncommon: may affect up to 1 in 100 people
• Changes in size or texture of lymph nodes
• Nasal congestion
• Itching
• Runny nose
• Sneezing
• Sore throat
• Excess mucus
• Trouble with sinus
• Abnormal changes in voice
• Coughing
• Shortness of breath
•Yawning
• Excessive gas production
• Dry mouth
• Painful shoulders, legs or knees
• Piles
• Ulcer
• Twitching
• Shaking of the body
• Groin pain
• Increased frequency of or discomfort during urination
• Oily Skin
• Spots
• Cold sores
• Athletes foot
• Loss of hair
• Depression
• Paranoia
• Confusion
• Hallucinations
• Tired
• Nightmares
• Blurred/burning eyes
• Light sensitive eyes
• Swollen/aching/strained eyes
• Clogged/aching ears
• Ringing in the ears
• Vertigo (spinning or swaying sensation)
• Drowsiness
• Increased appetite
• Weight loss or gain
• Pain

• Fever or feeling hot
• Swollen glands
• Changes in blood pressure
• Flushing
• Cold hands and feet
• Agitation
• Reduced libido
• Liver problems including inflammation

Rare: may affect up to 1 in 1,000 people
• Suicidal thoughts/feelings and attempts
• Bruising/bleeding

Very rare: may affect up to 1 in 10,000 people
• Breakdown of injured skeletal muscle tissue into the blood, which can harm the kidneys

Not known: frequency cannot be estimated from the available data
• Kidney failure

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

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store NALOREX

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 outer packaging of Nalorex tablets. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration.

Do not store your tablets above 25ºC. They should not get too hot or damp; so do not leave your tablets near a radiator, on a window sill or in the bathroom.

Store in the original packaging.

Do not throw away any medicines via waste water 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 Nalorex tablets contain
Each Nalorex tablet contains 50 mg of the active ingredient naltrexone hydrochloride. The other ingredients are: lactose monohydrate, microcrystalline cellulose, crospovidone, silica, colloidal anhydrous, magnesium stearate; pale yellow opadry YS-1-6378-G (hypromellose, macrogol, polysorbate 80 and colouring agents titanium dioxide (E171), and yellow and red iron oxide (E172).

What Nalorex tablets look like and contents of the pack
Nalorex tablets are pale yellow, capsule-shaped tablets marked on one side with "R11" and on the other side with "50".
Nalorex tablets are available in a blister pack of 28 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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