

NALTREXONE GH

naltrexone hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Naltrexone GH. It does not contain all of the available information.

All medicines have risks and benefits. Your doctor has weighed the risks of your taking Naltrexone GH against the benefits they expect it will have for you. If you have any concerns about taking Naltrexone GH, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may want to read it again.

What Naltrexone GH is used for

Naltrexone GH is used to help opiate drug addicts kick the habit. It is also used to help alcoholics dry out and remain abstinent.

Naltrexone GH tablets contain the active ingredient, naltrexone hydrochloride. It is an opiate antagonist. This means it fights the effects of opiate drugs like heroin on the body, and blocks euphoria (or “high”) due to these opiates.

Your doctor may have prescribed Naltrexone GH for another use. Ask your doctor if you have any questions about why Naltrexone GH has been prescribed for you.

Naltrexone GH is not addictive.

Before you take Naltrexone GH

Naltrexone GH is not suitable for everyone.

When you must not take it

- Do not take Naltrexone GH if you have had an allergic reaction to Naltrexone GH or any of the ingredients. Symptoms of an allergic reaction may include, but are not limited to, swelling of the face or tongue, difficulty in breathing, wheezing or an itchy skin rash.
- **Do not take Naltrexone GH if you are still using heroin or drugs like it.** If you take Naltrexone GH right after taking an opiate you will suffer withdrawal symptoms (cold turkey) (such as nausea, vomiting, shakiness, sweating and anxiety) which may be severe.
- Do not take Naltrexone GH if you are on certain pain killers. Ask your doctor or pharmacist.
- Do not take Naltrexone GH if you have hepatitis or liver failure. Hepatitis is liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine.
- Do not take Naltrexone GH if you are pregnant or breast feeding unless your doctor tells you it is safe.

- Do not take Naltrexone GH if you are experiencing withdrawal symptoms.
- Do not take Naltrexone GH after the expiry date printed on the packaging.
- Do not take Naltrexone GH if the packaging is torn or seems to have been opened, or the tablets do not look quite right. (See Product Description.)

Before you start to use it

Tell your doctor if you have any allergies to:

- Any other medicines
- Any other substances, such as foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend to become pregnant or breastfeeding.

Tell your doctor if you have or have had any liver disease.

Tell your doctor if you have or have had any kidney disease.

Tell your doctor if you are under 18 years of age.

Your doctor may give you a test called a NARCAN challenge. This is to see if you are still using heroin or drugs like it. If this test result is positive for heroin use, you will not be prescribed Naltrexone GH.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. These medicines may be affected by Naltrexone GH or they may affect how well Naltrexone GH works.

Tell your doctor if you are taking thioridazine or disulfiram.

Naltrexone GH may reduce or stop the effect of some cough and cold medicines, some medicines that treat loose bowel motions and some pain killers. If this happens, do not take larger doses of these other medicines. If you do, you may become very sick. Talk to your doctor. Your doctor will advise you.

How to take Naltrexone GH

Do not take Naltrexone GH to treat any condition other than that directed by your doctor.

Do not give Naltrexone GH to anyone else, even if their symptoms seem the same as yours. It may harm them.

How much to take

The usual adult dose is one tablet every day. You will usually take Naltrexone GH for at least 3 months, but it may be much longer. The time depends on how quickly you recover from alcohol or heroin addiction. Your doctor will decide the dose that is most appropriate for you. Please follow your doctor's instructions about how and when to take Naltrexone GH.

You should not stop taking Naltrexone GH, or reduce the dose without first talking to your doctor. Depending on your response and on any side effects that you may experience, your doctor may adjust your dose of Naltrexone GH, upward or downward, or may temporarily discontinue your medicine.

If you stop taking Naltrexone GH and restart your heroin habit, you are at risk of being more sensitive to opiates. Therefore restarting your heroin habit after stopping Naltrexone GH can lead to death from opiate overdose. You should talk to your doctor before you stop taking Naltrexone GH and

before you start taking heroin again.

If you take too much

Telephone your doctor or go to the emergency department at your nearest hospital immediately if you think that you or anyone else may have taken too much Naltrexone GH even if there are no signs of discomfort or poisoning.

While you are taking Naltrexone GH

Things you must do

Make sure that all of your doctors, dentists and pharmacists know about your use of Naltrexone GH. Remind them if any new medicines are about to be started, or if you are about to have a medical or dental procedure.

You must tell your doctor immediately if you become pregnant while taking Naltrexone GH.

If you forget to take it

If you forget to take a dose of Naltrexone GH, take your next dose at its regular time.

Do not take a double dose to make up for the dose that you missed. Call your doctor or pharmacist if you are not sure what to do.

Things you must not do

Do not use any other medicines while using Naltrexone GH unless you have discussed this with your doctor or pharmacist. This includes medicines you can buy without a prescription from a pharmacy, supermarket or health food shop or street drugs.

Naltrexone GH may not protect you if you take large amounts of an opiate in an attempt to overcome the blocking effects of Naltrexone GH. Large doses of opiate can lead

to difficulty in breathing and even to death from opiate overdose.

Do not use Naltrexone GH to treat any complaint other than that directed by your doctor. It may not be safe to use Naltrexone GH for another complaint.

Do not stop taking Naltrexone GH, or lower the dosage, without checking with your doctor.

Do not stop taking Naltrexone GH because you are feeling better unless advised to do so by your doctor.

Naltrexone GH should only be used by the person for whom it was prescribed. Do not give Naltrexone GH to someone else even if the symptoms are the same. It may not be safe for another person to use Naltrexone GH.

Do not give your tablets to people who are known to be dependent on opiate drugs because a withdrawal syndrome "cold turkey" may be precipitated. Signs and symptoms (such as nausea, vomiting, shakiness, sweating and anxiety) which may be severe may develop within five minutes. If this happens, call a doctor.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Naltrexone GH.

Like all medicines, Naltrexone GH can cause side effects. Sometimes they are serious, most of the time they are not.

Side-effects can include:

- Nausea, vomiting, diarrhoea, constipation, stomach pain or cramps.
- Headache, dizziness, nervousness, drowsiness.
- Chest pain, joint and muscle pain.
- Rash.

- Tiredness, feeling anxious or irritable, difficulty sleeping, thirsty, loss of appetite, delayed ejaculation, sweating, increased tears, feeling down, chills, increased energy.

Tell your doctor immediately if you notice any of the following:

- If you have stomach pain lasting more than a few days, white bowel movements, dark urine, or yellowing of your eyes, you should stop taking Naltrexone GH immediately and see your doctor as soon as possible.

These side effects may indicate a serious medical condition and you may need urgent medical attention or hospitalisation.

Tell your doctor immediately, or go to accident and emergency at your nearest hospital if you notice any of the following:

- swelling to the face, lips, tongue or throat which may cause difficulty in swallowing or breathing
- wheezing
- severe and sudden onset of pinkish, itchy swelling of the skin
- gastrointestinal bleeding (blood in your stool).

Naltrexone GH may affect your ability to drive or operate machinery. Be careful driving or operating machinery until you know how Naltrexone GH affects you. If you drink alcohol while you are taking Naltrexone GH, your blood alcohol level increases in the same way just as it would if you are not taking Naltrexone GH. As this level rises, you can become physically and mentally impaired. The use of Naltrexone GH will not change this.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

How to store Naltrexone GH

Storage

- Keep Naltrexone GH in its packaging until it is time to take it. If you take the tablets out of their packaging, they may not keep well.
- Keep Naltrexone GH in a cool dry place where the temperature stays below 25°C. Do not freeze.
- Do not store it or any other medicine in the bathroom or near a sink.
- Do not leave it in the car on hot or cold days.
- Keep Naltrexone GH where children cannot reach it.

Disposal

Return any unused medicine to your pharmacist.

Product description

What Naltrexone GH tablets look like

Naltrexone GH tablets are beige, film-coated and capsule shaped. They are marked with a line on both sides.

Ingredients

Each Naltrexone GH tablet contains 50 mg of naltrexone hydrochloride as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- microcrystalline cellulose
- silica-colloidal anhydrous
- magnesium stearate
- crospovidone
- hypromellose
- macrogol (4000)
- titanium dioxide
- iron oxide black CI77499

- iron oxide red CI77491
- iron oxide yellow CI77492

Naltrexone GH tablets are available in blister strips of aluminium foil backing packed in cardboard. Each carton contains 30 tablets.

Sponsor

Generic Health Pty Ltd
Level 1, 1102 Toorak Road
Camberwell, Victoria, 3124

Australian Registration Number

Naltrexone GH - AUST R 128710

Where to go for further information

Your doctor is the best person to answer any further questions you may have about Naltrexone GH.

Anything your doctor tells you about Naltrexone GH should be followed even if it is different from what is in this leaflet.

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

This leaflet was prepared in November 2017.