

Naltrexone GH

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Naltrexone GH?

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

For more information, see Section [1. Why am I using Naltrexone GH?](#) in the full CMI.

2. What should I know before I use Naltrexone GH?

Do not use if you have ever had an allergic reaction to naltrexone hydrochloride or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions.

For more information, see Section [2. What should I know before I use Naltrexone GH?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Naltrexone GH and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Naltrexone GH?

The usual adult dose is one tablet every day.

More instructions can be found in Section [4. How do I use Naltrexone GH?](#) in the full CMI.

5. What should I know while using Naltrexone GH?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Naltrexone GH.Tell your doctor immediately if you become pregnant while taking Naltrexone GH.
Things you should not do	<ul style="list-style-type: none">Do not stop taking Naltrexone GH suddenly.Do not use any other medicines while using Naltrexone GH unless you have discussed this with your doctor or pharmacist.
Driving or using machines	<ul style="list-style-type: none">Be careful driving or operating any machinery until you know how Naltrexone GH affects you.Naltrexone GH may affect your ability to drive or operate machinery.
Drinking alcohol	<ul style="list-style-type: none">Tell your doctor if you drink alcohol.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.
Looking after your medicine	<ul style="list-style-type: none">Keep Naltrexone GH in a cool dry place where the temperature stays below 25°C. Do not freeze.Keep Naltrexone GH in its packaging until it is time to take it.

For more information, see Section [5. What should I know while using Naltrexone GH?](#) in the full CMI.

6. Are there any side effects?

For Common side effects and more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

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 ARX-NALTREXONE immediately and see your doctor as soon as possible.

If you have an allergic reaction or notice gastrointestinal bleeding (blood in your stool), call your doctor straight away, or go straight to the Emergency Department.

Naltrexone GH

Active ingredient: *naltrexone hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Naltrexone GH. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Naltrexone GH.**

Where to find information in this leaflet:

- [1. Why am I using Naltrexone GH?](#)
- [2. What should I know before I use Naltrexone GH?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Naltrexone GH?](#)
- [5. What should I know while using Naltrexone GH?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Naltrexone GH?

Naltrexone GH contains the active ingredient naltrexone hydrochloride. Naltrexone GH 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.

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

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.

2. What should I know before I use Naltrexone GH?

Warnings

Naltrexone GH is not suitable for everyone. **Naltrexone GH may cause damage to the liver cells when consumed in excessive quantity.**

Do not use Naltrexone GH if:

- you have or have had allergic reaction to naltrexone hydrochloride, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.
Some of the symptoms of an allergic reaction may include, but are not limited:
 - difficulty in breathing, wheezing,
 - swelling of the face or tongue,

- 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. 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
- 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 on certain pain killers.** Ask your doctor or pharmacist.
- Do not take Naltrexone GH if you are experiencing withdrawal symptoms.**

Do not take Naltrexone GH after the expiry date printed on the pack or if the packaging is torn or seems to have been opened, or the tablets do not look quite right, see [7. Product details](#).

Check with your doctor if you:

- Are taking thioridazine or disulfiram
- have or had any liver disease
- have or had any kidney disease
- take any medicines for any other condition
- have any allergies to
 - any other medicines
 - any other substances, such as foods, preservatives or dyes
- are under 18 years of age

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take Naltrexone GH if you are pregnant or breast feeding unless your doctor tells you it is safe.

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or

supplements 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, acamprosate, 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.**

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect **Naltrexone GH**.

4. How do I take Naltrexone GH?

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 forget to take Naltrexone GH

Naltrexone GH should be used regularly at the same time each day. If you miss your dose at the usual time, and **if it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

Do not take a double dose to make up for the dose you missed.

Call your doctor or pharmacist if you are not sure what to do.

If you use too much Naltrexone GH

If you think that you have used too much Naltrexone GH, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Naltrexone GH?

Things you should 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.

Call your doctor straight away if you:

- become pregnant while taking Naltrexone GH

Remind any doctor, dentist or pharmacist you visit that you are using Naltrexone GH.

Things you should 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.**

Driving or using machines

Naltrexone GH may affect your ability to drive or operate machinery. **Be careful before you drive or use any machines or tools until you know how ARX-NALTREXONE affects you.**

Drinking alcohol

Tell your doctor if you drink alcohol.

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.

Looking after your medicine

Keep Naltrexone GH in a cool dry place where the temperature stays below 25°C. Do not freeze.

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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Other side effects not listed here may occur in some people. Do not be alarmed by this list of possible side effects. You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gastrointestinal:</p> <ul style="list-style-type: none"> • nausea, vomiting, diarrhoea, constipation, stomach pain or cramps <p>Nervous system:</p> <ul style="list-style-type: none"> • headache, dizziness, nervousness, drowsiness, feeling anxious or irritable, difficulty sleeping <p>Respiratory:</p> <ul style="list-style-type: none"> • chest pain <p>Musculoskeletal:</p> <ul style="list-style-type: none"> • joint and muscle pain 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<p>Skin and subcutaneous tissue:</p> <ul style="list-style-type: none"> • Rash <p>Reproductive system:</p> <ul style="list-style-type: none"> • delayed ejaculation <p>General:</p> <ul style="list-style-type: none"> • tiredness, thirsty, loss of appetite, sweating, increased tears, feeling down, chills, and increased energy 	
--	--

Serious side effects

Serious side effects	What to do
<p>General:</p> <ul style="list-style-type: none"> • swelling to the face, lips, tongue or throat which may cause difficulty in swallowing or breathing; <p>Respiratory:</p> <ul style="list-style-type: none"> • Wheezing <p>Skin and subcutaneous tissue:</p> <ul style="list-style-type: none"> • severe and sudden onset of pinkish, itchy swelling of the skin; <p>Gastrointestinal:</p> <ul style="list-style-type: none"> • gastrointestinal bleeding (blood in your stool); • 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. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Naltrexone GH contains

Active ingredient (main ingredient)	naltrexone hydrochloride
Other ingredients (inactive ingredients)	lactose monohydrate microcrystalline cellulose colloidal anhydrous silica magnesium stearate crospovidone hypromellose macrogol 4000 titanium dioxide iron oxide black iron oxide red iron oxide yellow
Potential allergens	Sugar as lactose

Do not take this medicine if you are allergic to any of these ingredients.

What Naltrexone GH looks like

Naltrexone GH 50 mg tablets are beige, film-coated and capsule shaped. They are marked with a line on both sides. (AUST R 128710).

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

Who distributes Naltrexone GH

Generic Health Pty Ltd
Suite 2, Level 2
19-23 Prospect Street
Box Hill, VIC, 3128, Australia

✉ ghinfo@generichealth.com.au

☎ +61 3 9809 7900

🌐 www.generichealth.com.au

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 March 2025.