

APO-NALTREXONE

Contains the active ingredient Naltrexone (as Naltrexone Hydrochloride)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about naltrexone. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. Your doctor has been provided with full information and can answer any questions you may have. Follow your doctor's advice even if it is different from what is in this leaflet.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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

What this medicine is used for

The name of your medicine is APO-NALTREXONE Tablets. It contains the active ingredient Naltrexone Hydrochloride. It is an opiate antagonist. This means it fights the effects of opiate drugs (such as heroin) on the body and, blocks the euphoria ("high") due to these opiates.

It is used:

- as part of a treatment programme for alcohol dependence.

- as adjunctive therapy in the maintenance of formerly opioid-dependent patients who have ceased the use of opioids such as diamorphine (heroin) and morphine
- Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

How it works

Naltrexone Hydrochloride blocks the effects of opioids by competitive binding (i.e., analogous to competitive inhibition of enzymes) at opioid receptors.

There is no evidence that this medicine is addictive.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- You are hypersensitive to, or have had an allergic reaction to, naltrexone or any of the ingredients listed at the end of this leaflet.
- **Do not take this medicine if you are still using heroin or similar drugs**
- If you take this medicine right after taking an opiate you will suffer from withdrawal symptoms (such as nausea,

vomiting, shakiness, sweating and anxiety) which may be severe.

- Do not take this medicine if you are experiencing withdrawal symptoms.
- Do not take this medicine if you are on certain pain killers. Ask your doctor or pharmacist.
- Do not take this medicine 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
- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - are pregnant or intend to become pregnant.

- are breastfeeding or intend to breastfeed.
- have or have had any liver disease.
- have or have had any kidney disease.
- are under 18 years of age

Taking other medicines

It is important that you 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.

Some medicines may interact with naltrexone. These include:

- thioridazine.
- disulfiram.

If you are taking any of these you may need a different dose or you may need to take different medicines.

This medicine 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 and your doctor will advise you

Other medicines not listed above may also interact with naltrexone.

How to take this medicine

The usual adult dose is one tablet every day. You will usually take naltrexone 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 this medicine.

Your doctor may give you a test called a NARCAN (naloxone) 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 tablets..

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

You should not stop taking this medicine, 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 this medicine, upward or downward, or may temporarily discontinue your medicine.

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

Make sure you have enough naltrexone tablets to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

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

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in

Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Use any other medicines while using this medicine unless you have discussed it with your doctor or pharmacist. This

includes medicines you can buy without a prescription from your pharmacy, supermarket, health food shop or street drugs. This medicine will not help you if you take large amounts of an opiate to overcome the blocking effects. Large doses of opiate can lead to difficulty breathing or even death.

Naltrexone tablets should only be used by the person for whom it was prescribed. Do not give this medicine to anyone else, even if their symptoms seem similar to yours. It may not be safe for another person to use.

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.

- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you. If you drink alcohol while you are taking this medicine, your blood alcohol level increases in the same way just as it would if you are not taking

it. As this level rises, you can become physically and mentally impaired. The use of this medicine will not change this.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking naltrexone or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Some common side effects are:

- Nausea, vomiting, diarrhoea, constipation, stomach pain or cramps
- Headache, dizziness, nervousness
- Joint and muscle pain
- Rash
- Tiredness, feeling anxious or irritable, difficulty sleeping, feeling down, chills, increased energy
- Thirsty, loss of appetite
- Delayed ejaculation, decreased potency

- Chest pain, euphoria and increased sweating have also been reported

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

- If you have stomach pain lasting more than a few days, light coloured bowel movements, dark urine, or yellowing of your eyes, you should stop taking this medicine immediately and see your doctor as soon as possible
- These may be serious side effects and you may need medical attention

Tell your doctor immediately, or go to the Accident and Emergency department 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)

These are very serious side effects and you may need urgent medical attention or hospitalisation.

This medicine may affect your ability to drive or operate machinery. Be careful driving or operating machinery until you know how this medicine affects you. If you drink alcohol

while you are taking this medicine, your blood alcohol level increases in the same way just as it would if you are not taking this medicine. As this level rises, you can become physically and mentally impaired. The use of this medicine will not change this.

Other side effects not listed above may occur in some patients.

Tell your doctor if you notice anything else that is making you feel unwell

Allergic reactions

If you think you are having an allergic reaction to naltrexone, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-NALTREXONE Tablets looks like

50 mg Tablets are pale yellow film-coated oval biconvex tablets, engraved with "NAL", score & "50" on one side and "APO" on the other.

It is supplied in bottle pack of 30 tablets

Ingredients

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

It also contains the following inactive ingredients:

- lactose,
- hypromellose,
- colloidal silicon dioxide,
- magnesium stearate,
- hydroxypropylcellulose,
- titanium dioxide,
- macrogol 8000,
- iron oxide yellow, and
- iron oxide red.

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-NALTREXONE 50 mg Tablets: AUST R 271013.

Sponsor

Apotex Pty Ltd

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