

REVIA®

Naltrexone hydrochloride (nal-TREX-own)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about REVIA®. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking REVIA against the benefits that are expected. This leaflet does not contain everything about REVIA. Your doctor has been provided with full information and can answer any questions you may have. Follow your doctor's advice even if it differs from what is in this leaflet.

Please read this leaflet carefully and keep it in a safe place so you may refer to it later.

What REVIA is used for

REVIA is used to help opiate drug addicts discontinue their habit. It is also used to help alcoholics dry out and remain abstinent. Your doctor may have prescribed REVIA for another use. Ask your doctor if you have any questions about why REVIA was prescribed for you.

REVIA is not addictive. This medicine is available only with a doctor's prescription.

How REVIA works

REVIA tablets contain 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 euphoria (or "high") due to these opiates.

The use of REVIA to treat your condition can lead to side-effects, which are discussed below.

Before you take REVIA

REVIA is not suitable for everyone.

When you must not take REVIA:

- You must not take REVIA if you have a history of severe allergic reactions to REVIA or to any of the ingredients listed at the end of this leaflet.
- **Do not take REVIA if you are still using heroin or drugs like it.**
If you take REVIA 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 REVIA if you are experiencing withdrawal symptoms.
- Do not take REVIA if you are on certain pain killers. Ask your doctor or pharmacist.

- Do not take REVIA 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 REVIA after the expiry date printed on the pack. If you take this medicine after the expiry date has passed, it may not work as well.
- Do not take REVIA if the packaging is torn or shows signs of tampering.

Before you take REVIA

Tell your doctor if you have allergies to:

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

Tell your doctor if you have or have had any medical conditions, especially the following:

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

Taking other medicines

It is especially important to 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 REVIA or they may affect how well REVIA works.

- Tell your doctor if you are taking thioridazine or disulfiram.
- REVIA 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.

Know the medicines you take. Keep a list of your medicines with you to show your doctor or pharmacist.

If you have not told your doctor about any of the above, tell them before you take REVIA.

While you are taking REVIA

Things you must do:

- You must tell your doctor immediately if you become pregnant while taking REVIA.
- Tell all of the doctors, dentists and pharmacists who are treating you that you are taking REVIA.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking REVIA.

Things you must not do:

- Do not use any other medicines while using REVIA 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. REVIA may not protect you if you take large amounts of an opiate in an attempt to overcome the blocking effects of REVIA. Large doses of opiate can lead to difficulty in breathing and even to death from opiate overdose.
- Do not use REVIA to treat any other complaints unless your doctor tells you to.
- Do not stop taking REVIA, or lower the dosage, without checking with your doctor.
- Do not stop taking REVIA tablets because you are feeling better unless advised to do so by your doctor.
- REVIA should only be used by the person for whom it was prescribed. Do not give REVIA to someone else even if the symptoms are the same. It may not be safe for another person to use REVIA.

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.

Things to be careful of:

- Be careful driving or operating machinery until you know how REVIA affects you.

How to take REVIA

The usual adult dose is one tablet every day. You will usually take REVIA 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 REVIA.

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 REVIA.

How long to take it:

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

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

If you forget to take it:

If you miss a dose of REVIA, take your next scheduled dose at its regular time. Don't make up for a missed dose by doubling up on your tablets. Call your doctor or pharmacist if you are not sure what to do.

If you take too much (overdose):

Immediately telephone your doctor or Poisons Information Centre (telephone: 13 11 26) or go to the Accident and Emergency Department at your nearest hospital, if you or anyone else may have taken too much REVIA. Do this even if there are no signs of discomfort or poisoning.

Side effects

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

Like all medicines, it is possible that REVIA may have unwanted side effects in some people.

The more common side effects of REVIA 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 since marketing REVIA.

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 REVIA 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)

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

Product Description

REVIA tablets are pale yellow, film-coated and capsule shaped. They are marked with "R11" on one side. The other side is marked with a line and "50".

REVIA tablets are available in packs containing 30 tablets.

Ingredients

Each REVIA tablet contains 50 mg of naltrexone hydrochloride as the active ingredient. It also contains the following inactive ingredients: lactose, microcrystalline cellulose, crospovidone, silicon dioxide, magnesium stearate, and pale yellow Opadry (colouring).

Storage

- Keep your tablets in the pack until it is time to take them. If you take the tablets out of the bottle or blister pack they may not keep well.
- Keep the pack in a cool dry place where the temperature stays below 25°C.
- Do not store REVIA or any other medicine in the bathroom or near a sink.
- Do not leave it in the car on hot days. Heat and dampness can destroy some medicines.
- Keep it 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

Return any unused medicine to your pharmacist.

Sponsored by

Bristol-Myers Squibb Australia Pty Ltd,
4 Nexus Court, Mulgrave,
Victoria 3170, Australia

Registration Numbers

- REVIA 50mg tablets, 30 tablets in blister pack (AUST R 165096)
- REVIA 50mg tablets, 30 tablets in plastic bottle (AUST R 65400)
- Not currently available in Australia

Where to get further information

Your doctor is the best person to answer any further questions you may have about REVIA. Anything your doctor tells you about REVIA should be followed even if it is different from what is in this leaflet.

Date of Preparation: November 2013

®REVIA is a trademark of Bristol-Myers Squibb Company.

AU_CMI_Revia_V4.0_Nov13.docx