

Package leaflet: Information for the user

Disulfiram tablets 200mg

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

What is in this leaflet

1. **What Disulfiram is and what it is used for**
2. **Before you take Disulfiram**
3. **How to take Disulfiram**
4. **Possible side effects**
5. **How to store Disulfiram**
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1. What Disulfiram is and what it is used for

Disulfiram is used as a supportive agent in the treatment of alcoholism. When you drink alcohol it is changed in the body into acetaldehyde, disulfiram blocks the enzyme which breaks down acetaldehyde. This leads to an increased level of acetaldehyde in the blood causing unpleasant physical reactions.

Disulfiram is used in the treatment of people with drinking problems. If you are treated with Disulfiram and drink alcohol you will experience unpleasant physical reactions, which may stop you from drinking further alcohol.

2. Before you take Disulfiram

Do not take Disulfiram tablets if you have:

- an **allergy** to disulfiram or any of the other ingredients of this medicine (listed in section 6)
- **severe heart** disease or heart failure
- **high blood pressure**
- **severe psychiatric** or **personality disorder**
- had a **stroke**.
- recently consumed **alcohol**

Warnings and precautions

Talk to your doctor or pharmacist before taking Disulfiram tablets if you have:

- **kidney, liver** or **lung** disease

- **diabetes**
- **low blood pressure**
- **brain damage**
- **epilepsy.**

Children and adolescents

Do not give this medicine to children.

Other medicines and Disulfiram

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Especially:

- warfarin (reduces blood clotting)
- phenytoin and paraldehyde (to treat epilepsy)
- theophylline (to treat asthma)
- chlordiazepoxide and diazepam (to treat anxiety)
- pethidine and morphine (painkillers)
- amphetamines (stimulants)
- pimozide, and chlorpromazine (to treat mental illnesses)
- isoniazid metronidazole, rifampicin (to treat infections)
- amitriptyline (to treat depression)

Other precautions

Certain foods, liquid medicines, remedies, tonics, toiletries, perfumes and sprays may contain enough alcohol to cause a disulfiram-alcohol reaction. Caution should also be exercised with low alcohol and “non-alcoholic” or “alcohol-free” beers and wines. If enough is taken they may produce unpleasant reactions.

Disulfiram and alcohol

If you drink alcohol during or within 2 weeks of stopping Disulfiram tablets, or you have been exposed to alcohol from other sources (see ‘Other precautions’) a disulfiram-alcohol reaction may occur. The reaction is unpredictable and symptoms may be severe or life threatening. Symptoms include;

flushing of the face and neck, increased body temperature, sweating, feeling or being sick, itchy skin or rash caused by an allergic reaction (pruritis, urticaria) anxiety, dizziness, headache, blurred vision, difficulty breathing, palpitations, rapid breathing. In severe cases; rapid heart beat, low blood pressure, abnormally slow breathing, chest pain, abnormal heart rhythm, coma or fits may occur.

Rare complications may include; high blood pressure, breathing problems, blood disorders.

If you get some of the symptoms, contact your doctor.

The disulfiram-alcohol reaction can occur within 15 minutes after drinking alcohol and may last several hours.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. The use of

Disulfiram tablets during the first 3 months of pregnancy or breast-feeding is not advised and should only be used if directed by your doctor.

Driving and using machines

Disulfiram tablets may cause drowsiness or tiredness (see '4. Possible side effects'). If you are affected do not drive or operate machinery.

Important information about some of the ingredients of Disulfiram

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Disulfiram

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. A check up is advised before starting treatment to check you are suitable for treatment.

Treatment with Disulfiram is usually started in a hospital or specialised clinic. It is important that you have **not drunk alcohol for at least 24 hours before** taking the first dose. Swallow the tablets with water.

The recommended dose is:

- **Adults and the elderly:**

Initially 4 tablets (800mg) on day 1, then 3 tablets (600mg) on day 2, then 2 tablets (400mg) on day 3 and then 1 tablet (200mg) on days 4 and 5.

Then ½ to 1 tablet (100mg – 200mg) a day for as long as told by your doctor, but for no longer than six months without review.

If you take more Disulfiram than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include; feeling or being sick, stomach pain, diarrhoea, drowsiness, mental disorders, tiredness, rapid heart beat, rapid breathing, high body temperature, low blood pressure, loss of muscle control, high blood sugar, changes in the blood (as seen in blood tests). Severe cases may result in coma, fits or death.

If you forget to take Disulfiram

If you forget to take a dose, and you do not remember it within 12 hours, you should not take it. Do not take a double dose to make up for a forgotten dose.

If you stop taking Disulfiram

Speak to your doctor or nurse before stopping treatment with Disulfiram.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking this medicine and immediately contact a doctor if you experience any of the following:

- allergic skin reactions such as itching and redness

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- depression, paranoia, schizophrenia, mania,
- decreased sexual desire
- drowsiness and fatigue (especially at start of treatment)
- damage/inflammation of peripheral nerves (causing pain and loss of sensation in hands and feet)
- inflammation of the optic nerve
- encephalopathy (brain disease)
- feeling or being sick
- bad breath
- inflammation of the liver (hepatitis), damage to liver cells, liver failure
- rash.

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 the Yellow Card Scheme website at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Disulfiram

Keep out of the sight and reach of children.

Store below 25°C in the tightly closed container, protect from light in a dry place.

Do not use Disulfiram tablets after the expiry date stated on the label. The expiry date refers to the last day of that month.

Do not throw any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Disulfiram tablets contain

- The active substance (the ingredient that makes the tablet work) is 200mg of disulfiram.
- The other ingredients are lactose, potato starch, povidone, microcrystalline cellulose, polysorbate 20, tartaric acid, colloidal anhydrous silica, sodium bicarbonate, maize starch and magnesium stearate.

What Disulfiram looks like and contents of the pack

The tablet is white and scored with a breakline marker ‘CJO’ on the side.

Pack sizes are 50 tablets

Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer

Recipharm Uppsala AB, Bjorkgatan 30, 751 82 Uppsala, Sweden

This leaflet was last revised in May 2022.

Label

Disulfiram tablets 200mg

PL 00289/2558

POM

50 tablets

Each tablet contains: Disulfiram 200 mg

Also contains: lactose, microcrystalline cellulose, tartaric acid.

Sodium content: 0.3mEq

To be taken by mouth. Keep tightly closed. Protect from light.

Store below 25°C in a dry place.

Keep out of the sight and reach of children.

MA holder:

Teva UK Limited,

Ridings Point,

Whistler Drive,

Castleford,

WF10 5HX,

United Kingdom

Barcode