

ANTABUSE®

Disulfiram Effervescent Tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Antabuse. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

If you have any concerns about taking Antabuse, ask your doctor or pharmacist.

Your doctor and pharmacist have more information.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT ANTABUSE IS USED FOR

Antabuse is designed to act as a deterrent to alcohol consumption.

Antabuse inhibits an enzyme, which assists in the breakdown of alcohol in the body. A build-up of a substance called acetaldehyde results. If alcohol is consumed when a patient has received Antabuse the so called "aldehyde reaction" may occur.

Antabuse tablets have been approved for the uses listed above. However, your doctor may prescribe this medicine for another use. If you want more information, ask your doctor.

Antabuse tablets are not addictive.

What will happen if you take alcohol and Antabuse

The "aldehyde reaction", which may occur if you take Antabuse and alcohol together, starts with a flushing from the head downwards involving the face, arms and chest. This is accompanied by a feeling of heat, sweating, palpitations, fast heart beat, shortness of breath, hyperventilation and headache. There is a feeling of constriction and irritation in the throat resulting in spasms and coughing. Chest pains may occur. Restlessness or a sense of uneasiness and fear of dying may develop. These symptoms are accompanied by a steep rise in blood pressure, which may be followed by a drop in blood pressure.

Flushing is then replaced by the patient becoming pale, weak, feeling dizzy and sick, which turns into violent vomiting and stomach cramps. Other symptoms may include thirst, dizziness, blurred vision, numbness of the hands and feet and the inability to sleep. Severe reactions may affect the heart, and there may be fits, loss of consciousness and death. The reaction usually lasts 2-4 hours and up to several hours in more severe cases.

Confusion, drowsiness and sleep usually follow. The intensity of the reaction varies with each individual, but generally depends on the amount of Antabuse and alcohol consumed.

If such a reaction is observed, the patient's doctor should be contacted. If the patient is not in hospital or a clinic, an ambulance should be called as the patient requires close monitoring.

BEFORE YOU TAKE ANTABUSE

When you must not take Antabuse

Do not use Antabuse:

- if you know you are allergic to it or any of its ingredients, or certain other chemicals (thiuram derivatives) used in pesticides and rubber processing. (See the last section of this leaflet for a full list of ingredients). Signs of allergy include rash, itching, shortness of breath and/or swollen face;
- if you have heart, liver or kidney disease;
- if you are pregnant, or are planning to become pregnant;
- if you have a mental illness with abnormal thoughts;
- if you are taking paraldehyde or metronidazole;
- if the packaging is torn or shows signs of being tampered with;
- to treat any other complaints unless your doctor says it is safe to do so.

IMPORTANT NOTE

Under all circumstances when taking Antabuse you MUST NOT take alcohol or alcohol-containing preparations e.g. certain cough syrups, sauces, vinegar, tonics, food prepared with wine. You should even avoid the use of after-shave lotions and alcoholic back rubs.

Before you start to take it

You should not take Antabuse until you have not taken any alcohol for 24 hours.

If you stop taking Antabuse, you should wait at least one week before consuming alcohol. Reactions may still occur for up to three weeks after taking Antabuse.

Your doctor may need to monitor closely if you suffer from certain conditions. Tell your doctor if you have any of the following:

- diabetes;
- epilepsy;
- thyroid problems;
- heart, kidney or liver disease;
- an allergic skin reaction if you come into contact with certain irritants;
- asthma;
- mental illness with abnormal thoughts.

Tell your doctor or pharmacist if you are breastfeeding.

They will advise you on whether you should take Antabuse.

Always tell your doctor if you are taking other medicines, including ones you buy from the pharmacy or supermarket.

Medicines which have interacted with Antabuse include:

- phenytoin and isoniazid;
- sleeping tablets such as Valium;
- medicines which stop blood clotting (warfarin);
- metronidazole and paraldehyde;
- pain killers such as morphine, pethidine, amphetamines and barbiturates.

USING ANTABUSE

How to take it

The following are the usual doses, but your doctor may adjust them to suit your needs:

Starting dose: Take between half a tablet (100 mg) and one and a half tablets (300 mg) dissolved in water as a single dose daily for one to two weeks. Your doctor will tell you the exact dosage. Then go back and see your doctor.

Maintenance dose: Take ONE tablet daily. Take the tablets in the morning when you wake up. However if you find the tablets make you sleepy you can take them before bedtime. If you are taking Antabuse for a long time, then your doctor will need to do a regular check up. This may include a blood test.

If you forget to take it

- If you forget to take Antabuse, do so as soon as you remember, and then go back to taking it as you would normally.
- 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 one you missed.
- If you have problems remembering when to take your medicine, ask your pharmacist for some hints.

Overdose

If you think you or anybody else has taken too much Antabuse, contact your doctor, pharmacist or the Poisons Information Centre in your state who will advise you what to do.

(You can contact the Poisons Information Centre by dialling 000 and ask for your local Poisons Centre). If you have taken too much Antabuse you may get drowsy, experience some pain or numbness in the hands and feet which may get worse if not treated.

WHILE YOU ARE TAKING ANTABUSE

Things you must do

- Always follow your doctor's instructions carefully, and seek your doctor's advice before changing or stopping treatment. Your doctor will be happy to discuss any concerns you may have with your treatment.
- Always read labels of food and medicines bought to check they contain no alcohol.

Things you must not do

- **DO NOT, UNDER ANY CIRCUMSTANCES, TAKE ANY ALCOHOL OR ALCOHOL-CONTAINING PRODUCTS.** You will suffer from the "aldehyde reaction" which needs immediate medical attention and, in some circumstances, may be fatal.
- **Do not take Antabuse if you have taken any alcohol in the last 24 hours. Also do not take any alcohol for at least a week after stopping Antabuse. You may still get a reaction for up to 3 weeks after stopping Antabuse.**

- Do not give this medicine to anybody else.

Things to be careful of

- **Ask your doctor before taking any other medicines. Antabuse can interact with other medicines. Especially check bought medicines from your chemist or supermarket to make sure they contain no alcohol.**

SIDE EFFECTS

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

All medicines have side effects. Often they are not serious but sometimes they can be. You may need medical treatment if you get some of the side effects.

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

- numbness, tingling, pain or weakness in hands or feet;
- change in vision or eye tenderness or pain;
- mood changes or abnormal thoughts;
- fatigue;
- malaise (generally feeling unwell);
- loss of appetite;
- nausea (feeling sick);
- vomiting;
- dark urine or yellowing of the skin or eyes (jaundice) or abdominal pain.

You may have some of the following effects for the first two weeks of treatment. If any of them worry you or continue please tell your doctor as soon as possible:

- headache;
- weakness;
- acne or skin rash;
- stomach upset;
- impotence in men;
- metallic or garlic-like after taste.

Do not hesitate to report any other side effects to your doctor or pharmacist.

AFTER USING ANTABUSE

Storage

- Keep your Antabuse in a cool, dry place where the temperature stays below 25°C.
- Do not store it or any medicines in the bathroom or near a sink. Heat and dampness can destroy some medicines.
- Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.
- Do not use Antabuse beyond the date (month and year) printed on the pack after the letters "EXP", even if it has been stored properly. Medicines cannot be stored indefinitely.

Disposal

Once you have finished using Antabuse, ask your pharmacist what to do with any that is left.

PRODUCT DESCRIPTION

What it looks like

Antabuse are white, flat tablets scored and marked with CDC. Antabuse comes in packs of 30 tablets.

Ingredients

Each tablet contains 200 milligrams of disulfiram as the active ingredient. They also contain maize starch, povidone, tartaric acid, sodium bicarbonate, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate and talc.

Distributor

Antabuse is distributed by:

Amneal Pharma Australia Pty Ltd
12 River Street
South Yarra VIC 3141

Australian Registration Number: AUST R 70468

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