

Patient Information Leaflet

Antabuse®, Tablets 200 mg

Read this information leaflet carefully before you start the treatment with Antabuse® tablets.

What does the drug contain and what does it look like?

1 tablet contains: Active ingredient: Disulfiram 20 mg. Other ingredients: Lactose, potatoe starch, gelatin, microcrystalline cellulose, polysorbate 20, tartaric acid, colloidal anhydrous silica, sodium bicarbonate, maize starch and magnesium stearate. Available in packages of 50 tablets. Identification: The tablet is white and scored with breakline marked "DUMEX" "110 L" on the side.

How does the drug act?

Disulfiram is an alcohol deterrent and is used as a supportive agent in the treatment of alcoholism. When you drink alcohol it is metabolized in the body to acetaldehyde. Disulfiram blocks the enzyme, which breaks down acetaldehyde. This leads to an increased level of acetaldehyde in the blood provoking a series of unpleasant physical effects.

License holder and manufacturer / information is available from

The license holder and manufacturer for Antabuse® is Dumex-Alpha A/S, Dalslandsgade 11, DK-2300 Copenhagen S, Denmark. Information is available from the distributor Dumex Ltd, Tring Business Centre Upper Ickneild Way, Tring, Herefordshire HP23 4JX.

What is the drug used for?

Antabuse® is used to deter persons from drinking alcohol. It is prescribed in the treatment of persons with drinking problems. If you are treated with Antabuse® and drink alcohol you will experience a series of unpleasant physical reactions. This reaction may be sufficiently unpleasant to dissuade you from consuming alcohol.

When should I not use the drug?

1. If you ever have had a rash or allergic reaction to Disulfiram or Antabuse®.
2. If you suffer from one or more of the following diseases; severe heart disease, hypertension, and a severe psychiatric disease.
3. If you have had a stroke.

If any of the above points apply to you, or you are not sure, tell your doctor.

What should I be aware of before and during treatment?

1. If you have an illness affecting the kidneys, liver, a lung disease, diabetes or epilepsy tell your doctor before the treatment is started.
2. A check up is advised before starting treatment to establish your suitability for the treatment.
3. You must not drink alcohol during or for at least a week after ceasing Antabuse® treatment.
4. Certain foods, liquid medicines, remedies, tonics, toiletries, perfumes and sprays may contain sufficient alcohol to cause an Antabuse® - alcohol reaction. Caution should also be exercised with low alcohol and “non-alcoholic” or “alcohol-free” beers and wines, taken in sufficient quantities it may produce the unpleasant reaction.

Warning

If alcohol is drunk during or within one week after ceasing Antabuse® treatment, or you have been exposed to a certain amount of alcohol from other sources (see item 4 above) the Antabuse® - alcoholic reaction may occur. The course of the reaction is unpredictable and potentially severe. The symptoms are headache, redness of the face, rapid pulse, rapid breathing, nausea, vomiting, paleness, hypertension, and dizziness. In severe cases collapse may occur.

If you get some of the above mentioned symptoms, you should contact your doctor. The Antabuse® - alcohol reaction can occur within ten minutes after drinking and may last several hours.