Package Leaflet: Information for the user

Antabuse® 400 mg Effervescent Tablets
Disulfiram

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, pharmacist or nurse.
- This medicine has been prescribed for you. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Antabuse® is and what it is used for

Disulfiram (Antabuse's active ingredient) 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.

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

2. What you need to know before you take Antabuse®

Do not take Antabuse® and **tell** your doctor if you have:
• an **allergy** (hypersensitivity) to the active substance or any of the other ingredients of this medicine listed in section 6.
• **severe heart** disease or heart failure
• had a **stroke**
• **high blood pressure**
• **severe psychiatric** or **personality disorder**
• **any thoughts of harming or killing yourself** or **psychosis**
• current **liver disease**
• had experienced a side effect on the liver while previously taking **disulfiram / Antabuse®**
• recently **consumed alcohol** or have **medication dependency**

Warnings and precautions
Talk to your doctor or pharmacist before taking Antabuse® if you have:
• **kidney, liver** or **lung** disease
• **diabetes**
• **epilepsy**

Drug induced liver injury – liver injury and liver disorder including fatal cases have been reported with disulfiram treatment. If at any stage during treatment you feel unwell or develop a fever or jaundice please seek urgent medical attention.

Other medicines and Antabuse®
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 (to help prevent blood clotting)
• phenytoin and paraldehyde (to treat epilepsy)
• chlordiazepoxide and diazepam (used to relax muscles and to reduce restlessness and anxiety)
• pethidine and morphine (painkillers)
• amphetamines (stimulants)
• pimozide, and chlorpromazine (to treat mental illnesses)
• isoniazid, metronidazole, rifampicin (to treat infections)
• amitriptyline (to treat depression)
• antihistamines e.g. cetirizine, or other products which may have an antihistamine effect e.g. cimetidine

Antabuse® with food, drink and alcohol
Certain foods, liquid medicines, remedies, tonics, toiletries, perfumes, and sprays may contain enough alcohol to cause an Antabuse®-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.

Alcohol
If you drink alcohol during or within one week after stopping Antabuse® or you have been exposed to alcohol from other sources (see 'Other precautions') the Antabuse®-alcohol reaction may occur. The reaction is unpredictable and potentially severe. Symptoms include headache, redness of the face, rapid pulse, rapid breathing, nausea, vomiting, paleness, low blood pressure, and dizziness. In severe cases collapse may occur. If you get any of the above mentioned symptoms, you should contact your doctor. The Antabuse®-alcohol reaction can occur within 10 minutes after drinking alcohol and may last several hours.

Pregnancy and breast-feeding
If you are pregnant or planning to become pregnant you should not take Antabuse®. Birth defects in infants whose mothers have received disulfiram during their pregnancy have been reported. The use of Antabuse® during breast-feeding is not advised. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Antabuse® may cause drowsiness and fatigue. Do not drive, if these side-effects are present.

3. How to take Antabuse®

Always take this medicine exactly as your doctor or pharmacist 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 Antabuse® (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.
You must not drink alcohol while you are taking Antabuse® (disulfiram) or for at least 1 week after stopping the treatment.

Doses:
• **Adults and the elderly:**
2 effervescent tablets (800 mg) on day 1, then 1½ tablets (600 mg) on day 2, then 1 tablet (400 mg) on day 3 and ½ tablet (200 mg) on days 4 and 5. Thereafter ½ tablet (200 mg) or ¼ tablet (100 mg) daily. The weekly dose of 1¾ to 3½ tablets (700 mg to 1400 mg) may be divided into two or three doses taken during the course of the week. Treatment is continued for as long as

the doctor advises.

The dose is dispersed in a glass of water and stirred immediately before it is taken.

Your doctor may feel that it is necessary to perform an alcohol challenge test to assess the effectiveness of the treatment.

If you take more Antabuse® 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 drowsiness, fatigue and feeling or being sick.

If you forget to take Antabuse®
If you forget to take a dose, and you do not remember it within 12 hours, you should not take it. Do not take two doses the next time.

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.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:
Common (occurs in less than 1 in 10 users): drowsiness, fatigue, general discomfort, abdominal pain, diarrhoea, feeling or being sick, bad breath, loss of taste, headache, depression, mania and changes in levels of liver enzymes (seen in blood tests).
Uncommon (occurs in less than 1 in 100 users): allergic skin reactions such as itching and redness, decreased sexual desire,
Rare (occurs in less than 1 in 1,000 users): yellowing of the skin or whites of the eyes, abnormal liver function tests, loss of sensation in the hands and feet, tremor, disturbed vision, paranoia, schizophrenia.
Very rare (occurs in less than 1 in 10,000 users, including isolated reports): inflammation of the liver (hepatitis), damage to liver cells, liver failure, convulsion, confusion, change in behaviour, acute organic brain syndrome.
Not known (cannot be estimated from the available data): drug induced liver injury.
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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Antabuse®

Keep this medicine out of the sight and reach of children.
Do not store above 25ºC. Keep the container tightly closed in order to protect from moisture and light.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicine 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 Antabuse® contains
• The active substance is disulfiram. Each effervescent tablet contains 400 mg disulfiram.
• The other ingredients are maize starch, povidone, microcrystalline cellulose, tartaric acid, colloidal anhydrous silica, sodium hydrogen carbonate, magnesium stearate and talc.

What Antabuse® looks like and contents of the pack
Antabuse® are white, flat, circular, effervescent tablets, with a cross score on one side and engraved CJ.
Pack size: 50 Effervescent Tablets

Marketing Authorisation Holder
Actavis Group PTC ehf., Reykjavikurvegi 76-78, 220 Hafnarfjordur, Iceland

Manufacturer
Kemwell AB, Bjorkgatan 30, 751 82 Uppsala, Sweden

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