

Package leaflet: Information for the user Isocarboxazid tablets 10mg

Read all of this leaflet carefully before you start using 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

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1. What Isocarboxazid tablets are and what they are used for

Isocarboxazid is one of the group of medicines known as Monoamine Oxidase Inhibitors (MAOIs). These are drugs that block the action of a substance called monoamine oxidase which is present in the brain and which plays an important part in controlling mood.

Isocarboxazid tablets are used in the treatment of depression.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Isocarboxazid tablets

Do not take these tablets if:

- You are allergic to Isocarboxazid or any of the other ingredients of this medicine (listed in section 6)
- You have severe heart disease or any disease of the blood vessels of the brain
- You have phaeochromocytoma which is a tumour of the adrenal glands causing high blood pressure
- You have known liver damage
- You are taking any medications for the treatment of depression and/or anxiety.

Warnings and precautions

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

- are elderly or in a weak state of health
- have any sort of heart problem
- suffer from seizures/fits (epilepsy)
- have diabetes
- have kidney damage
- have any disease affecting the blood cells
- are going to have surgery or dental work that requires an anaesthetic within the next two weeks it may affect the choice of anaesthetic.

This medicine may occasionally affect your liver. Your doctor may send you for a blood test to check your liver function.

Thoughts of suicide and worsening of your depression or anxiety disorder.

• If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

• You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Children and adolescents

Isocarboxazid tablets are not recommended for use in children

Other medicines and Isocarboxazid

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines. This includes medicines obtained without a prescription.

In particular, you should tell your doctor about:

- All other medicines which treat depression or anxiety including other MAOIs, selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants, eg clomipramine and imipramine
- Medicines for high blood pressure, e.g. reserpine, methyldopa
- Medicines to treat diabetes, e.g. insulin, metformin
- Medicines used for cough and colds such as decongestants (these may contain substances called sympathomimetic agents, eg ephedrine, pseudoephedrine)
- Medicines used for asthma or heart problems which contain sympathomimetic agents such as adrenaline and noradrenaline
- Medicines used to suppress the central nervous system such as anticonvulsants for epilepsy and phenothiazines for severe mental problems, eg chlorpromazine, fluphenazine
- Medicines to control appetite, eg amphetamine and fenfluramine
- Medicines that treat Parkinson's disease, e.g. levodopa
- Strong pain killers, e.g. pethidine and morphine
- Barbiturates used to treat severe sleeping problems, eg amylobarbitone

- Medicines called antimuscarinics which are used in Parkinson's disease, stomach and bladder problems
- Diuretic medicines ("water tablets")

Isocarboxazid with food, drink and alcohol

You should NOT take alcohol (especially red wine) whilst you are taking Isocarboxazid tablets. This includes non-alcoholic beer or lager.

Isocarboxazid tablets stop the breakdown of a substance called tyramine which is found in large amounts of certain foods. If this substance is not broken down, it can cause very high blood pressure. So, while you are taking Isocarboxazid and for two weeks after the course of treatment has finished, you should avoid the following foods:

- Matured cheeses (e.g. cheddar or processed cheese made from mature cheese)
- Yeast extracts (e.g. Bovril or Marmite)
- Meat, fish or poultry which is not fresh or has been pickled
- Broad bean pods
- Over-ripe fruit

Pregnancy and breast-feeding and fertility

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.

Isocarboxazid should not be used during pregnancy or breast feeding unless your doctor thinks it is essential to do so.

Driving and using machines

Isocarboxazid tablets may make you feel drowsy or dizzy or affect your concentration. You should not drive or use machines when you first start to take this medicine until you are certain that you are not getting these side effects. If in any doubt, speak to your doctor before you drive or use machines.

Isocarboxazid tablets contain Lactose

These tablets contain 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.

3. How to take Isocarboxazid tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is between one and three tablets daily, taken at different times or all together.

Sometimes this medicine needs to be taken for several weeks before you begin to feel better. Your symptoms should improve within a month but if no improvement is obtained in this time your doctor may increase the dose. It is very important to persist with the treatment course recommended by your doctor to obtain the maximum benefit from this medicine

Use in children and adolescents

Isocarboxazid tablets are not recommended for use in children.

Route and method of administration

For oral use only

If you take more Isocarboxazid tablets than you should

If you swallow too many tablets or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest accident and emergency department straight away. Take the medicine pack or this leaflet and any remaining tablets with you.

If you forget to take Isocarboxazid tablets

If you miss a dose, take it as soon as you remember provided that this is on the same day. You can take the full day's dose in one go, but do not take more than this on any one day.

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

4. Possible side effects

Like all medicines Isocarboxazid tablets can sometimes cause side-effects, although not everybody gets them.

- All medicines can cause allergic reactions although serious allergic reactions are very rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.
- The most common side effects are as follows, and can usually be controlled by reducing the dose:
 - Dizziness or fainting, especially on first standing up from a sitting or lying position; drowsiness or blurred vision; dryness of the mouth; heart palpitations; swelling of the feet or ankles; stomach upsets (feeling sick and vomiting); constipation; weakness, fatigue or difficulty in sleeping.

You should obtain medical help immediately if you experience all or some of the symptoms of unusually high blood pressure. These are severe chest pain and headache, enlarged pupils with sensitivity to light, sweating, stiff or sore neck, feeling sick and vomiting, fast or slow heartbeat.

• Less common side effects are mild headaches; sweating; abnormal tingling sensations and pain in the limbs; increased reflexes; feeling agitated or hyperactive; muscle tremors; confusion; difficulty in passing urine, obtaining an erection or ejaculating; skin rashes; disorders of blood cells causing purple spots under the skin or increased susceptibility to infection; changes in appetite and putting on weight.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme 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 Isocarboxazid tablets

Keep this medicine out of the sight and reach of children - preferably in a locked cupboard or medicine cabinet.

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

Return any left-over medicine to your pharmacist - only keep it if your doctor tells you to. The tablets should be stored at normal room temperature, below 25°C. Keep the bottle tightly closed.

REMEMBER this medicine is for you. Only a doctor can prescribe it for you. Never give it to others. It may harm them even if their symptoms are the same as yours.

Do not throw away 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 Isocarboxazid tablets contain

The active substance is Isocarboxazid. Each tablet contains 10mg of Isocarboxazid.

The other ingredients are starch, lactose, talc, magnesium stearate, gelatin, yellow and red iron oxides E172

What Isocarboxazid tablets look like and contents of pack

Each bottle of tablets contains 56 tablets.

Marketing Authorisation holder

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Manufacturer

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