

PACKAGE LEAFLET: INFORMATION FOR THE USER

OIKAMID

400 mg Capsules

PIRACETAM

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

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

1. WHAT OIKAMID IS AND WHAT IS IT USED FOR

OIKAMID Capsules belongs to a group of medicines known as GABA analogues.

OIKAMID Capsules contains the active ingredient Piracetam. It acts on the brain and nervous system and is thought to protect it against a shortness of oxygen.

OIKAMID Capsules are used in combination with other medicines to treat myoclonus. This is a condition in which the nervous system causes muscles, particularly in the arms and legs, to start to jerk or twitch uncontrollably.

2. BEFORE YOU TAKE OIKAMID

Do not take OIKAMID Capsules if:

- You are allergic to the active ingredient piracetam
- You are allergic to any of the other ingredients of OIKAMID
- You have ever had serious kidney problems
- You suffer from Huntington's Disease (also known as Huntington's Chorea)

- You have ever experienced a brain haemorrhage

If any of the above applies to you, do not take OIKAMID Capsules and talk to your doctor or pharmacist.

Check with your doctor before taking OIKAMID Capsules if:

- You think your kidneys may not be working perfectly. (Your doctor may need to start you on a lower dose.)
- You have ever had any kind of bleeding problem.

Tell your doctor if you are taking any of the following medicines:

- Thyroid extract or thyroxine
- Anticoagulants such as warfarin or aceno-coumarol
- Low dose aspirin
- Any other medicines, including medicines obtained without a prescription.
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Pregnancy and breast-feeding

If you are pregnant, trying to become pregnant or breast-feeding ask your doctor or pharmacist for advice before taking OIKAMID Capsules. If you are taking this medicine, use contraception to avoid becoming pregnant. If you are taking OIKAMID Capsules and you think you may be pregnant, consult your doctor immediately.

Driving and using machines

OIKAMID Capsules may cause drowsiness and shakiness. If this happens to you, do not drive or use machinery.

3. HOW TO TAKE OIKAMID

Always take OIKAMID Capsules exactly as your doctor has told you.

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Adults

How much medicine to take and when to take it

- The normal starting dose is 7.2 g each day.
- It is best to split the dose so that the Capsules are taken on two or three separate occasions during the day.
- When you start taking this medicine your doctor may tell you to gradually increase the dose to ensure that you receive the best dose to treat your condition.
- Follow your doctor's instructions carefully.

How to take your medicine

- Swallow the Capsules whole with a glass of water.
- Do not break or chew the Capsules as piracetam has a very bitter taste.
- If you find it difficult to swallow the Capsules tell your doctor as soon as possible as they can prescribe piracetam in the form of a solution.

Elderly and patients with kidney problems

If you are elderly or have kidney problems your doctor may reduce your dose.

If you take more OIKAMID Capsules than you should

If you accidentally take too much, immediately go to the nearest hospital casualty department or your doctor.

If you forget to take OIKAMID Capsules

Do not take a double dose to make up for a missed dose. Simply take the next dose as planned.

Stopping OIKAMID Capsules

Do not stop taking OIKAMID Capsules without first talking to your doctor. Abruptly stopping your medicine may cause twitching and jerking.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines OIKAMID Capsules can cause side effects, although not everybody gets them.

You may notice the following side effects:

- An allergic reaction and experience difficulty breathing, swelling, fever
- Spontaneous bleeding caused by defects in your blood clotting mechanism
- Worse fits
- Hallucinations
- Difficulty balancing and unsteadiness when standing
- Anxiety and agitation
- Confusion
- Restlessness
- Nervousness
- Sleepiness
- Depression
- Weakness
- Vertigo
- Weight increase
- Stomach pain
- Diarrhoea
- Feeling or being sick
- Headache
- Being unable to sleep
- Swelling of the skin, particularly around the face
- Skin rash and itching.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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

5. HOW TO STORE OIKAMID

Keep out of the reach and sight of children.

Do not use OIKAMID Capsules after the expiry date on the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Return any medicine you no longer need to your pharmacist.