Metopirone® Capsules 250 mg

1. What Metopirone is and what it is taken for

Metopirone is used to diagnose and treat Cushing’s syndrome (a condition where your body makes too much hormone cortisol). It is especially useful when this condition is caused by a tumour in your pituitary gland.

Metopirone belongs to a group of medicines called endocrine medicines. It works by suppressing the production of certain types of hormones.

2. Check before you take Metopirone

Do not take Metopirone:

- if you are allergic (hypersensitive) to metopirone or any of the ingredients of Metopirone (see Section 6 Further information).
- if you are pregnant. If you are breast-feeding, you may suffer from an under-active thyroid gland (causing weight gain, dry skin or sensitivity to the cold).
- if you are likely to have high blood pressure.
- if you suffer from a deficiency of growth hormone (gigantism).
- if you have cirrhosis of the liver

Taking Metopirone may make you feel dizzy or tired. If you are affected you should not drive or perform any other tasks that require you to be alert.

Metopirone should be swallowed whole with a drink of milk or after a meal. Do not chew the capsules. The usual dose is up to 3 capsules 4 times a day, divided throughout the day. You will be given a correct dose by your doctor.

Metopirone should be swallowed whole with a drink of milk or after a meal.

3. How to take Metopirone

Always take Metopirone exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Metopirone should be swallowed whole with a drink of milk or after a meal. Do not chew the capsules. The usual dose is up to 3 capsules 4 times a day, divided throughout the day. You will be given a correct dose by your doctor.

4. Possible side effects

Metopirone may cause some side effects, although not everyone gets them.

Common side effects (safely occur in more than 1 in 10 patients):

- feeling of nervousness
- feeling sick or vomiting
- flushing (warmth, redness or tingling of the face, neck or chest). Rare side effects (safely occur in less than 1 in 10 patients):

- allergic disorder (e.g. rash, itching, swelling of the face, lips or throat)
- dry mouth
- rare side effects (safely occur in less than 1 in 1000 patients):

- dizziness, feeling drowsy or tired
- diarrhoea
- bloating with fluid retention
- skin problems such as acne

If any of the side effects gets worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Metopirone

Keep out of the reach and sight of children.

Do not take Metopirone after the expiry date which is stated on the carton and bottle. The expiry date refers to the last day of that month.

Do not wash down BFC and protect from moisture and heat. Keep the container tightly closed.

Do not store Metopirone if you notice any change in the colour or the capsule.

Metopirone should not be disposed of via waste materials or household waste.

Ask your pharmacist on how to dispose of medicines no longer required. These measures will help protect the environment.

6. Further information

What is Metopirone?

The active ingredient in this medicine is metopirone 250 mg.

Capsules (HRA) are yellowish-white. Each capsule has ‘HRA’ printed on one side. The printing is in red ink.

Metopirone capsules come in plastic bottles of 100 capsules.

Each capsule contains a yellow core. Each capsule contains 250 mg of Metopirone.

The product is supplied in units of 300 mg, 600 mg and 1200 mg.

This will reduce the chance of the tablets making you feel sick.

Metopirone and all its ingredients pass environmental tests. Each capsule contains 250 mg of Metopirone.

For the purpose of this leaflet, each dose is a full capsule. Each capsule contains 250 mg of Metopirone.

If you mix the above ingredients with water, a single capsule will give you the correct dose for your test. You will then be told by your doctor whether or not you have Cushing’s disease.

Treatment of Cushing’s syndrome

The usual dose is between 100 to 200 mg capsules 4 times a day.

Your doctor will decide the correct dose for you.

3. How to take Metopirone

Always take Metopirone exactly as your doctor tells you. You should check with your doctor or pharmacist if you are not sure.

Metopirone should be swallowed whole with a drink of milk or after a meal. Do not chew the capsules. The usual dose is up to 3 capsules 4 times a day, divided throughout the day. You will be given a correct dose by your doctor.

Treatment of Cushing’s syndrome

The usual dose is between 100 to 200 mg capsules 4 times a day.

Your doctor will decide the correct dose for you.

Treatment of water retention

The usual dose is 12 capsules of 250 mg a day, divided throughout the day. You will also be given a special diet and medical advice.

If you are elderly or you receive the same dose as above.

If the patient is a child, the doctor will choose a suitable dose based on your child’s weight.

If you are not sure how many capsules to take, ask your doctor or pharmacist.

Do not stop taking Metopirone suddenly as this can make your condition worse.

DO NOT take a double dose. There go on as before.

If you take other medicines

Tell your doctor or pharmacist if you are taking or have recently taken:

- any hormone treatments (e.g. cortisone, oestrogens)
- any anticonvulsants to treat epilepsy (e.g. phenytoin or barbiturates)
- any of the following medicines as they may interfere with Metopirone:

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