

PATIENT INFORMATION LEAFLET

Metopirone[®] Capsules 250 mg

metyrapone

Read all of this leaflet carefully before you start taking this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

The information in this leaflet has been divided into the following sections:

1. **What Metopirone is and what it is taken for**
2. **Check before you take Metopirone**
3. **How to take Metopirone**
4. **Possible side effects**
5. **How to store Metopirone**
6. **Further information**

1. What Metopirone is and what it is taken for

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

Metopirone is used to diagnose and treat Cushing's syndrome (a condition when the body produces too much cortisol which is a type of steroid).

It is also used to treat some types of water retention in patients suffering from certain kidney problems, cirrhosis of the liver, or heart failure.

2. Check before you take Metopirone

Do not take Metopirone:

- if you are allergic (hypersensitive) to metyrapone or any of the ingredients of Metopirone (see Section 6 Further information)
- if you are pregnant, trying to become pregnant or breast-feeding
- if you suffer from an under-active adrenal gland (sometimes known as Addison's disease).

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Metopirone.

Take special care with Metopirone

Before you take Metopirone tell your doctor if:

- you have cirrhosis of the liver
- you suffer from an under-active thyroid gland (causing weight gain, dry brittle hair or sensitivity to the cold)
- you suffer from an under-active pituitary gland (causing an imbalance of some hormones)
- you have high blood pressure.

During treatment with Metopirone

Metopirone may temporarily lower the amount of hormones produced by your adrenal gland but your doctor will correct this using appropriate steroid medication.

If you develop shortness of breath and fever over hours or days contact your doctor as soon as possible as you may be developing a serious lung infection.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Metopirone.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken/used any of the following medicines as they may interfere with Metopirone:

- anticonvulsants to treat epilepsy (e.g. phenytoin or barbiturates)
- antidepressants or other medicines for mental illness (e.g. amitriptyline, chlorpromazine or alprazolam)
- any hormone treatments (e.g. clomifene, tetracosactide, growth hormone, treatments for infertility or thyroid hormone)
- anti-thyroid medicines (e.g. carbimazole, propylthiouracil or iodine).

- Allergic disorder (cyproheptadine)
- Fever, pain (paracetamol, acetaminophen)

Please tell your doctor or pharmacist if you are taking or have recently taken/used any other medicines, including medicines obtained without a prescription.

Taking with food and drink

Metopirone should be swallowed whole with a drink of milk or after a meal. This will reduce the chance of the tablets making you feel sick.

Pregnancy and breast-feeding

It is not known if Metopirone passes into breast-milk. Do not take Metopirone if you are pregnant, planning to become pregnant or breast-feeding. If you become pregnant whilst taking Metopirone tell your doctor immediately.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Taking Metopirone may make you feel dizzy or tired. If you are affected you should not drive or work with machinery until this effect has worn off.

Important information about some of the ingredients of Metopirone

Metopirone contains:

- sodium ethyl (E215) - this preservative can cause skin rashes and (rarely) breathing difficulties.
- sodium propyl hydroxybenzoate (E217) - this preservative can cause skin rashes and (rarely) breathing difficulties.
- glycerin - which can be harmful in high doses. It can cause headaches, stomach upsets and diarrhoea.

3. How to take Metopirone

Always take Metopirone exactly as your doctor has told you to. 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 for each condition is given below.

Diagnosis of Cushing's syndrome

To determine if you have Cushing's syndrome you will be kept in hospital for 4 days. Your urine will be tested each day. The first 2 days are used to check your normal test results. On the third day 3 Metopirone capsules (750 mg) will be given to you every 4 hours. In total 6 doses (4.5 g) will be given to you. The fourth day of your hospital stay will give the results of your test. You will then be told by your doctor whether or not you have Cushing's syndrome.

Treatment of Cushing's syndrome

The usual dose is between one (250 mg) and 24 capsules (6 g) each day. Your doctor will decide the correct dose for you.

Treatment of water retention

The usual dose is 12 capsules (3 g) a day, divided throughout the day. You will also be given a steroid medicine at the same time.

If you are elderly, you will receive the same doses 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.

What to do if you take more Metopirone than you should

If you accidentally take too many Metopirone capsules, or someone else takes any of this medicine, you should tell your doctor at once or contact your nearest accident and emergency department. Show any left over medicines or the empty packet to the doctor.

If you forget to take Metopirone

Don't worry. If you forget to take a dose, take it as soon as possible, unless it is almost time to take the next dose. DO NOT take a double dose. Then go on as before.

If you stop taking Metopirone

DO NOT stop taking Metopirone suddenly as this can make your condition worse.

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

4. Possible side effects

Do not worry. Like all medicines, Metopirone can cause side effects, although not everyone gets them.

Common side effects (that affect less than 1 person in 10) of Metopirone include:

- feeling or being sick
- dizziness, feeling drowsy or tired
- headache
- low blood pressure (causing dizziness and light-headedness).

Rare side effects (that affect less than 1 person in 1,000) of Metopirone include:

- stomach pain
- skin rash
- an under-active adrenal gland (resulting in an imbalance of hormones)
- an increase in body hair.

Other side effects (frequency unknown) of Metopirone include:

- Decreased or insufficient production of blood cells due to abnormal function of the bone marrow.
- High blood pressure
- Hair loss

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 store above 30°C and protect from moisture and heat. Keep the container tightly closed.

Do not take Metopirone if you notice any change in the colour of the capsules.

Medicines should not be disposed of via wastewater 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 in Metopirone?

The active ingredient in this medicine is metyrapone 250 mg.

The other ingredients are

- capsule core: glycerin, polyethylene glycol 400, polyethylene glycol 4000 and water
- capsule shell: sodium ethyl hydroxybenzoate (E215), ethyl vanillin, gelatin, p-methoxy acetophenone, sodium propyl hydroxybenzoate (E217) and titanium dioxide (E171).

What Metopirone looks like and contents of the pack

Metopirone capsules come in plastic bottles of 100 capsules.

Each oblong capsule is yellowish-white. Each capsule has 'HRA' printed on one side. The printing is in red ink.

Marketing Authorisation Holder and Manufacturer

The product licence holder is: Laboratoire HRA Pharma, 15 rue Béranger, 75003, Paris, FRANCE

Metopirone is manufactured by:

DELPHARM LILLE S.A.S.

PARC D'ACTIVITES ROUBAIX-EST

22 RUE DE TOUFFLERS CS 50070

59452 LYS-LEZ-LANNOY FRANCE

The information in this leaflet applies only to Metopirone. If you have any questions or you are not sure about anything, ask your doctor or a pharmacist.

This leaflet was last approved: December 2016

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