

Package leaflet: Information for the patient

Metyrapone HRA 250mg soft capsules
Metyrapone

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. See section 4.

What is in this leaflet

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1. What Metyrapone HRA is and what it is used for

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

Metyrapone HRA 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. What you need to know before you take Metyrapone HRA

Do not take Metyrapone HRA:

- if you are allergic (hypersensitive) to metyrapone or any of the ingredients of Metyrapone HRA (see Section 6)
- 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 Metyrapone HRA.

Warnings and precautions

Take special care with Metyrapone HRA

Before you take Metyrapone HRA 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 Metyrapone HRA

Metyrapone HRA 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 Metyrapone HRA.

Other medicines and Metyrapone HRA

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

- anti-convulsants to treat epilepsy (e.g. phenytoin or barbiturates)
- anti-depressants 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.

Metyrapone HRA with food and drink

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

Pregnancy and breast-feeding

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

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

Driving and using machines

Taking Metyrapone HRA 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 Metyrapone HRA

contains:

- **sodium ethylparaben (E215)** - may cause allergic reactions (possibly delayed).
- **sodium propylparaben (E217)** - may cause allergic reactions (possibly delayed).

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium free'.

3. How to take Metyrapone HRA

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

Metyrapone HRA 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 Metyrapone HRA (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.

If you take more Metyrapone HRA than you should

If you accidentally take too many Metyrapone HRA , or someone else takes any of this medicine, you should tell your doctor at once or contact your nearest accident and emergency department. You may also feel dizzy, tired, have a headache, begin sweating and your blood pressure increases. You may need to take activated charcoal and be given hydrocortisone. Show any left-over medicines or the empty packet to the doctor.

If you forget to take Metyrapone HRA

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 Metyrapone HRA

DO NOT stop taking Metyrapone HRA 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, Metyrapone HRA can cause side effects, although not everyone gets them.

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

- decrease of amount of red blood cells, white blood cells or platelets in blood and the symptoms may include: bleeding or bruising lasting longer than normal, blood seen in the gums, nose or skin and feeling tired most of the time, shortness of breath, colds that keep coming back
- high blood pressure
- hair loss.

Reporting side effects

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.

This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

United Kingdom

Yellow Card Scheme

Website: 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 Metyrapone HRA

Keep out of the reach and sight of children.

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

Store below 25°C. Keep the bottle tightly closed to protect the product from moisture. Do not take Metyrapone HRA 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. Contents of the pack and other information

What Metyrapone HRA contains

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 Metyrapone HRA looks like and contents of the pack

Metyrapone HRA come in plastic bottles of 100 soft capsules.

Each oblong soft 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: HRA Pharma Rare Diseases, 200 avenue de Paris, 92320 CHATILLON, FRANCE

Metyrapone HRA 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 Metyrapone HRA. If you have any questions or you are not sure about anything, ask your doctor or a pharmacist.

This leaflet was last revised in June 2022.

Metyrapone HRA is an on-going registered trademark of HRA Pharma Rare Diseases