

METOPIRONE[®]

Metyrapone
250mg Capsules

What is in this leaflet

This leaflet answers some common questions about METOPIRONE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.medsafe.govt.nz.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking METOPIRONE against the benefits they expect it will have for you.

If you have any concerns about this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine.

You may need to read it again.

What METOPIRONE is used for

METOPIRONE belongs to a group of medicines called diagnostic agents. It acts by reducing the production of the adrenal gland hormones: cortisol and corticosterone (which are also called corticosteroids).

METOPIRONE is used as a test to find out if ACTH (Adrenocorticotrophic hormone, a natural body hormone acting on corticosteroid secretion), is being produced properly. Changes in the production of ACTH may happen for a number of reasons, for example, due to changes in the function of the adrenal glands or the pituitary gland, or due to treatment with certain medicines.

METOPIRONE can be used to treat the signs and symptoms of Cushing's syndrome by lowering high levels of cortisol a hormone produced by the adrenal glands. This medicine may also be used to treat conditions where the adrenal glands produce too much of the hormone aldosterone, or hormone imbalances causing the build-up of fluid in the body.

Ask your doctor if you have any questions about how this medicine works or why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is only available with a doctor's prescription. It is not addictive.

Before you take METOPIRONE

When you must not take it

Do not take METOPIRONE if you have ever had an allergic reaction to metyrapone (the active ingredient) or to any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take METOPIRONE if you suffer from a condition whereby your adrenal glands do not produce enough steroid hormones (cortisol or aldosterone) known as Addison's disease.

Do not breast-feed while you are taking the METOPIRONE.

There is not enough information to recommend breast-feeding while you are taking this medicine and there is a possibility that metyrapone may be passed to your baby in breast milk. Talk to your doctor about stopping your treatment if you wish to breast-feed.

Do not take METOPIRONE after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor if you have allergies to other medicines, foods, dyes or preservatives.

Tell your doctor if you have any of the following medical conditions and you are about to have the METOPIRONE test:

- impaired liver function or cirrhosis of the liver (a chronic liver disorder leading to progressive loss of liver function)
- an underactive thyroid gland (which can cause weight gain, dry brittle hair, cold intolerance, constipation, forgetfulness, or personality changes)
- an underactive pituitary gland (which can cause an imbalance of some hormones)
- high blood pressure.

The results of the test may be affected by the above conditions.

Your doctor will perform tests before and during treatment with METOPIRONE to monitor your progress.

Your doctor will test your blood before you start the treatment and regularly during the treatment to check your potassium, electrolyte and hormone levels. Your doctor may check your blood pressure and also perform an electrocardiogram (ECG) to record the electrical activity of your heart. Your doctor may change your dose or medicines depending on the test results. Tell your doctor if you feel unwell during treatment (see Side Effects section).

If you are pregnant, or think you are pregnant or planning to become pregnant, tell your doctor before you take METOPIRONE.

There is not enough information to recommend its use during pregnancy. Your doctor can discuss with you the risks and benefits involved.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the results of the METOPIRONE test. These include:

- corticosteroid medicines
- any hormone treatments (e.g. tetracosactide, growth hormone, treatments for infertility, the birth control pill and hormone replacement therapy (HRT))
- medicines to treat epilepsy (e.g. phenytoin or barbiturates)
- medicines used to treat anxiety, depression (feelings of deep sadness), psychosis (a severe mental condition in which the person loses contact with reality and is unable to think and judge clearly) (e.g. amitriptyline, alprazolam, or chlorpromazine)
- medicines for your thyroid gland (e.g. levothyroxine, carbimazole, propylthiouracil)
- cyproheptadine, a medicine used for treatment of allergic disorders
- paracetamol, a medicine used for the treatment of fever and pain.

Tell your doctor if you are taking insulin or oral medicines for diabetes.

Your doctor may ask you stop taking some of your medicines during the METOPIRONE test. You may need different amounts of your medicines or you may need to take different medicines while taking METOPIRONE for ongoing treatment.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take METOPIRONE

Follow all directions given to you by your doctor or pharmacist carefully.

Check with your doctor or pharmacist if you are not sure.

How much to take for the METOPIRONE test

There are two types of METOPIRONE test. Your doctor will advise you which one you will have.

1. Short single dose test:

This test can either be done at home or you may be admitted to hospital overnight. At around midnight you will take a number of capsules calculated by your doctor, according to your body weight. This may be up to 3 grams (12 capsules) of METOPIRONE. Eight hours later, a blood sample will be taken. After the test you may also have to take a dose of 50 mg cortisone to prevent any unwanted effects on your adrenal glands.

2. Multiple dose test:

This test is always done in hospital. First, your urine is collected for 24 hours. Then you will take 500 to 750 mg (2 to 3 capsules) of METOPIRONE every 4 hours for the next 24 hours.

Urine will be collected again for the following 24 hours and the results of the urine tests will be compared.

Use in children

For the multiple-dose test children will be given 15 mg/kg based on body weight with a minimum dose of 250 mg every 4 hours.

How much to take for treatment of Cushing's syndrome and other conditions

Your doctor will decide how many METOPIRONE capsules you need depending on your body weight.

The dose you are given will be specific to you and your dose may range from 1 capsule (250 mg) to 24 capsules (6 grams) per day in three or four divided doses.

Your doctor may adjust your dose based on tests performed to check on your progress with the aim to restore normal hormone levels.

Use in children

The dose will be adjusted based on the child's hormone levels and how well they tolerate this medicine.

Do not exceed the recommended dose. Follow all of your doctor's instructions carefully. Continue taking your medicine for as long as your doctor tells you.

They may differ from the general information contained in this leaflet.

How to take it

Take the capsules with milk or yoghurt or after a meal to minimise nausea and vomiting. Do not chew the capsules.

This will help to prevent stomach upset.

If you forget to take it

If you accidentally forget to take a dose of capsules, you should take it as soon as you remember. If it is nearly time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

Things to be careful of

METOPIRONE may temporarily lower the amount of hormones produced by your adrenal glands but your doctor will correct this using appropriate hormone medication.

If you feel dizzy or drowsy after taking this medicine, you should not drive or operate machinery until these effects have passed. Children should avoid doing things like riding bicycles or climbing trees.

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

METOPIRONE capsules contain sodium propyl hydroxybenzoate (E217) and sodium ethyl hydroxybenzoate (E215). These preservatives can cause skin rashes and (rarely) breathing difficulties. This product also contains glycerol, which can cause headaches, stomach upsets, and diarrhoea in high doses.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital if you think that you may have taken more capsules than you have been told to take, or if anyone else has accidentally taken any METOPIRONE capsules.

Make sure that you take this leaflet and any remaining capsules in the packet with you to show them to the medical staff. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Some of the symptoms of an overdose may include: nausea, vomiting, stomach pain, diarrhoea, anxiety, dizziness, confusion, dehydration, weakness.

Side effects

Tell your doctor or hospital staff (if you are having the METOPIRONE test) as soon as possible if you do not feel well, even if you do not think it is connected with the medicine.

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor or hospital staff if you notice any of the following and they worry you:

- rash, itching or hives on the skin
- dizziness or light headedness
- drowsiness, tiredness or weakness
- low or high blood pressure
- loss of appetite
- nausea (feeling sick) or vomiting
- pain in the abdomen
- diarrhoea
- headache
- hair loss or excessive hair growth in unusual areas (hirsutism)
- acne
- muscle or joint pain
- swelling of limbs, hands or feet
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- bleeding or bruising more easily than normal
- 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
- low level of potassium (hypokalaemia).

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects (for example, low potassium levels, increases in liver enzymes, changes in blood cells or blood pressure) can only be found when your doctor does tests from time to time to check your progress.

Product description

What it looks like

METOPIRONE capsules are white to yellowish-white oblong soft gelatin capsules marked “HRA” on one side with red ink. Each bottle contains 50 capsules.

Ingredients

Each capsule of METOPIRONE contains 250 mg of the active ingredient, metyrapone. Each capsule also contains:

- glycerol
- macrogol 400 and 4000
- purified water
- sodium ethyl hydroxybenzoate (E215)
- sodium propyl hydroxybenzoate (E217)
- ethyl vanillin
- gelatin
- acetanisole
- titanium dioxide (E171)
- red ink which contains carmine (E120), aluminium chloride hexahydrate, sodium hydroxide and hypromellose.

Storage

Store your capsules in the original container in a cool dry place where the temperature stays below 25°C.

Do not store your medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Keep the medicine where children cannot reach it.

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Sponsor Details

METOPIRONE is supplied in New Zealand by:

Asteri Pharma Limited (Asteri NZ)

C/- Pharmacy Retailing (NZ) Limited t/a Healthcare Logistics (Richard Pearse Drive),
58 Richard Pearse Drive, Mangere Auckland 2022

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