METOPIRONE®

metyrapone

Consumer Medicine Information

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.

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 (adrenocorticotropic hormone, a natural body hormone acting on corticosteroid secretion), is being produced properly.

Changes in the production of ACTH may happen for several reasons, for example, due to changes in the function of the adrenal or pituitary gland, or due to treatment with certain medicines.

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

If any of the following apply to you, tell your doctor without taking METOPIRONE.

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 having the METOPIRONE test.

There is not enough information to recommend breast-feeding while you are having the test.

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

In that case, return it to your pharmacist.

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:

- 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 these medical conditions.

If you are pregnant or think you are pregnant, tell your doctor before you have the METOPIRONE test.

There is not enough information to recommend its use during pregnancy. If there is an urgent need for you to have the METOPIRONE test, your doctor can advise you about the risks and benefits.

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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 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 test. If you are unsure whether any of the medicines you are taking will affect the test, your doctor can advise you.

If you have not told your doctor about any of these things, tell him/her before you have the METOPIRONE test.

How to take METOPIRONE

How the test is done

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 METOPIRONE capsules calculated by your doctor, according to your body weight. This may be up to maximum 3 grams (12 capsules). 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. Your urine will be collected again for the following 24 hours and the results of the urine tests will be compared.

How much to take

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

Do not exceed the recommended dose.

Follow all of your doctor's instructions carefully.

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.

Things to be careful of

METOPIRONE may temporarily lower the amount of hormones produced by your adrenal gland. 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 and sodium ethyl hydroxybenzoate. 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.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) 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.

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

Side effects

Tell your doctor or hospital staff as soon as possible if you do not feel well while you are having the METOPIRONE test, even if you don't 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 as soon as possible 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
- nausea (feeling sick) or vomiting
- pain in the abdomen
- headache
- 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.

The above list includes side effects that may require medical attention.

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.

Product description

What it looks like

METOPIRONE capsules are white to yellowish white oblong soft gelatin capsules marked "HRA" on one side in red ink. Each bottle contains 50 capsules.

Ingredients

Active

Each METOPIRONE capsule contains metyrapone 250 mg.

Inactive ingredients

METOPIRONE capsules also contain:

- acetanisole
- · ethyl vanillin
- gelatin
- glycerol
- macrogol 400 and 4000
- sodium propyl hydroxybenzoate
- sodium ethyl hydroxybenzoate
- titanium dioxide
- · purified water
- Edible ink Red (PI 3115).

Sponsor

METOPIRONE is supplied in Australia by:

good place to store medicines.

A locked cupboard at least one-and-

a-half metres above the ground is a

Chiesi Australia Pty Ltd

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Australian Registration Number AUST R 11043

This leaflet was prepared in July 2023.

After using METOPIRONE

Storage

If you must keep METOPIRONE capsules at home before you have the test:

- Store them 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 a window sill.

Keep the medicine where children cannot reach it.

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