

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.

The information in this leaflet was last updated on the date listed on the final page. Some more recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Metopirone against the benefits they expect it will give 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 a number of 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 Metopirone works or why the Metopirone test 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 have an underactive adrenal gland (also 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 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, 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.

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

Your doctor will want to know if you are prone to allergies.

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:

- glucocorticoid medicines
- any hormone preparations, including natural or synthetic hormones, 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
- 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 is usually 1 to 2 grams (or 4 to 8 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. 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 minimize nausea and vomiting. Do not chew the capsules.

This will help to prevent stomach upset or other unwanted effects.

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.

Be careful driving, operating machinery or doing jobs that require you to be alert during or immediately after the Metopirone test until you know how it has affected you.

Some patients taking this medicine may experience dizziness, light headedness or drowsiness.

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.

If you take too much

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.

Keep the telephone numbers for these places handy.

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 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 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
- low blood pressure
- hair loss, changes in hair growth

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

It is possible that other side effects not listed above may happen in some people.

Product description

What it looks like

Metopirone capsules are cream coloured oblong capsules, marked "HRA" on one side in red ink. Each carton contains 50 capsules.

Ingredients

Active

Each Metopirone capsule contains metyrapone 250 mg.

Inactive Ingredients

Metopirone capsules also contain:

- acetanisole
- ethyl vanillin
- gelatin
- glycerol 85% (E 422)
- macrogol 400 and 4000
- sodium propyl hydroxybenzoate (E217)
- sodium ethyl hydroxybenzoate (E 215)

- titanium dioxide (E 171)
- purified water
- Edible ink Red (PI3115)

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 30°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 metres above the ground is a good place to store medicines.

Sponsor

Metopirone is supplied in Australia by:

Clinect Pty Ltd
120-132 Atlantic Drive
Keysborough Victoria 3173

Telephone: 1 800 899 005

®= Registered Trademark

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Metopirone capsules AUST R 11043

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