

Metopirone®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Metopirone®?

Metopirone® contains the active ingredient metyrapone. 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.

For more information, see Section [1. Why am I using Metopirone®?](#) in the full CMI.

2. What should I know before I use Metopirone®?

Do not use if you have ever had an allergic reaction to Metopirone® or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Metopirone®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Metopirone® and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Metopirone®?

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

More instructions can be found in Section [4. How do I use Metopirone®?](#) in the full CMI.

5. What should I know while using Metopirone®?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Metopirone®.• 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.
Things you should not do	<ul style="list-style-type: none">• Do not use Metopirone® if you have a known, severe allergic reaction to Metopirone® or any of its ingredients.
Driving or using machines	<ul style="list-style-type: none">• 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.
Looking after your medicine	<ul style="list-style-type: none">• If you need to store Metopirone®, please store in the original container in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using Metopirone®?](#) in the full CMI.

6. Are there any side effects?

The most common side effects are 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 and being short of breath when exercising, dizziness and looking pale, and bleeding or bruising more easily than normal.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Metopirone[®] (Met – oww – pyr - own)

Active ingredient(s): *metryrapone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Metopirone[®]. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Metopirone[®].**

Where to find information in this leaflet:

- [1. Why am I using Metopirone[®]?](#)
- [2. What should I know before I use Metopirone[®]?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Metopirone[®]?](#)
- [5. What should I know while using Metopirone[®]?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Metopirone[®]?

Metopirone[®] contains the active ingredient metyrapone. Metopirone[®] is a prescription only medicine.

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

2. What should I know before I use Metopirone[®]?

Warnings

Do not use Metopirone[®] if:

- you are allergic to metyrapone, or any of the ingredients listed at the end of this leaflet.
- you suffer from a condition whereby your adrenal glands do not produce enough steroid hormones (cortisol or aldosterone) known as Addison's disease.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions such as:
 - 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.
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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.

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your 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 them before you have the Metopirone[®] test.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Metopirone[®].

4. How do I use Metopirone[®]?

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.

When to take / use Metopirone[®]

- Your doctor will provide directions when to use Metopirone[®]. Refer to How the Metopirone[®] test is done in the following section.

How the Metopirone[®] 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 to take Metopirone[®]

- 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 use too much Metopirone[®]

If you think that you have used too much Metopirone[®], you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

Make sure that you take this leaflet and any remaining capsules in the packet with you to show them to the medical staff.

You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while using Metopirone[®]?

Things you should do

Follow the instructions of your doctor or medical staff.

Tell your doctor or medical staff if you have any side effects and they worry you.

Call your doctor or talk to medical staff straight away if you:

- develop shortness of breath and fever over hours or days. You may be developing a serious lung infection.

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.
- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Metopirone® affects you.

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.

Looking after your medicine

Metopirone® will generally be stored in the hospital.

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.

Keep it where young children cannot reach it.

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

When to discard your medicine (as relevant)

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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
General conditions: <ul style="list-style-type: none">• 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	Tell your doctor or hospital staff if you have any of these side effects and they worry you, even if you don't think it is connected with the medicine.

Side effects	What to do
<ul style="list-style-type: none">• 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. [list as appropriate]	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Metopirone® contains

Active ingredient (main ingredient)	Each Metopirone® capsule contains metyrapone 250 mg.
Other ingredients (inactive ingredients)	Metopirone® capsules also contain: <ul style="list-style-type: none">• acetanisole• ethyl vanillin• gelatin• glycerol• macrogol 400 and 4000• sodium propyl hydroxybenzoate• sodium ethyl hydroxybenzoate• titanium dioxide• purified water• Edible ink Red (PI 3115).
Potential allergens	The presence of sodium ethyl parahydroxybenzoate and sodium propyl parahydroxybenzoate can cause allergic reactions, which might be delayed.

Do not take this medicine if you are allergic to any of these ingredients.

What Metopirone® looks like

Metopirone® (Aust R 11043) capsules are white to yellowish white oblong soft gelatin capsules marked "M01" on one side in red ink. Each bottle contains 50 capsules.

Who distributes Metopirone®

Asteri Pharma Pty Ltd
6 Lux Way
Brunswick, Victoria 3056
Australia

Telephone: 1800 175 659

Website: <https://www.asteripharma.com>

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