

MODURETIC®

amiloride hydrochloride dihydrate 5 mg/hydrochlorothiazide 50 mg

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MODURETIC. 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 MODURETIC against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What MODURETIC is used for

MODURETIC contains a combination of two diuretics, amiloride hydrochloride and hydrochlorothiazide as the active ingredients.

MODURETIC is used to help reduce the amount of excess fluid in the body for people who have:

- oedema, swelling of the ankles, feet and legs
- ascites due to liver disease resulting in fluid accumulation in the stomach area.

MODURETIC is also used to help people with hypertension or high blood pressure.

Everyone has blood pressure. This pressure helps get your blood all around your body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have hypertension or high blood pressure when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems. You may feel fine and have no symptoms, but eventually hypertension can cause stroke, heart disease and kidney failure.

The combination of active ingredients in MODURETIC work by making your kidneys pass more water and salt whilst minimizing potassium loss. This helps reduce high blood pressure and some forms of swelling, while at the same time helping to maintain normal levels of potassium in your blood.

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

Your doctor may have prescribed it for another purpose.

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

There is no evidence that it is addictive.

Before you take it

When you must not take it

Do not take MODURETIC if you have ever had an allergic reaction to:

- amiloride hydrochloride dihydrate
- hydrochlorothiazide, sulfonamide or sulfur medicines
Hydrochlorothiazide is a sulfur-containing medicine (a sulfonamide).

Therefore, if you are allergic to sulfur medicines, such as some antibiotics, you are likely to be allergic to MODURETIC.

Check with your doctor or pharmacist if you are not sure whether you are allergic to sulfur medicines.

- any of the ingredients listed at the end of this leaflet.

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

Do not take MODURETIC if you are pregnant or intend to become pregnant unless you and your doctor have discussed the risks and benefits involved.

It may affect your developing baby if you take it during pregnancy.

Do not take MODURETIC if you are breast-feeding or intend to breast-feed.

This medicine can pass into breast milk and therefore may harm the baby.

Do not take MODURETIC if:

- you have kidney disease
- your doctor advises you that you have too much potassium in your blood
- you are taking medicines which can increase the amount of potassium in the blood or you are eating a potassium-rich diet.

MODURETIC helps maintain normal levels of potassium in your blood. If you are taking potassium tablets or supplements, other potassium-conserving medicines or a potassium-rich diet, your potassium levels may increase too much.

Ask your doctor or pharmacist if you are not sure whether you are taking any of these.

Do not give MODURETIC to a child.

The safety of MODURETIC in children has not been established.

Do not take MODURETIC if the packaging is torn or shows signs of tampering.

Do not take this medicine after the expiry date printed on the pack.

Before you start to take it

Tell your doctor if you are allergic to any other medicines or any foods, dyes or preservatives.

Tell your doctor if you have or have had any of the following medical conditions:

- high potassium levels in the blood
- diabetes
- liver disease
- kidney disease
- heart and lung disease
- high cholesterol
- gout
- asthma
- lupus erythematosus.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your

pharmacy, supermarket or health food shop.

Some medicines and MODURETIC may interfere with each other. These include:

- potassium tablets or other potassium-conserving medicines
- ACE inhibitors, medicines used to treat high blood pressure
- other medicines used to treat high blood pressure
- other fluid tablets (diuretics)
- digoxin, used to treat heart failure
- lithium, used to treat severe mood swings and some types of depression
- non-steroidal anti-inflammatory medicines (NSAIDs), used to treat inflammation, pain and arthritis
- steroid medicines such as cortisone, prednisone
- insulin and tablets used to treat diabetes
- cyclosporin and tacrolimus, medicines used to suppress the immune system
- barbiturates, used to treat epilepsy, such as phenobarbitone
- strong pain killers such as codeine, morphine, dextropropoxyphene
- cholestyramine and colestipol, used to treat high cholesterol
- medicines used to relax muscles before and during surgery
- medicines used in emergency situations such as adrenaline
- alcohol.

These medicines may be affected by MODURETIC or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking MODURETIC.

How to take it

How much to take

Your doctor will tell you how many tablets you need to take each day.

This depends on your condition and whether you are taking other medicines. Your initial dose will be maintained or adjusted until a satisfactory response is noted, but should not exceed 4 tablets per day.

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

They may differ from the information contained in this leaflet.

When to take it

If you are taking a single dose a day, take it in the morning. If you are taking more than one dose a day, take the last dose in the early evening, unless your doctor tells you otherwise.

MODURETIC may increase the amount of urine you pass and the number of times you go to the toilet. By taking the last dose in the early evening there may be less chance of your sleep being disturbed.

Take MODURETIC at about the same time each day, unless your doctor tells you otherwise.

This will help you remember when to take the tablets.

How long to take it

Continue taking MODURETIC for as long as your doctor tells you.

If you have high blood pressure, this medicine helps to control this condition but does not cure it. Therefore MODURETIC must be taken every day.

If you have oedema or ascites, your doctor will tell you how long to take it.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre on 13 11 26 (Australia) or 0800 POISON or 0800 764 766 (New Zealand) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much MODURETIC. Do this even if there are no signs of discomfort or poisoning. You may need medical attention.

While you are taking it

Things you must do

Visit your doctor regularly for a blood pressure test so they can make sure that MODURETIC is working properly and to check for any unwanted side effects.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

You may feel light-headed or dizzy when you begin to take MODURETIC. This is because your blood pressure is falling suddenly.

If this problem gets worse or continues, talk to your doctor.

Have regular skin cancer checks.

Treatment with Moduretic may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer).

If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking MODURETIC.

Tell any other doctor, dentist or pharmacist who is treating you that you are taking MODURETIC, especially if you are about to be started on any new medicines.

Tell your doctor if you become pregnant while taking MODURETIC.

Things to be careful of

Protect your skin from sun exposure and UV rays while taking Moduretic if you have had skin cancer or if you develop an unexpected skin lesion while taking Moduretic.

Be careful driving or operating machinery until you know how this medicine affects you.

MODURETIC may cause dizziness or light-headedness in some people, especially after the first few doses or if the dose is increased. Make sure you know how you react to it before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or light-headed.

If you drink alcohol, or take strong pain killers or barbiturates, dizziness and light-headedness may be worse.

Talk to your doctor about foods or drinks that have a high potassium content.

MODURETIC helps to maintain normal potassium levels in your body. However, if you eat foods or have drinks that are high in potassium this may lead to an increase of potassium in your body. Too much potassium can be harmful, therefore it is important to discuss your diet with your doctor.

Tell your doctor if you are being treated for diabetes.

MODURETIC may change how well your diabetes is controlled. Your doses of diabetic medicines, including insulin, may need to change.

Things that would be helpful for your blood pressure

Some self-help measures suggested below may help your blood pressure.

Talk to your doctor or pharmacist about these measures and for more information.

- **Alcohol**
your doctor may advise you to limit your alcohol intake.
- **Diet**
eat a healthy diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.
- **Exercise**
regular exercise helps to reduce blood pressure. Try regular walking, swimming, cycling or games such as tennis and golf. Before starting any exercise, ask your doctor about the best kind of programme for you.
- **Salt**
your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake you should avoid using salt in cooking or at the table.
- **Smoking**
your doctor may advise you to stop smoking or at least cut down.
- **Weight**
your doctor may suggest losing some weight to help lower your blood pressure. Some people may need a dietician's help to lose weight.

Side Effects

Tell your doctor as soon as possible if you do not feel well while you are taking MODURETIC.

MODURETIC helps most people with high blood pressure or some forms of swelling, but it may have unwanted side-effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

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

- nausea, vomiting, loss of appetite
- diarrhoea, constipation, stomach pain, wind
- dry mouth, thirst
- dizziness or lightheadedness
- weakness, drowsiness
- restlessness
- transient blurred vision or yellow vision
- passing less urine than normal.

Tell your doctor immediately if you notice any of the following:

- muscle cramps
- severe dizziness, spinning sensation
- fainting
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bruising or bleeding more easily than normal, nose bleeds
- tiredness, headaches, being short of breath when exercising, looking pale
- yellowing of the skin and/or eyes, also called jaundice
- numbness or tingling in the hands or feet
- skin rash, itchiness
- lesion or sore on the lips or on the skin that does not heal
- changes in the way your heart beats.

These may be serious side effects. You may need urgent medical attention.

Serious side effects are rare.

If any of the following happen, stop taking MODURETIC and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty swallowing or breathing
- shortness of breath
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- severe skin reaction which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell
- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black, sticky bowel motions (stools) or bloody diarrhoea
- chest pain or tightness.

These are serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking it

Storage

Keep your tablets in the blister pack until it is time to take them.

Keep it in a cool dry place where the temperature stays below 30°C.

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

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

If your doctor tells you to stop taking MODURETIC or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

MODURETIC tablets are plain, peach, diamond shaped, compressed tablets.

Available in packs of 50 tablets.

Ingredients

Active ingredients:

Each MODURETIC tablet contains amiloride hydrochloride dihydrate 5 mg and hydrochlorothiazide 50 mg.

Inactive ingredients:

- calcium hydrogen phosphate
- lactose
- starch-pregelatinised maize
- starch-maize
- guar gum
- magnesium stearate
- sunset yellow FCF CI15985.

MODURETIC tablets do not contain sucrose, gluten or tartrazine.

Sponsor

In Australia:

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos St
St Leonards NSW 2065

In New Zealand:

Pharmacy Retailing (NZ) Limited
t/a Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks Auckland

Australian Registration Number:

AUST R 10499

This leaflet was revised in December 2019