

Micardis® Plus

Tablets

telmisartan and hydrochlorothiazide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Micardis Plus.

It does not contain all available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking this medicine against the benefits it is expected to have for you.

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

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medicines.org.au and may

contain important information about the medicine and its use of which you should be aware.

Keep this leaflet with the medicine.

You may need to read it again.

What Micardis Plus is used for

Micardis Plus is used to lower high blood pressure (hypertension).

Everyone has blood pressure. This pressure helps your blood move 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 (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm or relaxed.

There are usually no signs 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, including stroke, heart disease and kidney failure.

How Micardis Plus works

Micardis Plus contains telmisartan and hydrochlorothiazide in one single tablet. These two active ingredients help to reduce blood pressure in different ways:

- Telmisartan belongs to a group of medicines called angiotensin II receptor blockers. Angiotensin II is a

substance in the body which causes blood vessels to narrow, thus increasing blood pressure. Telmisartan works by blocking the effect of angiotensin II. When the effect of angiotensin II is blocked, your blood vessels relax and your blood pressure goes down.

- Hydrochlorothiazide belongs to the group of medicines called diuretics. Diuretics help to reduce the amount of excess fluid in the body by increasing the amount of urine produced. They help with lowering blood pressure particularly when used with other blood pressure lowering medicines.

Your doctor may have prescribed Micardis Plus for another reason.

Ask your doctor if you have any questions about why Micardis Plus has been prescribed for you.

Micardis Plus is not addictive.

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

Before you take Micardis Plus

When you must not take it

Do not take Micardis Plus if you have an allergy to:

- any medicine containing telmisartan or hydrochlorothiazide (the two active ingredients in Micardis Plus)

- other sulfonamide-derived medicines
- any of the other ingredients listed at the end of this leaflet.

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 Micardis Plus if you have a rare hereditary condition of fructose intolerance.

The maximum recommended daily dose of Micardis Plus contains 169 mg of sorbitol (in the 40/12.5 mg tablets) and approximately 338 mg of sorbitol (in the 80/12.5 mg and 80/25 mg tablets).

Do not take Micardis Plus if you have a rare hereditary condition of galactose intolerance.

The maximum recommended daily dose of Micardis Plus contains 112 mg of lactose monohydrate (in the 40/12.5 mg and 80/12.5 mg tablets) and 99 mg of lactose monohydrate (in the 80/25 mg tablets).

Do not take Micardis Plus if you are pregnant.

Like other similar medicines, it may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking Micardis Plus.

It is not known if telmisartan or hydrochlorothiazide, the active ingredients in Micardis Plus, pass into breast milk and there is a possibility that your baby may be affected.

Do not give Micardis Plus to a child under the age of 18 years.

Safety and effectiveness in children and teenagers up to 18 years of age have not been established.

Do not take Micardis Plus if you have any of the following medical conditions:

- severe liver disease
- severe kidney disease
- cholestasis or biliary obstructive disorders (problem with the flow of bile from the gall bladder)
- low potassium levels in the blood
- high calcium levels in the blood
- low sodium levels that is treatment resistant
- low blood volume causing very low blood pressure
- gout
- diabetes or kidney problems and you are taking aliskiren (a medicine used to treat high blood pressure).

Do not take Micardis Plus 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.

If you are not sure whether you should start taking Micardis Plus, talk to your doctor.

Before you start to take it

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

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

- kidney problems
- liver problems
- heart problems
- diabetes
- high cholesterol levels
- a condition known as primary hyperaldosteronism (raised aldosterone levels, also known as Conn's syndrome)
- fructose intolerance
- galactose intolerance

- recent severe diarrhoea or vomiting
- asthma
- systemic lupus erythematosus (a disease affecting the skin, joints and kidney)
- eye problems
- skin cancer.

Tell your doctor if you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past.

Tell your doctor if you are following a very low salt diet.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell your doctor before you start taking Micardis Plus.

Taking other medicines

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

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

- any other medicines used to treat high blood pressure such as beta-blockers
- heart medicines such as digoxin, a medicine used to treat heart failure or antiarrhythmic medicines
- other diuretics or fluid tablets, medicines used to help the kidneys get rid of salt and water by increasing the amount of urine produced
- laxatives
- potassium supplements or potassium-containing salt substitutes
- medicines or salt substitutes which may increase your potassium levels
- amphotericin B, a medicine used to treat fungal infections
- penicillin antibiotics used to treat bacterial infections
- alcohol
- sleeping tablets
- lithium, a medicine used to treat certain mental illnesses
- medicines used to treat depression

- antipsychotics, medicines used to treat certain mental and emotional conditions
- antiepileptic's, medicines used to treat epilepsy or fits
- strong pain killing medicines
- medicines for diabetes (oral tablets or capsules or insulin)
- powder or granules used to help reduce cholesterol
- corticosteroid medicines such as prednisolone, cortisone or ACTH (a hormone)
- aspirin
- nonsteroidal anti-inflammatory agents (medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis)
- medicines used to treat gout
- medicines used to increase blood pressure, such as noradrenaline
- ciclosporin, a medicine used to help prevent organ transplant rejection or to treat certain problems with the immune system
- calcium supplements or medicines containing calcium
- vitamin D supplements

- anticholinergic medicines, which can be used to treat Parkinson's disease, relieve stomach cramps or prevent travel sickness
- amantadine, a medicine used to treat Parkinson's disease or to prevent influenza
- medicines used to treat cancer (cytotoxic medicines).

These medicines may be affected by Micardis Plus, or may affect how well it works. Other medicines used to treat high blood pressure may have an additive effect with Micardis Plus in lowering your blood pressure. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to take Micardis Plus

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

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

The usual dose for adults is one Micardis Plus 40/12.5 mg tablet once a day.

If your blood pressure is still too high after 4-8 weeks of starting treatment, your doctor may increase your dose to one Micardis Plus 80/12.5 mg tablet once a day.

If your blood pressure is still not satisfactorily controlled with Micardis Plus 80/12.5 mg, your doctor may increase your dose to one Micardis Plus 80/25 mg tablet once a day.

It is important to take Micardis Plus exactly as your doctor or pharmacist has told you.

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

Take Micardis Plus at about the same time each day, either morning or evening.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

You can take Micardis Plus with or without food.

How long to take it

Continue taking Micardis Plus for as long as your doctor tells you.

Micardis Plus helps control your high blood pressure but does not cure it. It is important to keep taking Micardis Plus every day even if you feel well.

People who have high blood pressure often feel well and do not notice any signs of this problem.

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 the dose as soon as you remember, and then go back to taking it as you would normally.

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

This may increase the chance of you getting unwanted side effects.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice or go to Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Micardis Plus.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Micardis Plus you may feel dizzy, light-headed or faint. Your heartbeat may be faster or slower than usual. You may experience dehydration, nausea, drowsiness and muscle spasm.

While you are taking Micardis Plus

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you are taking Micardis Plus.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking Micardis Plus.

If you feel that Micardis Plus is not helping your condition, tell your doctor or pharmacist.

Tell your doctor if, for any reason, you have not used Micardis Plus exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor immediately if you become pregnant while taking Micardis Plus.

If you are going to have surgery, tell your doctor, surgeon and anaesthetist that you are taking Micardis Plus.

Micardis Plus may affect some medicines you receive during surgery.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Tell your doctor if you develop an unexpected abnormal lump, bump, ulcer, sore or coloured area on the skin (skin lesion) during the treatment.

Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer).

Protect your skin from sun exposure and UV rays while taking Micardis Plus.

If you develop any severe shortness of breath or difficulty breathing after taking Micardis Plus, seek medical attention immediately.

Things you must not do

Do not take Micardis Plus to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not stop taking Micardis Plus or lower the dosage without checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how Micardis Plus affects you.

Like other medicines used to treat high blood pressure, Micardis Plus may cause sleepiness, dizziness or light-headedness in some people.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

You may feel dizzy or light-headed when you begin to take Micardis Plus, especially if you are also taking a diuretic (or fluid tablet) or if you are dehydrated.

If you feel dizzy or light-headed, and you wish to stand up, you should do so slowly.

Standing up slowly, especially when you get up from a bed or chair, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

If you exercise, or if you sweat, or if the weather is hot, you should drink plenty of water.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Micardis Plus.

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.

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

You may not experience any of them.

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:

- 'flu-like' symptoms
- fainting, dizziness or spinning sensation
- a feeling of tension or fullness in the nose, cheeks and behind the eyes, sometimes with a throbbing ache (sinusitis)
- infections of the air passages
- shortness of breath or difficulty breathing
- abnormal or blurred vision

- eye pain
- back pain
- changes in heart rhythm or increased heart rate
- rash or redness or itchiness of skin
- increased sweating
- dizziness or light-headedness when you stand up (postural hypotension)
- stomach pain or discomfort (abdominal pain, dyspepsia, gastritis)
- wind or excessive gas in the stomach or bowel
- vomiting
- diarrhoea or constipation
- dry mouth
- pins and needles
- sleep disturbances or trouble sleeping
- feeling anxious
- depression
- impotence
- leg pain or cramps in legs

- aching muscles or aching joints not caused by exercise or muscle spasms
- chest pain
- pain
- liver problems
- changes in the levels of potassium or sodium or uric acid in your blood (such changes are usually detected by a blood test)
- symptoms that may indicate low sodium levels in the blood, such as headache, dizziness, confusion, forgetfulness, weakness, unsteadiness or difficulty concentrating
- decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye or acute angle- closure glaucoma).

Tell your doctor as soon as possible if you experience any side effects during or after taking Micardis Plus, so that these may be properly treated.

Symptoms such as feeling very thirsty, sleepy, sick or vomiting, a dry mouth, general weakness, restlessness, seizures (fits), confusion, muscle pain or cramps, passing less urine than normal and a very fast heart rate, may mean that the hydrochlorothiazide part of Micardis Plus is having an excessive effect.

You should tell your doctor if you experience any of these symptoms.

Tell your doctor as soon as possible if you notice any unexpected changes to your skin, including your lips.

This could be a type of skin or lip cancer (non-melanoma skin cancer).

Tell your doctor immediately or go to Emergency at your nearest hospital if you notice any of the following:

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash
- developing or worsening of a disease called systemic lupus erythematosus which affects the skin, joints and kidney.
- acute respiratory distress which is a very rare but possible side effect (signs include severe shortness of breath, fever, weakness and confusion)
- increased sensitivity of the skin to the sun with symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal.

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

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

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

After taking Micardis Plus

Storage

Keep the tablets in the blister strip until it is time to take a dose.

The blister pack protects the tablets from light and moisture.

Keep Micardis Plus in a cool, dry place where the temperature stays below 25°C.

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

Heat and dampness can destroy some medicines.

Keep Micardis Plus 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 Micardis Plus or the expiry date has passed, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

Micardis Plus is the brand name of your medicine.

Micardis Plus tablets are available in three strengths: 40/12.5 mg, 80/12.5 mg and 80/25 mg tablets.

Micardis Plus 40/12.5 mg tablets are oblong, white-red, biconvex, two-layer tablets, possibly with red specks in the white layer. The white face is marked with H4 and the Boehringer Ingelheim company symbol.

Micardis Plus 80/12.5 mg tablets are oblong, white-red, biconvex, two-layer tablets, possibly with red specks in the white layer. The white face is marked with H8 and the Boehringer Ingelheim company symbol.

Micardis Plus 80/25 mg tablets are oblong, white-yellow, biconvex, two-layer tablets, possibly with yellow specks in the white layer. The white face is marked with H9 and the Boehringer Ingelheim company symbol.

Micardis Plus tablets are available in blister packs of 7* (sample), 14*, 28, 56* and 98* tablets.

* Not currently distributed in Australia.

Ingredients

Each Micardis Plus 40/12.5 mg tablet contains 40 mg telmisartan and 12.5 mg hydrochlorothiazide.

Each Micardis Plus 80/12.5 mg tablet contains 80 mg telmisartan and 12.5 mg hydrochlorothiazide.

Each Micardis Plus 80/25 mg tablet contains 80 mg telmisartan and 25 mg hydrochlorothiazide.

The other ingredients found in the tablets are:

- maize starch
 - iron oxide red CI77491 (in Micardis Plus 40/12.5 mg tablet and Micardis Plus 80/12.5 mg tablets)
- or
- iron oxide yellow CI77492 (in Micardis Plus 80/25 mg tablets)
 - magnesium stearate
 - meglumine
 - microcrystalline cellulose
 - povidone
 - lactose monohydrate

- sodium hydroxide
- sodium starch glycollate type A
- sorbitol.

Supplier

Micardis Plus tablets are supplied in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

Sydney, Australia

www.boehringer-ingelheim.com.au

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Australian Registration Numbers

Micardis Plus 40/12.5 mg tablets:

AUST R 82416

Micardis Plus 80/12.5 mg tablets:

AUST R 82418

Micardis Plus 80/25 mg tablets:

AUST R 143761