

Micardis® Plus

Consumer Medicine Information (CMI) summary

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

1. Why am I taking Micardis Plus?

Micardis Plus contains the active ingredients telmisartan and hydrochlorothiazide, in one single tablet. Micardis Plus is used to lower high blood pressure. For more information, see Section [1. Why am I taking Micardis Plus?](#) in the full CMI.

2. What should I know before I take Micardis Plus?

Do not take if you have ever had an allergic reaction to telmisartan or hydrochlorothiazide (the two active ingredients in Micardis

Plus), or any of the ingredients listed at the end of this leaflet.

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.

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

Micardis Plus is not prescribed for children under the age of 18 years.

For more information, see Section [2. What should I know before I take Micardis Plus?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Micardis Plus 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 take Micardis Plus?

The usual dose for adults is one Micardis Plus 40/12.5 tablet once a day. More instructions can be found in Section [4. How do I take Micardis Plus?](#) in the full CMI.

5. What should I know while taking Micardis Plus?

Things you should do	<ul style="list-style-type: none">● Remind any doctor, dentist or pharmacists you visit that you are taking Micardis Plus.● Stop taking Micardis Plus and call your doctor straight away if you
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	<p>develop an unexpected abnormal lump, bump, ulcer, sore or coloured area on the skin (skin lesion) during the treatment or if you develop any shortness of breath or difficulty breathing after taking Micardis Plus.</p>
<p>Things you should not do</p>	<ul style="list-style-type: none"> • Do not take any other medicines for your hypertension (high blood pressure) without checking with your doctor. • Do not stop taking Micardis Plus or lower the dosage, without checking with your doctor or pharmacist.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how Micardis Plus affects you.
<p>Drinking alcohol</p>	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your Micardis Plus in a cool, dry place where the temperature stays below 25°C and protect from light and moisture
- Do not store your medication in bathroom or in car or on windowsills.

For more information, see Section [5. What should I know while taking Micardis Plus?](#) in the full CMI.

6. Are there any side effects?

Do not be alarmed, and speak to your doctor if you feel nausea, 'flu-like' symptoms, increased heart rate, chest pain, dizziness, stomach pain or discomfort, sleeping disturbances or pain in muscles or joints. **Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you develop any severe shortness of breath or difficulty breathing after taking Micardis Plus or if you develop an unexpected abnormal lump, bump, ulcer, sore or coloured area on the skin (skin lesion) during the treatment.** 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.

Micardis® Plus

Active ingredients: *Telmisartan and Hydrochlorothiazide*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking Micardis Plus. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Micardis Plus.**

Where to find information in this leaflet:

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

1. Why am I taking Micardis Plus?

Micardis Plus contains the active ingredients telmisartan and hydrochlorothiazide.

Micardis Plus is used to lower high blood pressure.

Everyone has blood pressure. This pressure helps get your blood 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 and relaxed. If high blood pressure is not treated, it can lead to serious health problems, including stroke, heart disease and kidney failure.

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.

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. Telmisartan works by blocking the effect of angiotensin II (a substance which causes blood vessels to narrow, thus increasing blood pressure). 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.

2. What should I know before I take Micardis Plus?

Warnings

Do not take Micardis Plus if you have:

- an allergic reaction to telmisartan or hydrochlorothiazide (the two active ingredients in Micardis Plus), or any of the ingredients listed at the end of this leaflet. Signs of an allergic reaction may include shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of body; rash, itching or hives on the skin.
- hypersensitivity to sulfonamide containing medicines
- severe liver disease
- severe kidney disease
- problem with the flow of bile from the gall bladder (cholestasis or biliary obstructive disorders)
- 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
- a disease with painful, swollen joints caused by uric acid crystals (gout)
- diabetes or kidney disease and you are taking medicine used to treat high blood pressure (aliskiren)

Check with your doctor if you:

- have any of the following medical conditions, especially:
 - liver problems
 - kidney problems
 - heart problems
 - diabetes
 - high cholesterol levels
 - a condition with raised aldosterone levels (primary hyperaldosteronism or Conn's syndrome)
 - fructose intolerance
 - galactose intolerance
 - recent severe diarrhoea or vomiting
 - asthma
 - a disease affecting the skin, joints and kidney (systemic lupus erythematosus)
 - 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.

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

Do not take Micardis Plus if you are pregnant or intend to become pregnant.

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

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

Do not take Micardis Plus if you are breastfeeding or intend to breastfeed.

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 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 tablets) and approximately 338 mg of sorbitol (in the 80/12.5 and 80/25 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 and 80/12.5 tablets) and 99 mg of lactose monohydrate (in the 80/25 tablets).

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.

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 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Micardis Plus.

4. How do I take Micardis Plus?

How much to take

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

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

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

When to take Micardis Plus

Take Micardis Plus around the same time each day, either morning or evening, with or without food.

How to take Micardis Plus

- **Swallow the tablet whole with a full glass of water.**

If you forget to take Micardis Plus

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 you missed.

If you take too much Micardis Plus

If you think that you have taken 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 - 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.

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

5. What should I know while taking Micardis Plus?

Things you should do

Stop taking Micardis Plus and Call your doctor straight away 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)
- develop any severe shortness of breath or difficulty breathing after taking Micardis Plus
- become pregnant while taking Micardis Plus

You should make sure that you:

- protect your skin from sun exposure and UV rays while taking Micardis Plus

- keep all of your doctor's appointments so that your progress can be checked
- tell your doctor that you are taking Micardis Plus, if you are about to be started on any new medicine
- tell your doctor if, for any reason, have not taken Micardis Plus exactly as prescribed
- tell your doctor if you feel that Micardis Plus is not helping your condition

Things you should 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.

Tell your surgeon or anesthetists that you are taking Micardis Plus if you plan to have surgery. It may affect other medicines during surgery.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Do not drive, operate machinery, or perform hazardous physical activity if you experience any of these side effects.

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.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your Micardis Plus in a cool, dry place where the temperature stays below 25°C and protect from light and moisture.
- Keep the tablets in the blister strip until it is time to take a dose

Do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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

Do not take 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.

Less serious side effects

Less serious side effects	What to do
<p>Breathing related disorders:</p> <ul style="list-style-type: none">• 'flu-like' symptoms• infections of the air passages• shortness of breath or difficulty breathing• chest pain• a feeling of tension or fullness in the nose, cheeks and behind the eyes, sometimes with a throbbing ache (sinusitis)	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<p>Stomach related disorders:</p> <ul style="list-style-type: none"> ● dry mouth ● nausea, vomiting ● change in bowel movements (e.g. constipation or diarrhoea) ● stomach pain or discomfort (abdominal pain, dyspepsia, gastritis) ● flatulence (wind or excessive gas in the stomach or bowel) <p>General body related disorders:</p> <ul style="list-style-type: none"> ● back pain ● dizziness or light-headedness when you stand up (postural hypotension) ● pins and needles ● leg pain or cramps in legs ● rash or redness or itchiness of skin 	

Less serious side effects	What to do
<ul style="list-style-type: none"> ● aching muscles or aching joints not caused by exercise or muscle spasms ● 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 ● sleep disturbances or trouble sleeping ● increased sweating ● impotence <p>Nervous system disorders:</p> <ul style="list-style-type: none"> ● fainting ● dizziness ● spinning sensation ● feeling anxious 	

Less serious side effects	What to do
<ul style="list-style-type: none"> ● depression <p>Eye related disorders:</p> <ul style="list-style-type: none"> ● 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) ● eye pain ● abnormal or blurred vision <p>Heart related disorders:</p> <ul style="list-style-type: none"> ● chest pain ● changes in heart rhythm or increased heart rate <p>Liver related problems</p>	

Serious side effects

Serious side effects	What to do
<p>Immune system disorders:</p> <ul style="list-style-type: none"> ● developing or worsening of a disease called systemic lupus 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you</p>

Serious side effects	What to do
<p>erythematosus which affects the skin, joints and kidney</p> <p>Breathing related disorders:</p> <ul style="list-style-type: none"> ● acute respiratory distress which is a very rare but possible side effect (signs include severe shortness of breath, fever, weakness and confusion) <p>Skin related disorders:</p> <ul style="list-style-type: none"> ● 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 ● increased sensitivity of the skin to the sun with symptoms of sunburn (such as redness, itching, swelling, blistering) which may 	<p>notice any of these serious side effects.</p>

Serious side effects	What to do
occur more quickly than normal <ul style="list-style-type: none"> ● any changes to your skin, including lips 	

Tell your doctor or pharmacist if you experience symptoms like - 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. It may mean that the hydrochlorothiazide part of Micardis Plus is having an excessive effect.

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 that 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 Micardis Plus contains

Active ingredient (main ingredient)	Micardis Plus 40/12.5 - 40 mg telmisartan and 12.5 mg hydrochlorothiazide per tablet. Micardis Plus 80/12.5 - 80 mg telmisartan and 12.5 mg hydrochlorothiazide per tablet. Micardis Plus 80/25 - 80 mg telmisartan and 25 mg hydrochlorothiazide per tablet.
Other ingredients (inactive ingredients)	maize starch iron oxide red CI77491 (in Micardis Plus 40/12.5 tablet and Micardis Plus 80/12.5 tablets) or iron oxide yellow CI77492 (in Micardis Plus 80/25 tablets)

	magnesium stearate meglumine microcrystalline cellulose povidone lactose monohydrate sodium hydroxide sodium starch glycollate type A sorbitol
Potential allergens	lactose monohydrate, sorbitol

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

What Micardis Plus looks like

Micardis Plus is the brand name of your medicine.

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

Micardis Plus 40/12.5 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. (AUST R 82416)

Micardis Plus 80/12.5 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. (AUST R 82418)

Micardis Plus 80/25 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. (AUST R 143761)

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

* Not currently distributed in Australia.

Who distributes Micardis Plus

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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