

Micardis® Plus

Tablets

Telmisartan and Hydrochlorothiazide

Consumer Medicine Information

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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.

Keep this information with your Micardis Plus tablets.

You may need to read it again later.

To find out more about Micardis Plus

Ask your doctor or pharmacist if you have any questions about your medicine or if you have any trouble before, during or after using Micardis Plus.

1. What Micardis Plus is used for

Micardis Plus lowers high blood pressure, also called 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 when your blood pressure stays higher than normal, 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. You may feel fine and have no symptoms, but if high blood pressure is not treated, it can lead to serious health problems (such as heart disease).

Micardis Plus helps to lower your blood pressure but does not cure hypertension.

Micardis Plus contains telmisartan and hydrochlorothiazide. Both medicines reduce blood pressure in different ways. Telmisartan belongs to a group of medicines called angiotensin II receptor antagonists. It works by widening the blood vessels of the body, and therefore helping to lower your blood pressure.

Hydrochlorothiazide belongs to the group of medicines called diuretics. Diuretics cause an increase in the volume of urine. They also help with lowering blood pressure particularly when combined with other blood pressure reducing medicines.

Micardis Plus may be used either alone or in combination with other medicines used to treat high blood pressure.

Micardis Plus may have been prescribed for you for another reason.

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

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2. Before you take Micardis Plus

2a) When not to take Micardis Plus

Only take Micardis Plus if it has been prescribed for you by a doctor.

Never give it to someone else even if their symptoms seem to be the same as yours.

Do not take Micardis Plus if you are allergic to telmisartan, hydrochlorothiazide, sulfonamide-derived medicines or to any of the other ingredients in Micardis Plus.

These ingredients are listed in full at the end of this leaflet.

If you are uncertain as to whether you have these allergies you should raise those concerns with your doctor.

Do not take Micardis Plus if you suffer from:

- 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.

Do not take Micardis Plus if you are pregnant or breastfeeding.

Do not take Micardis Plus after the EXPIRY DATE on the carton or blister strips has passed.

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

2b) Before you start to take Micardis Plus

It is essential that your doctor knows your medical history before prescribing **Micardis Plus**.

Before taking Micardis Plus, tell your doctor if you have, or have had, any of the following conditions:

- kidney problems
- a kidney transplant
- liver problems
- heart problems
- primary aldosteronism, also known as Conn's syndrome;
- diabetes
- gout
- fructose intolerance
- a low salt diet
- recent severe diarrhoea or vomiting
- have a history of allergy or asthma
- lupus erythematosus

If you are uncertain as to whether you have, or have had, any of these conditions you should raise those concerns with your doctor.

Before taking **Micardis Plus** it is advisable to tell your doctor if you are taking any other medicines, obtained with or without a doctor's prescription.

In particular, tell your doctor if you are taking:

- any other medicines used to treat high blood pressure
- lithium, a medicine used to treat certain mental illnesses
- other diuretics or fluid tablets
- laxatives
- potassium tablets (potassium supplements)

- potassium containing salt substitutes
- medicines or salt substitutes which may increase your potassium levels
- heart medicines such as digoxin, a medicine used to treat heart failure or antiarrhythmic medicines
- alcohol
- sleeping tablets
- 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
- aspirin
- nonsteroidal anti-inflammatory agents (medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis)
- medicines used to treat gout
- calcium supplements or medicines containing calcium
- beta-blockers (a type of medicine used to treat high blood pressure or other heart conditions)
- 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 the way it works. Also, other medicines used to treat high blood pressure may have an

additive effect with **Micardis Plus** in lowering your blood pressure. Therefore, you may need different amounts of your medicines.

Your doctor or pharmacist will be able to tell you what to do if you are taking **Micardis Plus** with other medicines.

2c) Pregnancy

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication.

Micardis Plus should not be taken if you are pregnant.

2d) Breastfeeding

Ask for your doctor's advice if you are breastfeeding or likely to breastfeed during the course of your medication.

Micardis Plus should not be taken if you are breastfeeding.

2e) Children

Micardis Plus is not recommended for use in children and teenagers up to 18 years of age.

3. Taking Micardis Plus

3a) How much Micardis Plus to take

The usual recommended 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.

Follow all directions given to you by your doctor or pharmacist. They may differ from the information contained in this leaflet. The amount of **Micardis Plus** you have to take will depend on your condition and whether or not you are taking any other medicines.

3b) How to take Micardis Plus

Take Micardis Plus at about the same time each day.

Micardis Plus should be swallowed with a glass of water.

Micardis Plus can be taken with or without food.

Do not take extra doses of Micardis Plus without consulting your doctor.

3c) If you forget to take a dose

It is important to take **Micardis Plus** as directed.

If you miss a dose, take it as soon as you remember. However, if you remember when it is almost time for your next dose, take only your usual dose at that time.

Do not take a double dose of Micardis Plus to make up for a dose that you missed.

3d) How long to take Micardis Plus

Micardis Plus helps control your high blood pressure but does not cure it. Therefore **Micardis Plus** must be taken every day.

Continue taking Micardis Plus for as long as your doctor prescribes it.

3e) If you have taken too much Micardis Plus (overdose)

Seek medical advice if you have taken more than the recommended or prescribed dose of Micardis Plus.

Advice can be provided by a doctor, pharmacist or Poisons Information Centre (telephone 13 11 26).

Signs of overdose may include increased or slower heart rate, low blood pressure (dizziness, lightheadedness), dehydration, nausea, drowsiness and muscle spasm.

4. While taking Micardis Plus

4a) Things you must do

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

Tell your doctor or pharmacist if you begin using any other medicine while you are taking Micardis Plus.

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

You may feel dizzy or lightheaded when you begin to take **Micardis Plus**, especially if you are also taking a diuretic or fluid tablet. If this problem occurs, talk to your doctor.

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

If you plan to have surgery or other treatment (even at the dentist) that needs an anaesthetic, make sure you tell your doctor or dentist that you are taking Micardis Plus.

4b) Ability to drive or operate machinery

It is advisable to be careful when driving or operating machinery until you know how Micardis Plus affects you.

It is always possible that **Micardis Plus**, like other medicines used to treat high blood pressure, may cause dizziness or drowsiness in some people.

When taken as recommended, and when there are no side effects, **Micardis Plus** is not known to have any effect on the ability to drive or operate machinery.

5. Side effects

You should be aware that all prescription medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing. Your doctor has weighed the risks of you taking **Micardis Plus** against the benefits they expect it will have for you.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of using this medicine.

Most side effects of **Micardis Plus** are mild and temporary.

The overall frequency of side effects reported by patients taking **Micardis Plus** is similar to patients taking a placebo (sugar tablet).

The following side effects have been reported by patients taking **Micardis Plus**. It is not known if these side effects are caused by **Micardis Plus**.

- tiredness
- 'flu-like' symptoms
- dizziness or spinning sensation

- diarrhoea
- feeling sick (nausea)
- 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
- back pain
- an uncomfortable feeling in the stomach (dyspepsia)
- vomiting
- increased heart rate
- low potassium levels in the blood
- bronchitis
- sore throat
- rash
- dizziness or lightheadedness when you stand up (postural hypotension)
- stomach pain or discomfort (abdominal pain)
- feeling anxious
- painful joints (arthralgia)
- loss of diabetic control
- gastritis
- impotence
- leg pain
- aching muscles, not caused by exercise (myalgia)
- pain
- headache
- cough
- urinary tract infection (including cystitis)
- changes in your cholesterol or uric acid levels may occur (such changes are usually detected by a blood test)

Symptoms such as feeling very thirsty, sleepy, sick or vomiting, a dry mouth, general weakness, muscle pain or cramps, 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.

In patients taking telmisartan alone, rare cases of angioedema have also been reported. This is a condition that causes swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing. This is a serious condition which requires urgent medical attention.

Skin rash or hives have also been reported occasionally. This is a serious condition which requires urgent medical attention.

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.

In addition, other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything unusual, during or after taking Micardis Plus.

6. After taking Micardis Plus

6a) Storage

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

The blister pack protects the tablets.

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

Do not store in direct sunlight or heat.

For example, do not leave **Micardis Plus** in the car on hot days.

Keep Micardis Plus where young children cannot reach it.

6b) Disposal

If you have been told by your doctor that you will not be needing **Micardis Plus** anymore, or the tablets have passed their expiry date, the unused medicine should be returned to your pharmacist so that it can be disposed of safely.

7. Product Description

7a) What Micardis Plus is

Micardis Plus is the brand name of your medicine.

Micardis Plus tablets are available in two strengths: 40/12.5 mg and 80/12.5 mg tablets.

Micardis Plus 40/12.5 mg tablets are red and white oval shaped two layer tablets. The white face is marked with the Boehringer Ingelheim logo and 'H4'.

Micardis Plus 80/12.5 mg tablets are red and white oval shaped two layer tablets. The white face is marked with the Boehringer Ingelheim logo and 'H8'.

Micardis Plus tablets are available in blister packs of 28 tablets.

The following Australian Registration Numbers appear on the carton:

- AUST R 82416 for **Micardis Plus** 40/12.5 mg tablets
- AUST R 82418 for **Micardis Plus** 80/12.5 mg tablets

7b) 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.

The other ingredients found in both strengths are:

- starch-maize
- iron oxide red CI77491
- magnesium stearate
- meglumine
- cellulose-microcrystalline
- povidone (K25)
- lactose
- sodium hydroxide
- sodium starch glycollate type A
- sorbitol

7c) Manufacturer

Micardis Plus tablets are made in Germany and supplied in Australia by:

BOEHRINGER INGELHEIM PTY LIMITED

(ABN 52 000 452 308)

85 Waterloo Road

NORTH RYDE NSW 2113



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