

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tablet Micardis 20 mg (MAL 20014487A)

Tablet Micardis 40 mg (MAL 19992673A)

Tablet Micardis 80 mg (MAL 19992674A)

Telmisartan

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Micardis is and what it is used for
2. Before you take Micardis
3. How to take Micardis
4. Possible side effects
5. How to store Micardis
6. Further information

1. WHAT MICARDIS IS AND WHAT IT IS USED FOR

Micardis belongs to a class of medicines known as angiotensin II receptor antagonists. Angiotensin II is a substance produced in your body which causes your blood vessels to narrow, thus increasing your blood pressure. Micardis blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

Micardis is used to treat essential hypertension (high blood pressure). ‘Essential’ means that the high blood pressure is not caused by any other condition.

High blood pressure, if not treated, can damage blood vessels in several organs, which could lead sometimes to heart attack, heart or kidney failure, stroke, or blindness. There are usually no symptoms of high blood pressure before damage occurs. Thus it is important to regularly measure blood pressure to verify if it is within the normal range.

Micardis is also used to reduce cardiovascular events (i.e. heart attack or stroke) in patients who are at risk because they have a reduced or blocked blood supply to the heart or legs, or have had a stroke or have high risk diabetes. Your doctor can tell you if you are at high risk for such events.

2. BEFORE YOU TAKE MICARDIS

Do not take Micardis

- if you are allergic (hypersensitive) to telmisartan or any other ingredients included in Micardis tablets (see section Further information for a list of other ingredients).

- if you are more than 3 months pregnant. (It is also better to avoid Micardis in early pregnancy – see pregnancy section.)
- if you have severe liver problems such as cholestasis or biliary obstruction (problems with drainage of the bile from the liver and gall bladder) or any other severe liver disease.

If any of the above applies to you, tell your doctor or pharmacist before taking Micardis.

Take special care with Micardis

Please tell your doctor if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Kidney disease or kidney transplant.
- Renal artery stenosis (narrowing of the blood vessels to one or both kidneys).
- Liver disease.
- Heart trouble.
- Raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals).
- Low blood pressure (hypotension), likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy ('water tablets'), low-salt diet, diarrhoea, or vomiting.
- Elevated potassium levels in your blood.
- Diabetes.

You must tell your doctor if you think you are (or might become) pregnant. Micardis is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

In case of surgery or anaesthesia, you should tell your doctor that you are taking Micardis.

The use of Micardis in children and adolescents up to the age of 18 years is not recommended.

As with all other angiotensin antagonists, Micardis may be less effective in lowering the blood pressure in black patients.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Your doctor may need to change the dose of these other medicines or take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below taken at the same time with Micardis:

- Lithium containing medicines to treat some types of depression.
- Medicines that may increase blood potassium levels such as salt substitutes containing potassium, potassium-sparing diuretics (certain 'water tablets'), ACE inhibitors, angiotensin II receptor antagonists, NSAIDs (non steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen), heparin, immunosuppressives (e.g. cyclosporin or tacrolimus), and the antibiotic trimethoprim.
- Diuretics ('water tablets'), especially if taken in high doses together with Micardis, may lead to excessive loss of body water and low blood pressure (hypotension).

As with other blood pressure lowering medicines, the effect of Micardis may be reduced when you take NSAIDs (non steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids. Micardis may increase the blood pressure lowering effect of other medicines used to treat high blood pressure.

Taking Micardis with food and drink

You can take Micardis with or without food.

Pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Micardis before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Micardis. Micardis is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Micardis is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

No information is available on the effect of Micardis on the ability to drive or operate machinery. Some people feel dizzy or tired when they are treated for high blood pressure. If you feel dizzy or tired, do not drive or operate machinery.

Important information about some of the ingredients of Micardis

Micardis contains sorbitol.

If you are intolerant to some sugars, consult your doctor before taking Micardis.

3. HOW TO TAKE MICARDIS

Always take Micardis exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose of Micardis is one tablet a day. Try to take the tablet at the same time each day. You can take Micardis with or without food. The tablets should be swallowed with some water or other non-alcoholic drink. It is important that you take Micardis every day until your doctor tells you otherwise. If you have the impression that the effect of Micardis is too strong or too weak, talk to your doctor or pharmacist.

For treatment of high blood pressure, the usual dose of Micardis for most patients is one 40 mg tablet once a day to control blood pressure over the 24 hour period. However, sometimes your doctor may recommend a lower dose of 20 mg or a higher dose of 80 mg. Alternatively, Micardis may be used in combination with diuretics ('water tablets') such as hydrochlorothiazide which has been shown to have an additive blood pressure lowering effect with Micardis.

For reduction of cardiovascular events, the usual dose of Micardis is one 80 mg tablet once a day. At the beginning of the preventive therapy with Micardis 80 mg, blood pressure should be frequently monitored.

If your liver is not working properly, the usual dose should not exceed 40 mg once daily.

If you take more Micardis than you should

If you accidentally take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately.

If you forget to take Micardis

If you forget to take a dose, do not worry. Take it as soon as you remember then carry on as before. If you do not take your tablet on one day, take your normal dose on the next day. **Do not** take a double dose to make up for forgotten individual doses.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Micardis can cause side effects, although not everybody gets them. These side effects may occur with certain frequencies, which are defined as follows:

- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000

Some side effects can be serious and need immediate medical attention:

You should see your doctor immediately if you experience any of the following symptoms:

Sepsis* (often called "blood poisoning", is a severe infection with whole-body inflammatory response), rapid swelling of the skin and mucosa (angioedema); these side effects are rare but are extremely serious and patients should stop taking the product and see their doctor immediately. If these effects are not treated they could be fatal.

Possible side effects of Micardis:

Common side effects may include:

Low blood pressure (hypotension) in users treated for reduction of cardiovascular events.

Uncommon side effects may include:

Urinary tract infections, upper respiratory tract infections (e.g. sore throat, inflamed sinuses, common cold), deficiency in red blood cells (anaemia), high potassium levels, difficulty falling asleep, feeling sad (depression), fainting (syncope), feeling of spinning (vertigo), slow heart rate (bradycardia), low blood pressure (hypotension) in users treated for high blood pressure, dizziness on standing up (orthostatic hypotension), shortness of breath, abdominal pain, diarrhoea, discomfort in the abdomen, bloating, vomiting, itching, increased sweating, drug rash, back pain, muscle cramps, muscle pain (myalgia),

kidney impairment including acute kidney failure, pain in the chest, feeling of weakness, and increased level of creatinine in the blood.

Rare side effects may include:

Sepsis* (often called "blood poisoning", is a severe infection with whole-body inflammatory response which can lead to death), increase in certain white blood cells (eosinophilia), low platelet count (thrombocytopenia), severe allergic reaction (anaphylactic reaction), allergic reaction (e.g. rash, itching, difficulty breathing, wheezing, swelling of the face or low blood pressure), low blood sugar levels (in diabetic patients), feeling anxious, impaired vision, fast heart beat (tachycardia), dry mouth, upset stomach, abnormal liver function**, rapid swelling of the skin and mucosa which can also lead to death (angioedema also with fatal outcome), eczema (a skin disorder), redness of skin, hives (urticaria), severe drug rash, joint pain (arthralgia), pain in extremity, tendon pain, flu-like-illness, decreased haemoglobin (a blood protein), increased levels of uric acid, increased hepatic enzymes or creatine phosphokinase in the blood.

*In a long-term study involving more than 20,000 patients, more patients treated with telmisartan experienced sepsis compared with patients who received no telmisartan. The event may have happened by chance or could be related to a mechanism currently not known.

** Most cases of abnormal liver function and liver disorder from post-marketing experience with telmisartan occurred in Japanese patients. Japanese patients are more likely to experience this side effect.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE MICARDIS

Keep out of the reach and sight of children.

Do not use Micardis after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions. You should store your medicine in the original package in order to protect the tablets from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Micardis contains

The active substance is telmisartan. Each tablet contains 20 mg, 40mg or 80 mg telmisartan. The other ingredients are povidone, meglumine, sodium hydroxide, sorbitol (E420) and magnesium stearate.

What Micardis looks like and contents of the pack

Micardis 20 mg tablets are white, round and engraved with the code number '50H' on one side and the company logo on the other side.

Micardis 40 mg tablets are white, oblong-shaped and engraved with the code number '51H' on one side and the company logo on the other side.

Micardis 80 mg tablets are white, oblong-shaped and engraved with the code number '52H' on one side and the company logo on the other side.

Micardis is available in blister packs containing 30 tablets (3 blister packs x 10 tablets).

Marketing Authorisation Holder

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Date of Revision: 27 Mar 2012