PACKAGE LEAFLET: INFORMATION FOR THE USER
Tablet Micardis Plus 40 mg/12.5 mg (MAL 20034439A)
Tablet Micardis Plus 80 mg/12.5 mg (MAL 20034440A)
Tablet Micardis Plus 80 mg/25 mg (MAL 09032035A)
Telmisartan/Hydrochlorothiazide

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 PLUS IS AND WHAT IT IS USED FOR

Micardis Plus is a combination of two active substances, telmisartan and hydrochlorothiazide in one tablet. Both of these substances help to control high blood pressure.

- Telmisartan belongs to a group of medicines called 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. Telmisartan blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

- Hydrochlorothiazide belongs to a group of medicines called thiazide diuretics, which cause your urine output to increase, leading to a lowering of your blood pressure.

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 Plus is used to treat high blood pressure (essential hypertension) in patients whose blood pressure is not controlled enough when either telmisartan or hydrochlorothiazide is used alone.

2. BEFORE YOU TAKE MICARDIS PLUS

Do not take Micardis Plus

- if you are allergic (hypersensitive) to telmisartan or any other ingredients included in Micardis Plus tablets (see "Further information" for a list of other ingredients).
- if you are allergic (hypersensitive) to hydrochlorothiazide or to any other sulfonamide-derived medicines.

- if you are more than 3 months pregnant. (It is also better to avoid Micardis Plus 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 gall bladder) or any other severe liver disease.
- if you have severe kidney disease.
- if your doctor determines that you have low potassium levels or high calcium levels in your blood that do not get better with treatment.

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

Take special care with Micardis Plus

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

- 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, vomiting, or haemodialysis.
- Kidney disease or kidney transplant.
- Renal artery stenosis (narrowing of the blood vessels to one or both kidneys).
- Liver disease.
- Heart trouble.
- Diabetes.
- Gout.
- Raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals).
- Systemic lupus erythematosus (also called “lupus” or “SLE”) a disease where the body’s immune system attacks the body.

You must tell your doctor if you think you are (or might become) pregnant. Micardis Plus 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).

Treatment with hydrochlorothiazide may cause electrolyte imbalance in your body. Typical symptoms of fluid or electrolyte imbalance include dry mouth, weakness, lethargy, drowsiness, restlessness, muscle pain or cramps, nausea (feeling sick), vomiting, tired muscles, and an abnormally fast heart rate (faster than 100 beats per minute). If you experience any of these you should tell your doctor.

You should also tell your doctor, if you experience an increased sensitivity of the skin to the sun with symptoms of sunburn (such as redness, itching, swelling, blistering) occurring more quickly than normal.

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

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

As with all other angiotensin II receptor antagonists, telmisartan 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 medications 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 Plus:

- Lithium containing medicines to treat some types of depression.
- Medicines associated with low blood potassium (hypokalaemia) such as other diuretics, ('water tablets'), laxatives (e.g. castor oil), corticosteroids (e.g. prednisone), ACTH (a hormone), amphotericin (an antifungal medicine), carbenoxolone (used to treat mouth ulcers), penicillin G sodium (an antibiotic), and salicylic acid and derivatives.
- Potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium, ACE inhibitors that may increase blood potassium levels.
- Heart medicines (e.g. digoxin) or medicines to control the rhythm of your heart (e.g. quinidine, disopyramide).
- Medicines used for mental disorders (e.g. thioridazine, chlorpromazine, levomepromazine).
- Other medicines used to treat high blood pressure, steroids, painkillers, medicines to treat cancer, gout, or arthritis, and vitamin D supplements.

Micardis Plus may increase the blood pressure lowering effect of other medicines and you should consult with your doctor if you need to adjust the dose of your other medicine while taking Micardis Plus .

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

Taking Micardis Plus with food and drink

You can take Micardis Plus 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 Plus before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Micardis Plus. Micardis Plus 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 Plus 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 Plus 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 Plus

Micardis Plus contains milk sugar (lactose) and sorbitol.
If you are intolerant to some sugars, consult your doctor before taking Micardis Plus.

3. HOW TO TAKE MICARDIS PLUS

Always take Micardis Plus 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 Plus is one tablet a day. Try to take a tablet at the same time each day. You can take Micardis Plus with or without food. The tablets should be swallowed with some water or other non-alcoholic drink. It is important that you take Micardis Plus every day until your doctor tells you otherwise.

If your liver is not working properly, the usual dose should not exceed 40 mg/12.5 mg once a day.

If you take more Micardis Plus 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 Plus

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 further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Micardis Plus 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
- not known: frequency cannot be estimated from the available data.

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 Plus:

Common side effects may include:
Dizziness

Uncommon side effects may include:
Decreased blood potassium levels, anxiety, fainting (syncope), sensation of tingling, pins and needles (paraesthesia), feeling of spinning (vertigo), fast heart beat (tachycardia), heart rhythm disorders, low blood pressure, a sudden fall in blood pressure when you stand up, shortness of breath (dyspnoea), diarrhoea, dry mouth, flatulence, back pain, muscle spasm, muscle pain, erectile dysfunction (inability to get or keep an erection), chest pain, increased blood uric acid levels.

Rare side effects may include:
Inflammation of the lung (bronchitis), activation or worsening of systemic lupus erythematosus (a disease where the body's immune system attacks the body, which causes joint pain, skin rashes and fever); sore throat, inflamed sinuses, feeling sad (depression), difficulty falling asleep (insomnia), impaired vision, difficulty breathing, abdominal pain, constipation, bloating (dyspepsia), feeling sick, inflammation of the stomach (gastritis), abnormal liver function*, rapid swelling of the skin and mucosa which can also lead to death (angioedema also with fatal outcome), redness of the skin (erythema), allergic reactions such as itching or rash, increased sweating, hives (urticaria), joint pain (arthralgia) and pain in extremities, muscle cramps, flu-like-illness, pain, increased levels of uric acid, low levels of sodium, increased levels of creatinine, hepatic enzymes or creatine phosphokinase in the blood.

*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 these side effects.

Telmisartan

In patients taking telmisartan alone the following additional side effects have been reported:

Uncommon side effects may include:
Upper respiratory tract infection (e.g. sore throat, inflamed sinuses, common cold), urinary tract infections, deficiency in red blood cells (anaemia), high potassium levels, slow heart rate (bradycardia), kidney impairment including acute kidney failure, weakness.

Rare side effects may include:
Sepsis** (often called "blood poisoning", is a severe infection with whole-body inflammatory response which can lead to death), low platelet count (thrombocytopenia), increase in certain white blood cells (eosinophilia), serious allergic reaction (e.g. hypersensitivity, anaphylactic reaction, drug rash), low blood sugar levels (in diabetic patients), upset stomach, eczema (a skin disorder), arthrosis, inflammation of the tendons, decreased haemoglobin (a blood protein).

**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.

Hydrochlorothiazide

In patients taking hydrochlorothiazide alone the following additional side effects have been reported:

Side effects of unknown frequency may include:
Inflammation of the salivary gland, decreases in the number of cells in the blood, including low red and white blood cell count, low platelet count (thrombocytopenia), serious allergic reactions (e.g. hypersensitivity, anaphylactic reaction), decreased or loss of appetite, restlessness, light-headedness, blurred or yellowing of vision, inflammation of blood vessels (vasculitis necrotising), inflamed pancreas, upset stomach, yellowing of the skin or eyes (jaundice), lupus-like syndrome (a condition mimicking a disease called systemic lupus erythematosus where the body's immune system attacks the body); skin disorders such as inflamed blood vessels in the skin, increased sensitivity to sunlight, or blistering and peeling of the top layer of skin (toxic epidermal necrolysis), weakness, kidney inflammation or impaired kidney function, glucose in the urine (glycosuria), fever, impaired electrolyte balance, high blood cholesterol levels, decreased blood volume, increased levels of glucose, or fat in the blood.

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

5. HOW TO STORE MICARDIS PLUS

Keep out of the reach and sight of children.

Do not use Micardis Plus 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.

Occasionally, the outer layer of the blister pack separates from the inner layer between the blister pockets. You do not need to take any action if this happens.

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 Plus contains

The active substances are telmisartan and hydrochlorothiazide. Each tablet contains 40 mg telmisartan and 12.5 mg hydrochlorothiazide, 80 mg telmisartan and 12.5 mg hydrochlorothiazide or 80 mg telmisartan and 25 mg hydrochlorothiazide.
The other ingredients are lactose monohydrate, magnesium stearate, maize starch, meglumine, microcrystalline cellulose, povidone, red iron oxide (E172), sodium hydroxide, sodium starch glycollate (type A), sorbitol (E420)

What Micardis Plus looks like and contents of the pack

Micardis Plus 40 mg/12.5 mg tablets are red and white, oval-shaped two-layer tablets engraved with the company logo and the code 'H4'.
Micardis Plus 80 mg/12.5 mg tablets are red and white, oval-shaped two-layer tablets engraved with

the company logo and the code 'H8'.
Micardis Plus 80 mg/25 mg tablets are yellow and white, oval-shaped two-layer tablets engraved with the company logo and the code 'H9'.
Micardis Plus is available in blister packs containing 30 tablets (3 blister packs x 10 tablets).

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Date of Revision: 27 Mar 2012