



## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### 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 including fatal outcome), blistering and peeling of the top layer of skin (toxic epidermal necrolysis); these side effects are rare (may affect up to 1 in 1 000 people) or very rare (toxic epidermal necrolysis; may affect up to 1 in 10 000 people) but are extremely serious and patients should stop taking the medicine and see their doctor immediately. If these effects are not treated they could be fatal. Increased incidence of sepsis has been observed with telmisartan only, however can not be ruled out for MicardisPlus.

### Possible side effects of MicardisPlus:

**Common side effects (may affect up to 1 in 10 people)**  
Dizziness.

### Uncommon side effects (may affect up to 1 in 100 people)

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 affect up to 1 in 1 000 people)

Inflammation of the airways to the lungs (bronchitis), sore throat, inflamed sinuses, increased level of uric acid, low sodium level, feeling sad (depression), difficulty falling asleep (insomnia), sleep disorder, impaired vision, blurred vision, difficulty breathing, abdominal pain, constipation, bloating (dyspepsia), feeling sick (vomiting), inflammation of the stomach (gastritis), abnormal liver function (Japanese patients are more likely to experience this side effect), redness of the skin (erythema), allergic reactions such as itching or rash, increased sweating, hives (urticaria), joint pain (arthralgia) and pain in extremities (leg pain), muscle cramps, 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), flu-like illness, pain, increased levels of creatinine, hepatic enzymes or creatine phosphokinase in the blood.

Adverse reactions reported with one of the individual components may be potential adverse reactions with MicardisPlus, even if not observed in clinical trials with this product.

### Telmisartan

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

### Uncommon side effects (may affect up to 1 in 100 people)

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

### Rare side effects (may affect up to 1 in 1 000 people)

Low platelet count (thrombocytopenia), increase in certain white blood cells (eosinophilia), serious allergic reaction (e.g. hypersensitivity, anaphylactic reaction), low blood sugar levels (in diabetic patients), somnolence, upset stomach, eczema (a skin disorder), drug eruption, toxic skin eruption, tendon pain (tendonitis-like symptoms), decreased haemoglobin (a blood protein).

### Very rare side effects (may affect up to 1 in 10 000 people)

Progressive scarring of lung tissue (interstitial lung disease)\*\*

### Not known (frequency cannot be estimated from the available data)

Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting, and diarrhoea has been reported after the use of similar products.

\* The event may have happened by chance or could be related to a mechanism currently not known.

\*\* Cases of progressive scarring of lung tissue have been reported during intake of telmisartan. However, it is not known whether telmisartan was the cause.

### Hydrochlorothiazide

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

### Very common side effects (may affect more than 1 in 10 people)

Elevated blood fat levels.

### Common side effects (may affect up to 1 in 10 people)

Feeling sick (nausea), low blood magnesium level, decreased appetite.

### Uncommon side effects (may affect up to 1 in 100 people)

Acute kidney failure.

### Rare side effects (may affect up to 1 in 1 000 people)

Low platelet count (thrombocytopenia), which increases risk of bleeding or bruising (small purple-red marks in skin or other tissue caused by bleeding), high blood calcium level, high blood sugar level, headache, abdominal discomfort, yellowing of the skin or eyes

(jaundice), excess of biliary substances in the blood (cholestasis), photosensitivity reaction, uncontrolled blood levels of glucose in patients with a diagnosis of diabetes mellitus, sugars in the urine (glucosuria).

### Very rare side effects (may affect up to 1 in 10 000 people)

Abnormal breakdown of red blood cells (haemolytic anaemia), inability of the bone marrow to work properly, reduction of white blood cells (leukopenia, agranulocytosis), serious allergic reactions (e.g. hypersensitivity), increased pH due to low blood chloride level (disturbed acid-base balance, alkalosis hypochloroemic), acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion), inflammation of the pancreas, lupus-like syndrome (a condition mimicking a disease called systemic lupus erythematosus where the body’s immune system attacks the body), inflammation of blood vessels (vasculitis necrotising).

### Not known (frequency cannot be estimated from the available data)

Skin and lip cancer (non-melanoma skin cancer), blood cell deficiency (aplastic anaemia), decrease in vision and eye pain (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute-angle closure glaucoma), skin disorders such as inflamed blood vessels in the skin, increased sensitivity to sunlight, rash, redness of the skin, blistering of the lips, eyes or mouth, skin peeling, fever (possible signs of erythema multiforme), weakness, kidney impairment.

Low levels of sodium accompanied by symptoms relating to the brain or nerves (feeling sick, progressive disorientation, lack of interest or energy) occurs in isolated cases.

### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

### Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store

## 5. How to store MicardisPlus

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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 temperature storage conditions. Store in the original package in order to protect from moisture. Remove your MicardisPlus tablet from the sealed blister only directly prior to intake.

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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What MicardisPlus contains

- The active substances are telmisartan and hydrochlorothiazide. Each tablet contains 80 mg telmisartan and 25 mg hydrochlorothiazide.
- The other ingredients are lactose monohydrate, magnesium stearate, maize starch, meglumine, microcrystalline cellulose, povidone K25, yellow iron oxide (E172), sodium hydroxide, sodium starch glycollate (type A), sorbitol (E420).

### What MicardisPlus looks like and contents of the pack

MicardisPlus 80 mg/25 mg tablets are yellow and white, oblong-shaped, two-layer tablets engraved with the company logo and the code ‘H9’. MicardisPlus is available in blister packs containing 14, 28, 56, or 98 tablets, or unit dose blister packs containing 28 × 1, 30 × 1 or 90 × 1 tablets.

Not all pack sizes may be available in your country.

### Marketing Authorisation Holder

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