

PACKAGE LEAFLET: INFORMATION FOR THE USER

Macsart 80 (Telmisartan Tablets USP 80mg)

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

In this leaflet:

1. What Telmisartan Tablets are and what they are used for
2. What you need to know before you take Telmisartan Tablets
3. How to take Telmisartan Tablets
4. Possible side effects
5. How to store Telmisartan Tablets
6. Contents of the pack and other information

1. WHAT TELMISARTAN TABLETS ARE AND WHAT THEY ARE USED FOR

Telmisartan Tablet is a prescription medicine used:

- To treat high blood pressure (hypertension)
- In certain high risk people aged 55 years and older to help lower their risk of having certain cardiovascular problems such as stroke, heart attack, or death

It is not known if Telmisartan Tablets are safe and effective in children.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TELMISARTAN TABLETS

Do not take Telmisartan Tablets:

You should not take Telmisartan Tablets if you are allergic (hypersensitive) to the active ingredient (telmisartan) or any of the other ingredients listed at the end of this leaflet.

For patients with diabetes, if you are taking Telmisartan Tablets you should not take aliskiren.

Warnings and precautions

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Before you take Telmisartan Tablets, tell your doctor if you:

- Are pregnant or are planning to become pregnant.
- Are breast-feeding or plan to breast-feed. It is not known if Telmisartan passes into your breast milk. You and your doctor should decide if you will take Telmisartan Tablets or breast-feed. You should not do both. Talk with your doctor about the best way to feed your baby if you take Telmisartan Tablets.
- Have liver problems
- Have kidney problems
- Have heart problems
- Have any other medical conditions

Children and adolescents

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

Other medicines and Telmisartan Tablets

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

For patients with diabetes, if you are taking Telmisartan Tablets you should not take aliskiren.

Telmisartan Tablets may affect the way other medicines work, and other medicines may affect how Telmisartan Tablets works. Especially tell your doctor if you take:

- Aliskiren
- Digoxin (Lanoxin)
- Lithium (Lithobid , lithium carbonate, lithium citrate)
- Aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs)
- Other medicines used to treat your high blood pressure or heart problem
- Water pills (diuretic)

Know the medicines you take. Keep a list of them and show it to your doctor or pharmacist when you get a new medicine.

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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 Telmisartan Tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Telmisartan Tablets. Telmisartan Tablets are 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. Telmisartan Tablets are 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

Some people feel dizzy or tired when taking Telmisartan Tablets. If you feel dizzy or tired, do not drive or operate machinery.

3. HOW TO TAKE TELMISARTAN TABLETS

- Take Telmisartan Tablets exactly as your doctor tells you to take it.
- Your doctor will tell you how much Telmisartan Tablets to take and when to take it.
- Do not change your dose unless your doctor tells you to.
- Take Telmisartan Tablet one time each day at the same time.
- Take Telmisartan Tablets with or without food.
- If you miss a dose, take it as soon as you remember. If it is close to your next dose, do not take the missed dose. Take the next dose at your regular time.
- If you take too much Telmisartan Tablets, call your doctor, or go to the nearest hospital emergency room right away.

If you take more Telmisartan Tablets than you should

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

If you forget to take Telmisartan Tablets

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.

4. POSSIBLE SIDE EFFECTS

Telmisartan Tablets may cause serious side effects, including:

- **Injury or death to your unborn baby.**
- **Low blood pressure (hypotension)** is most likely to happen if you also:
 - take water pills (diuretics)
 - are on a low-salt diet
 - get dialysis treatments
 - have heart problems
 - get sick with vomiting or diarrhea

If you feel faint or dizzy, lie down and call your doctor right away.

- **Kidney problems**, which may get worse if you already have kidney disease. You may have changes in your kidney test results, and you may need a lower dose of Telmisartan Tablets. Call your doctor if you get:
 - swelling in your feet, ankles, or hands
 - unexplained weight gain

Call your doctor right away if you get any of the symptoms listed above.

- **High potassium in the blood (hyperkalemia).** Your doctor may check your potassium levels as needed.

Rare, serious allergic reactions may happen. Tell your doctor right away if you get any of these symptoms:

- swelling of the face, tongue, throat
- difficulty breathing
- skin rash

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The most common side effects of Telmisartan Tablets include:

- sinus pain and congestion (sinusitis)
- back pain
- diarrhea

These are not all the possible side effects with Telmisartan Tablets. Tell your doctor if you have any side effect that bothers you or that does not go away.

5. HOW TO STORE TELMISARTAN TABLETS

Store below 30°C in a dry place. Protect from light.

6. FURTHER INFORMATION

What Telmisartan Tablets contains

Active Ingredient: Telmisartan

Inactive Ingredients: Light Magnesium Oxide, Mannitol, Crospovidone, Colloidal Anhydrous Silica, Sodium Hydroxide, Methanol, Microcrystalline Cellulose, Magnesium Stearate, Purified Water

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