

MIZART HCT

Telmisartan and Hydrochlorothiazide

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Mizart HCT. It does not contain all available information.

It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet.

More recent information may be available.

The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medicines.org.au and may contain important information about the medicine and its use of which you should be aware.

Keep this information with your Mizart HCT tablets.

You may need to read it again later.

To find out more about Mizart HCT

Ask your doctor or pharmacist if you have any questions about your medicine if you have any concerns or if you have any trouble before, during or after using Mizart HCT.

What Mizart HCT is used for

Mizart HCT 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 stroke, heart disease and kidney failure).

Mizart HCT helps to lower your blood pressure but does not cure hypertension.

Mizart HCT 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.

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

Mizart HCT may have been prescribed for you for another reason.

Ask your doctor if you have any questions about why Mizart HCT has been prescribed for you.

Mizart HCT is not addictive.

This medicine is available only with a doctor's prescription.

Before you take Mizart HCT

When you must not take it

Only take Mizart HCT 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 Mizart HCT if you are allergic to telmisartan, hydrochlorothiazide, sulfonamide-derived medicines or to any of the other ingredients in Mizart HCT.

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 Mizart HCT 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
- diabetes or kidney problems and you are taking aliskiren (a medicine used to treat high blood pressure).

Do not take Mizart HCT if you have rare hereditary condition of fructose intolerance.

The maximum recommended daily dose of Mizart HCT contains 170 mg of mannitol (in the 40/12.5 mg tablets) and approximately 340 mg of mannitol (in the 80/12.5 mg and 80/25 mg tablets).

Do not take Mizart HCT if you have rare hereditary condition of galactose intolerance.

The maximum recommended daily dose of Mizart HCT contains 84 mg of lactose monohydrate in the 40/12.5 mg tablets, 180.5 mg of lactose monohydrate in the 80/12.5 mg tablets, and 169.4 mg of lactose monohydrate in the 80/25 mg tablets.

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

Do not take Mizart HCT if you are pregnant or breastfeeding.

Like other similar medicines, it may affect your developing baby if you take it during pregnancy.

It is not known if telmisartan or hydrochlorothiazide, the active ingredients in Mizart HCT, pass into breast milk and there is a possibility your baby may be affected.

Do not take Mizart HCT after the EXPIRY DATE on the carton or blister strips has passed.

Do not take Mizart HCT if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking Mizart HCT, talk to your doctor.

Before you start to take it

It is essential that your doctor knows your medical history before prescribing Mizart HCT.

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

- kidney problems
- a kidney transplant
- liver problems
- heart problems
- primary hyperaldosteronism (raised aldosterone levels also known as Conn's syndrome)
- diabetes
- gout
- fructose intolerance
- galactose intolerance
- a low salt diet
- recent severe diarrhoea or vomiting
- have a history of allergy or asthma
- systemic lupus erythematosus (a disease affecting the skin, joints and kidney)
- eye problems

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 Mizart HCT it is advisable to tell your doctor if you are taking any other medicines, obtained with or without a doctor's prescription from your pharmacy, supermarket or health food shop.

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
- amphotericin B (amphotericin), a medicine used to treat fungal infections
- penicillin antibiotics used to treat bacterial infections
- 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 Mizart HCT, or may affect the way it works. Also, other medicines used to treat high blood pressure may have an additive effect with Mizart

HCT 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 Mizart HCT with other medicines.

Pregnancy

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

Mizart HCT should not be taken if you are pregnant.

Breastfeeding

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

Mizart HCT should not be taken if you are breastfeeding.

Children

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

How to take Mizart HCT

How much to take

The usual recommended dose for adults is one Mizart HCT 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 Mizart HCT 80/12.5 mg tablet once a day.

If your blood pressure is still not satisfactorily controlled with Mizart HCT 80/12.5 mg, your doctor may increase your dose to one Mizart HCT 80/25 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.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The amount of Mizart HCT you have to take will depend on your condition and whether or not you are taking any other medicines.

How to take it

Take Mizart HCT at about the same time each day.

Mizart HCT should be swallowed with a glass of water.

Mizart HCT can be taken with or without food.

Do not take extra doses of Mizart HCT without consulting your doctor.

If you forget to take a dose

It is important to take Mizart HCT 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 Mizart HCT to make up for a dose that you missed.

How long to take it for

Mizart HCT helps control your high blood pressure but does not cure it. Therefore Mizart HCT must be taken every day.

Continue taking Mizart HCT for as long as your doctor prescribes it.

If you have taken too much (overdose)

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

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

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

While taking Mizart HCT

Things you must do

Tell your doctor immediately if you become pregnant while taking Mizart HCT.

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

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 Mizart HCT, 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 Mizart HCT.

Tell your doctor if you develop an unexpected abnormal lump, bump, ulcer, sore or coloured area on the skin (skin lesion) during the treatment.

Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer).

Protect your skin from sun exposure and UV rays while taking Mizart HCT.

Ability to drive or operate machinery

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

It is always possible that Mizart HCT, 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, Mizart HCT is not known to have any effect on the ability to drive or operate machinery.

Lifestyle measures that help reduce heart disease risk

By following these simple measures, you can further reduce the risk from heart disease.

- Quit smoking and avoid second-hand smoke.
- Limit alcohol intake.
- Enjoy healthy eating by:
 - eating plenty of vegetables and fruit;
 - reducing your saturated fat intake (eat less fatty meats, full fat dairy products, butter, coconut and palm oils, most take-away foods, commercially-baked products).

- Be active. Progress, over time, to at least 30 minutes of moderate-intensity physical activity on 5 or more days each week. Can be accumulated in shorter bouts of 10 minutes duration. If you have been prescribed anti-angina medicine, carry it with you when being physically active.
- Maintain a healthy weight.
- Discuss your lifestyle and lifestyle plans with your doctor.
- For more information and tools to improve your heart health, call Heartline, the Heart Foundation's national telephone information service, on 1300 36 27 87 (local call cost).

Know warning signs of heart attack and what to do:

- Tightness, fullness, pressure, squeezing, heaviness or pain in your chest, neck, jaw, throat, shoulders, arms or back.
- You may also have difficulty breathing, or have a cold sweat or feel dizzy or light headed or feel like vomiting (or actually vomit).
- If you have heart attack warning signs that are severe, get worse or last for 10 minutes even if they are mild, call triple zero (000). Every minute counts.

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 Mizart HCT 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 Mizart HCT are mild and temporary. The overall frequency of side effects reported by patients taking Mizart HCT is similar to patients taking a placebo (sugar tablet).

The following side effects have been reported by patients taking Mizart HCT.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

It is not known if these side effects are caused by Mizart HCT:

- 'flu-like' symptoms
- fainting, dizziness or spinning sensation
- 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
- shortness of breath or difficulty breathing
- eye pain, abnormal or blurred vision

- back pain
- changes in heart rhythm or increased heart rate
- rash or redness or itchiness of skin
- increased sweating
- dizziness or lightheadedness when you stand up (postural hypotension)
- stomach pain or discomfort (abdominal pain, dyspepsia, gastritis)
- wind or excessive gas in the stomach or bowel
- vomiting
- diarrhoea or constipation
- dry mouth
- pins and needles
- sleep disturbances or trouble sleeping
- feeling anxious
- depression
- impotence
- leg pain or cramps in legs

- aching muscles or aching joints not caused by exercise or muscle spasms
- chest pain
- pain
- liver problems
- changes in the levels of potassium or sodium or uric acid in your blood (such changes are usually detected by a blood test)

Tell your doctor as soon as possible if you experience any side effects during or after taking Mizart HCT, so that these may be properly treated.

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 Mizart HCT is having an excessive effect. You should tell your doctor if you experience any of these symptoms.

Tell your doctor as soon as possible if you notice any unexpected changes to your skin, including your lips.

This could be a type of skin or lip cancer (non-melanoma skin cancer).

If any of the following happens, stop taking Mizart HCT and either tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash
- developing or worsening of a disease called systemic lupus erythematosus which affects the skin, joints and kidney.

These are rare but serious side effects and may indicate a severe allergic reaction. You may need urgent medical attention or hospitalisation.

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 Mizart HCT.

After taking Mizart HCT

Storage

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

The blister pack protects the tablets from light and moisture.

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

Do not store Mizart HCT or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Mizart HCT where young children cannot reach it.

Disposal

If you have been told by your doctor that you will not be needing Mizart HCT 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.

Product description

What Mizart HCT is

Mizart HCT is the brand name of your medicine.

Mizart HCT tablets are available in three strengths: 40/12.5 mg, 80/12.5 mg and 80/25 mg tablets.

Mizart HCT 40/12.5 mg tablets are pink mottled and white to off-white biconvex, oval shaped, two layer tablets. The white to off-white layer may contain pink specks.

The pink mottled face of Mizart HCT 40/12.5 mg tablets are marked with L199.

Mizart HCT 80/12.5 mg tablets are pink mottled and white to off-white, biconvex, oval shaped, two layer tablets. The white to off-white layer may contain pink specks.

The pink mottled face of Mizart HCT 80/12.5 mg tablets are marked with L200.

Mizart HCT 80/25 mg tablets are yellow mottled and white to off-white biconvex, oval shaped, two layer tablets. The white to off-white layer may contain yellow specks.

The white face of Mizart HCT 80/25 mg tablets are marked with L201.

Mizart HCT tablets are available in blister packs of 28 tablets.

Ingredients

Each Mizart HCT 40/12.5 mg tablet contains 40 mg telmisartan and 12.5 mg hydrochlorothiazide.

Each Mizart HCT 80/12.5 mg tablet contains 80 mg telmisartan and 12.5 mg hydrochlorothiazide.

Each Mizart HCT 80/25 mg tablet contains 80 mg telmisartan and 25 mg hydrochlorothiazide.

The other ingredients found in the tablets are:

- povidone
- lactose monohydrate
- magnesium stearate
- meglumine
- sodium hydroxide
- sodium stearyl fumarate

- mannitol

Mizart HCT 40/12.5 mg and 80/12.5 mg tablets also contain Pigment Blend PB-24880 Pink and Mizart HCT 80/25 mg tablets also contain Pigment Blend PB-52290 Yellow, as colouring agent.

Mizart HCT tablets contain lactose.

Sponsor

Mizart HCT is supplied in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

Mizart HCT 40/12.5 mg (blister)-

AUST R 246472

Mizart HCT 80/12.5 mg (blister)-

AUST R 246473

Mizart HCT 80/25 mg (blister)-

AUST R 246474

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