

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.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking MIZART HCT against the benefits they expect it will have for you.

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 blockers. Angiotensin II is a substance in the body which causes blood vessels to narrow, thus increasing blood pressure. Telmisartan works by blocking the effect of angiotensin II. When the effect of angiotensin II is blocked, your blood vessels relax and your blood pressure goes down.

Hydrochlorothiazide belongs to the group of medicines called diuretics. Diuretics help to reduce the amount of excess fluid in the body by increasing the amount of urine produced. 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 have an allergy to:

- any medicine containing telmisartan or hydrochlorothiazide (the two active ingredients in MIZART HCT)
- other sulfonamide-derived medicines
- 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.

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

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
- low sodium levels that is treatment resistant
- low blood volume causing very low blood pressure
- gout
- 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 it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

Tell your doctor if you have, or have had, any of the following medical conditions:

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

If you are uncertain as to whether you have, or have had, any of these conditions you should raise those concerns with your doctor.

Tell your doctor if you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past.

Tell your doctor if you are following a very low salt diet.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell your doctor before you start taking MIZART HCT.

Taking other medicines

Before taking MIZART HCT it is advisable to tell your doctor or pharmacist 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
- heart medicines such as digoxin, a medicine used to treat heart failure or antiarrhythmic medicines
- other diuretics or fluid tablets, medicines used to help the kidneys get rid of salt and water by increasing the amount of urine produced
- laxatives
- potassium tablets (potassium supplements)
- potassium containing salt substitutes
- medicines or salt substitutes which may increase your potassium levels
- amphotericin B, a medicine used to treat fungal infections
- penicillin antibiotics used to treat bacterial infections
- alcohol
- sleeping tablets
- lithium, a medicine used to treat certain mental illnesses
- medicines used to treat depression
- antipsychotics, a medicine used to treat certain mental and emotional conditions
- antiepileptic's, medicines used to treat epilepsy or fits
- 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
- medicines used to increase blood pressure, such as noradrenaline
- ciclosporin, a medicine used to help prevent organ transplant rejection or to treat certain problems with the immune system
- calcium supplements or medicines containing calcium
- vitamin D supplements
- 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, or you may need to take different 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.

Safety and effectiveness in children and teenagers up to 18 years of age have not been established.

How to take MIZART HCT

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

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

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

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.

It is important to take MIZART HCT exactly as your doctor or pharmacist has told you.

How to take it

MIZART HCT should be swallowed whole with a glass of water.

When to take it

Take MIZART HCT at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

MIZART HCT can be taken with or without food.

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

How long to take it for

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

MIZART HCT helps control your high blood pressure but does not cure it. Therefore MIZART HCT must be taken every day even if you feel well.

People who have high blood pressure often feel well and do not notice any signs of this problem.

If you forget to take a dose

It is important to take MIZART HCT as directed.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose of MIZART HCT to make up for a dose that you missed.

This may increase the chance of you getting unwanted side effects.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you have taken too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia telephone 13 11 26) harmonised for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much MIZART HCT.

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, light-headedness, feeling faint), dehydration, nausea, drowsiness and muscle spasm.

While taking MIZART HCT

Things you must do

Tell any other doctor, dentists or pharmacist if you begin using any other medicine while you are taking MIZART HCT.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking MIZART HCT.

If you feel that MIZART HCT is not helping your condition, tell your doctor or pharmacist.

Tell your doctor if, for any reason, you have not used MIZART HCT exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

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

If you plan to have surgery or other treatment (even at the dentist) that needs an anaesthetic, make sure you tell your

doctor, surgeon, anaesthetist or dentist that you are taking MIZART HCT.

MIZART HCT may affect some medicines you received during surgery.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests (add specific tests as per PI) from time to time to make sure the medicine is working and to prevent unwanted side effects.

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.

If you develop any severe shortness of breath or difficulty breathing after taking MIZART HCT, seek medical attention immediately.

Things you must not do

Do not take MIZART HCT to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not stop taking MIZART HCT or lower the dosage without checking with your doctor.

Things to be careful of

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 sleepiness, dizziness, light-headedness or drowsiness in some people.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

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.

You may feel dizzy or lightheaded when you begin to take MIZART HCT, especially if you are also taking a diuretic or fluid tablet or if you are dehydrated. If this problem occurs, talk to your doctor.

If you feel dizzy or lightheaded, and you wish to stand up, you should do so slowly.

Standing up slowly, especially when you get up from a bed or chair, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

If you exercise, or if you sweat, or if the weather is hot, you should drink plenty of water.

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.

It is not known if these side effects are caused by MIZART HCT.

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

You may not experience any of them.

Tell your doctor if you notice any of the following and they worry you:

- '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 light-headedness 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)
- symptoms that may indicate low sodium levels in the blood, such as headache, dizziness, confusion, forgetfulness, weakness, unsteadiness or difficulty concentrating
- decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye or acute angle-closure glaucoma).

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, restlessness, seizures (fits), confusion, muscle pain or cramps, passing less urine than normal and 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.
- acute respiratory distress which is a very rare but possible side effect (signs

include severe shortness of breath, fever, weakness and confusion)

- increased sensitivity of the skin to the sun with symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal.

These are rare but serious side effects. 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

Keep 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.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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 it looks like

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, oblong shaped, two layer tablets. The white to off-white layer may contain pink color 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, oblong shaped, two layer tablets. The white to off-white layer may contain pink color 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, oblong shaped, two layer tablets. The white to off-white layer may contain yellow color 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
- purified water
- mannitol
- MIZART HCT 40/12.5 mg and 80/12.5 mg tablets also contain Pigment Blend PB-24880 PINK (ARTG PI No. 108327) and MIZART HCT 80/25 mg tablets also contain Pigment Blend PB-52290 YELLOW (ARTG PI No: 108950), as colouring agent.

MIZART HCT 40/12.5 tablets contain lactose and sulfites.

MIZART HCT 80/12.5 and 80/25 tablets contain sulfites and sugars as lactose.

Sponsor

MIZART HCT is supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

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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