

MIZART® HCT

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking MIZART HCT?

MIZART HCT contains the active ingredients telmisartan and hydrochlorothiazide, in one single tablet. MIZART HCT is used to lower high blood pressure. For more information, see Section [1. Why am I taking MIZART HCT?](#) in the full CMI.

2. What should I know before I take MIZART HCT?

Do not take if you have ever had an allergic reaction to telmisartan or hydrochlorothiazide (the two active ingredients in MIZART HCT) or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

Do not take MIZART HCT if you have a rare hereditary condition of fructose intolerance and/or galactose intolerance.

MIZART HCT is not prescribed for children under the age of 18 years.

For more information, see Section [2. What should I know before I take MIZART HCT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MIZART HCT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take MIZART HCT?

Swallow the tablet whole with a full glass of water. More instructions can be found in Section [4. How do I take MIZART HCT?](#) in the full CMI.

5. What should I know while taking MIZART HCT?

Things you should do	- Remind any doctor, dentist or pharmacists you visit that you are taking MIZART HCT. - Stop taking MIZART HCT and call your doctor straight away if you develop an unexpected abnormal lump, bump, ulcer, sore or coloured area on the skin (skin lesion) during the treatment or if you develop any shortness of breath or difficulty breathing after taking MIZART HCT.
Things you should not do	- Do not take any other medicines for your hypertension (high blood pressure) without checking with your doctor. - Do not stop taking MIZART HCT or lower the dosage, without checking with your doctor or pharmacist.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how MIZART HCT affects you.
Drinking alcohol	Tell your doctor if you drink alcohol.
Looking after your medicine	Keep your MIZART HCT in a cool, dry place where the temperature stays below 25°C and protect from light and moisture.

For more information, see Section [5. What should I know while taking MIZART HCT?](#) in the full CMI.

6. Are there any side effects?

Do not be alarmed, and speak to your doctor if you feel nausea, 'flu-like' symptoms, increased heart rate, chest pain, dizziness, stomach pain or discomfort, sleeping disturbances or pain in muscles or joints. Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you develop any severe shortness of breath or difficulty breathing after taking MIZART HCT or if you develop an unexpected abnormal lump, bump, ulcer, sore or coloured area on the skin (skin lesion) during the treatment. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

MIZART® HCT

Active ingredient(s): Telmisartan and Hydrochlorothiazide

Consumer Medicine Information (CMI)

This leaflet provides important information about taking MIZART HCT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking MIZART HCT.**

Where to find information in this leaflet:

1. [Why am I taking MIZART HCT?](#)
2. [What should I know before I take MIZART HCT?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take MIZART HCT?](#)
5. [What should I know while taking MIZART HCT?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking MIZART HCT?

MIZART HCT contains the active ingredient telmisartan and hydrochlorothiazide.

MIZART HCT is used to lower high blood pressure.

Everyone has blood pressure. This pressure helps get your blood 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 (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed. If high blood pressure is not treated, it can lead to serious health problems, including stroke, heart disease and kidney failure.

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.

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

How MIZART HCT works?

MIZART HCT contains telmisartan and hydrochlorothiazide in one single tablet. These two active ingredients help to reduce blood pressure in different ways:

Telmisartan belongs to a group of medicines called angiotensin II receptor blockers. Telmisartan works by blocking the effect of angiotensin II (a substance which causes blood vessels to narrow, thus increasing blood pressure). 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 help with lowering blood pressure particularly when used with other blood pressure lowering 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.

2. What should I know before I take MIZART HCT?

Warnings

Do not take MIZART HCT if :

- you have an allergy to:
 - o any medicine containing telmisartan or hydrochlorothiazide (the two active ingredients in MIZART HCT)
 - o other sulfonamide-derived medicines
 - o 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. Signs of an allergic reaction may include:
 - o shortness of breath;
 - o wheezing or difficulty breathing;
 - o swelling of the face, lips, tongue or other parts of body;
 - o rash, itching or hives on the skin.
- Always check the ingredients to make sure you can take this medicine.
- you suffer from:
 - o hypersensitivity to sulfonamide containing medicines
 - o severe liver disease
 - o severe kidney disease
 - o problem with the flow of bile from the gall bladder (cholestasis or biliary obstructive disorders)
 - o low potassium levels in the blood
 - o high calcium levels in the blood
 - o low sodium levels that is treatment resistant
 - o low blood volume causing very low blood pressure
 - o a disease with painful, swollen joints caused by uric acid crystals (gout)
 - o diabetes or kidney disease and you are taking medicine used to treat high blood pressure (aliskiren)

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.

Check with your doctor if you:

- have allergies to any other medicines, food, preservatives or dyes.

It is essential that your doctor knows your medical history before prescribing MIZART HCT.
- have any of the following medical conditions, especially:
 - o kidney problems
 - o a kidney transplant
 - o liver problems
 - o heart problems
 - o diabetes
 - o high cholesterol levels
 - o gout
 - o a condition with raised aldosterone levels (primary hyperaldosteronism or Conn's syndrome)
 - o fructose intolerance
 - o galactose intolerance
 - o recent severe diarrhoea or vomiting
 - o allergy or asthma
 - o a disease affecting the skin, joints and kidney (systemic lupus erythematosus)
 - o eye problems
 - o 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.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take MIZART HCT if you are pregnant or plan to become pregnant.

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

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

Do not take MIZART HCT if you are breastfeeding or plan to breastfeed.

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

Tell your doctor if you are breastfeeding. Your doctor can discuss with you the risks and benefits involved.

Children

Do not give MIZART HCT to a child under the age of 18 years.

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with MIZART HCT and affect how it works. These include:

- any other medicines used to treat high blood pressure or other heart conditions such as beta-blockers
- 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 supplements or 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, medicines used to treat certain mental and emotional conditions
- antiepileptics, 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 (a hormone)
- 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
- 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 how well it works. 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MIZART HCT.

4. How do I take MIZART HCT?

How much to take

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

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.

When to take MIZART HCT

Take MIZART HCT around the same time each day, either morning or evening, with or without food.

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

How to take MIZART HCT

Swallow the tablet whole with a full glass of water.

How long to take MIZART HCT

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 MIZART HCT

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 your medicine as you would normally.

Do not take a double dose to make up for the dose 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 take too much MIZART HCT

If you think that you or anyone else has taken too much MIZART HCT, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while taking MIZART HCT?

Things you should do

Stop taking MIZART HCT and Call your doctor straight away 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)
- develop any severe shortness of breath or difficulty breathing after taking MIZART HCT
- become pregnant while taking MIZART HCT

You should make sure that you:

- protect your skin from sun exposure and UV rays while taking MIZART HCT

- 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, dentist or pharmacist that you are taking MIZART HCT, if you are about to be started on any new medicine
- tell your doctor if, for any reason, have not taken MIZART HCT exactly as prescribed

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

- tell your doctor if you feel that MIZART HCT is not helping your condition
- tell your doctor, surgeon, anaesthetist or dentist that you are taking MIZART HCT, if you plan to have surgery or other treatment (even at the dentist) that needs an anaesthetic

MIZART HCT may affect some medicines you receive during surgery.

Remind any doctor, dentist or pharmacist you visit that you are taking MIZART HCT.

Things you should 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.

Driving or using machines

Be careful before you drive or take any machines or tools until you know how MIZART HCT affects you.

Like other medicines used to treat high blood pressure, MIZART HCT may cause sleepiness, dizziness or light-headedness in some people.

Do not drive, operate machinery, or perform hazardous physical activity if you experience any of these side effects.

Things to be careful of

You may feel dizzy or light-headed when you begin to take MIZART HCT, especially if you are also taking a diuretic (or fluid tablet) or if you are dehydrated.

If you feel dizzy or light-headed, 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

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 a 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.

Looking after your medicine

- Store below 25°C.
- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it 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.

Getting rid of any unwanted medicine

If you no longer need to take this medicine, it is out of date or is damaged, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date on the carton/blister strips or if the packaging shows signs of tampering.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
Breathing related disorders: • 'flu-like' symptoms • infections of the air passages • shortness of breath or difficulty breathing • a feeling of tension or fullness in the nose, cheeks and behind the eyes, sometimes with a throbbing ache (sinusitis) Stomach related disorders: • dry mouth • nausea, vomiting • change in bowel movements (e.g. constipation or diarrhoea) • stomach pain or discomfort (abdominal pain, dyspepsia, gastritis) • flatulence (wind or excessive gas in the stomach or bowel) General body related disorders: • back pain • dizziness or light-headedness when you stand up (postural hypotension) • pins and needles • leg pain or cramps in legs • rash or redness or itchiness of skin	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
• aching muscles or aching joints not caused by exercise or muscle spasms • 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 • sleep disturbances or trouble sleeping • increased sweating • impotence • pain • liver problems Nervous system disorders: • fainting • dizziness • spinning sensation • feeling anxious • depression Eye related disorders: • 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) • eye pain • abnormal or blurred vision Heart related disorders: • chest pain • changes in heart rhythm or increased heart rate	

Serious side effects

Serious side effects	What to do
Immune system disorders: • developing or worsening of a disease called systemic lupus erythematosus which affects the skin, joints and kidney Breathing related disorders: • acute respiratory distress which is a very rare but possible side effect (signs include severe	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
shortness of breath, fever, weakness and confusion) Skin related disorders: - 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 - 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 - any changes to your skin, including lips (could be a type of skin or lip cancer called non-melanoma skin cancer)	These are rare but serious side effects.

Tell your doctor or pharmacist if you experience symptoms like - 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. It may mean that the hydrochlorothiazide part of MIZART HCT is having an excessive effect.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What MIZART HCT contains

Active ingredient (main ingredient)	Telmisartan and hydrochlorothiazide
Other ingredients (inactive ingredients)	- povidone - lactose monohydrate - magnesium stearate - meglumine - sodium hydroxide

	- sodium stearyl fumarate - purified water - mannitol - Pigment Blend PB-24880 PINK (ID: 108327) (in MIZART HCT 40/12.5 mg and 80/12.5 mg tablets) - Pigment Blend PB-52290 YELLOW (ID: 108950) (as colouring agent in MIZART HCT 80/25 mg tablets).
Potential allergens	- Lactose and sulfites (MIZART HCT 40/12.5 tablets) - Sulfites and sugars as lactose (MIZART HCT 80/12.5 AND 80/25 tablets)

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.

Do not take this medicine if you are allergic to any of these ingredients.

What MIZART HCT looks like

- MIZART HCT 40/12.5 mg** - Each tablet is an oblong shaped, biconvex, bilayered, uncoated tablets with one white to off-white color layer and one pink color mottled layer debossed with 'L199'. White to off-white color layer may contain pink color specks (AUST R 246472).
- MIZART HCT 80/12.5 mg** - Each tablet is an oblong shaped, biconvex, bilayered, uncoated tablets with one white to off-white color layer and one pink color mottled layer debossed with 'L200'. White to off-white color layer may contain pink color specks (AUST R 246473).
- MIZART HCT 80/25 mg** - Each tablet is an oblong shaped, biconvex, bilayered, uncoated tablets with one white to off-white color layer and one yellow color mottled layer debossed with 'L201'. White to off-white color layer may contain yellow color specks (AUST R 246474).

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

Who distributes MIZART HCT

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

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