

# ZAN-EXTRA®

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## Consumer Medicine Information (CMI) summary

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

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### 1. Why am I taking ZAN-EXTRA?

ZAN-EXTRA contains the active ingredients lercanidipine hydrochloride and enalapril maleate. ZAN-EXTRA is used to lower high blood pressure. For more information, see Section [1. Why am I taking ZAN-EXTRA?](#) in the full CMI.

### 2. What should I know before I take ZAN-EXTRA?

Do not take ZAN-EXTRA if you have ever had an allergic reaction to lercanidipine, enalapril, any medicines closely related to lercanidipine 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.**

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

### 3. What if I am taking other medicines?

Some medicines and ZAN-EXTRA may interfere with each other and affect how they work.

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 ZAN-EXTRA?

- The usual dose is one tablet taken once daily.
- Take ZAN-EXTRA at about the same time each day, at least 15 minutes before a meal. Swallow ZAN-EXTRA whole with a glass of water.

More instructions can be found in Section [4. How do I take ZAN-EXTRA?](#) in the full CMI.

### 5. What should I know while taking ZAN-EXTRA?

#### Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are taking ZAN-EXTRA.
- Tell your doctor if you become pregnant while you are taking ZAN-EXTRA.

	<ul style="list-style-type: none"> <li>• Tell the anaesthetist that you are taking ZAN-EXTRA if you have an operation.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not take ZAN-EXTRA with grapefruit or grapefruit juice as these may increase the effects of this medicine.</li> <li>• Do not give ZAN-EXTRA to anyone else, even if they have the same condition as you.</li> <li>• Do not use ZAN-EXTRA to treat any other complaints unless your doctor tells you to.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful before you drive or use any machines or tools until you know how ZAN-EXTRA affects you.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Tell your doctor if you drink alcohol.</li> <li>• Your doctor may ask you to limit or stop your alcohol intake while taking ZAN-EXTRA as alcohol may increase</li> </ul>

	the effects of ZAN-EXTRA.
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep your tablets in the blister pack until it is time to take them.</li> <li>• Store it in a cool dry place below 25°C away from moisture, heat or sunlight.</li> </ul>

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

## 6. Are there any side effects?

**Speak to your doctor if you have any of these less serious side effects and they worry you:** flushing, swelling of the ankles, feet or lower legs, headache, dizziness, gastrointestinal disturbances such as nausea, abdominal pain, taste alteration or diarrhoea, fatigue or sleepiness, dry cough. **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:** angina (chest pain or tightness), increased or irregular heart beat, signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or throat, difficulty in breathing.

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.



# ZAN-EXTRA®

**Active ingredients:** *lercanidipine hydrochloride and enalapril maleate*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using ZAN-EXTRA. **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 ZAN-EXTRA.**

**Where to find information in this leaflet:**

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

## 1. Why am I taking ZAN-EXTRA?

**ZAN-EXTRA contains the active ingredients lercanidipine hydrochloride and enalapril maleate.** ZAN-EXTRA is a combination of the two medicines. Lercanidipine belongs to a group of medicines called

calcium channel blockers, enalapril belongs to a group called Angiotensin Converting Enzyme (ACE) inhibitors.

**ZAN-EXTRA is used to lower high blood pressure, which doctors call hypertension.** It works by relaxing some of the blood vessels in the body and reducing resistance to the flow of blood through the blood vessels.

### **Hypertension:**

Everyone has blood pressure. This pressure helps get your blood all 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.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems. You may feel fine and have no symptoms, but eventually hypertension can cause stroke, heart disease and kidney failure.

ZAN-EXTRA helps to lower your blood pressure.

## 2. What should I know before I take ZAN-EXTRA?

### Warnings

#### Do not take ZAN-EXTRA if:

- you are allergic to lercanidipine, enalapril or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.
- you are allergic to any medicines closely related to lercanidipine (such as amlodipine, felodipine or nifedipine) or other ACE inhibitors.
- you have an obstruction to flow of blood from the heart
- you have untreated heart failure
- you have unstable angina (chest pain or tightness at rest or that progressively increases) or you have had a heart attack one month ago or less
- you have severe liver or kidney disease, or if you are undergoing dialysis.
- you are also taking medicines such as:
  - antifungals (e.g. itraconazole, ketoconazole)
  - ciclosporin
  - macrolide antibiotics (e.g. clarithromycin, erythromycin, troleandomycin)
  - antivirals (e.g. ritonavir)
- you eat grapefruit or drink grapefruit juice.



- you have diabetes or impaired kidney function and you are also taking a medicine containing aliskiren.
- you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term heart failure in adults.
- you have had swelling of the face, lips, mouth, tongue or throat which caused difficulty in swallowing or breathing (angioedema), swelling of hands or feet after taking a medicine containing ACE inhibitor, or for no apparent reason.
- you are pregnant, intend to become pregnant or if you are breastfeeding.
- the packaging is torn or shows signs of tampering.
- the tablets show visible sign of deterioration (for example, are broken or discoloured).
- the expiry date printed on the pack has passed. If you take this medicine after the expiry date has passed, it may not work as well.

**If you are not sure whether you should start taking ZAN-EXTRA, talk to your doctor.**

**Do not give ZAN-EXTRA to a child under the age of 18 years.**

ZAN-EXTRA is not recommended for use in children.

**Check with your doctor if you:**

- intend to get pregnant or intend to breast-feed.  
ZAN-EXTRA should not be used during pregnancy or while breast-feeding.

- are taking other drugs for high blood pressure, such as beta-blockers, diuretics, ACE-inhibitors or angiotensin II receptor antagonists.
- have low blood pressure (you may notice this as faintness or dizziness, especially when standing)
- have been very sick (excessive vomiting) or have had diarrhoea recently
- are a black patient you should be aware that black patients are at increased risk of allergic reactions with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing when taking ACE inhibitors
- have or have ever had any other health problems/ medical conditions including:
  - heart problem
  - condition involving blood vessels in the brain
  - kidney problem (including kidney transplantation). This may lead to higher levels of potassium in your blood which can be serious. Your doctor may need to adjust your dose of enalapril or monitor your blood level of potassium.
  - liver problem
  - blood problem, such as low or lack of white blood cells (leucopenia, agranulocytosis), low platelet count (thrombocytopenia) or a decreased number of red blood cells (anaemia).
  - collagen vascular disease (e.g. lupus erythematosus, rheumatoid arthritis or scleroderma)
  - diabetes. You should monitor your blood for low blood glucose levels, especially during the first

month of treatment. The level of potassium in your blood can also be higher.

- require a pacemaker.
- require surgery or receive anaesthetics.
- are undergoing a treatment to remove cholesterol from your blood called "LDL apheresis".
- are undergoing a desensitisation treatment to lower the effect of any allergy to bee or wasp stings.
- are following a very low salt diet.
- are allergic to any other medicine or any foods, dyes or preservatives.

If you have not told your doctor about any of the above or if you are not sure, tell them before you take ZAN-EXTRA.

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 ZAN-EXTRA if you are pregnant, intend to become pregnant or if you are breastfeeding.**

**Tell your doctor immediately if you become pregnant while you are taking Zan-Extra.**

Check with your doctor if intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.

### **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 and ZAN-EXTRA may interfere with each other and affect how they work. These include:**

- allopurinol, procainamide
- any anti-diabetic medicine including insulin or vildagliptin (used to lower blood glucose).

You should be closely monitored for low blood glucose levels, especially during the first month of treatment with ZAN-EXTRA.

- arthritis medicines including gold therapy
- carbamazepine, phenobarbital (phenobarbitone), phenytoin
- certain anaesthetic, tricyclic antidepressant and antipsychotic medicines
- certain cough and cold medicines and weight reducing medicines which contain a sympathomimetic medicine
- ciclosporin (an immunosuppressant medicine used to prevent organ transplant rejection)
- cimetidine (more than 800 mg daily)
- clarithromycin, erythromycin, troleandomycin

- diuretic tablets (also called fluid or water tablets)
- heparin (a medicine used to thin blood to prevent clots)
- itraconazole, ketoconazole
- lithium (a medicine used to treat mood swings and some types of depression)
- medicines used to prevent organ transplant rejection and for cancer (e.g. everolimus, sirolimus, temsirolimus)
- metoprolol, propranolol
- non-steroidal anti-inflammatory medicines (used to relieve pain, swelling and other symptoms of inflammation)
- other blood pressure medications
- potassium-containing salt substitutes and potassium tablets
- racecadotril
- rifampicin
- ritonavir
- sacubitril/valsartan
- vildagliptin

These medicines may be affected by ZAN-EXTRA or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

**Also, ask your doctor or pharmacist what to do if you are taking or are about to take the following medicines: amiodarone, digoxin, quinidine, simvastatin or sotalol.**

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZAN-EXTRA.**

## **4. How do I take ZAN-EXTRA?**

### **How much to take**

- Follow all directions given to you by your doctor carefully.
- These directions may differ from the information contained in this leaflet.
- The usual dose is one tablet taken once daily.
- If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

### **When to take ZAN-EXTRA**

- **Take ZAN-EXTRA at about the same time each day, at least 15 minutes before a meal.** Swallow ZAN-EXTRA whole with a glass of water.
- ZAN-EXTRA will have the best effect if it is taken at the same time each day at least 15 minutes before meals. This will also help you remember when to take the tablets.

## **How long to take it**

ZAN-EXTRA helps control your condition, but does not cure it. Therefore you must take ZAN-EXTRA every day. Continue taking the tablets for as long as your doctor tells you to.

## **If you forget to take ZAN-EXTRA**

**If you forget to take a dose but remember within 12 hours from when the dose was due, take it straight away, then continue as normal the next day. Otherwise skip that day's dose but be sure to take the next day's dose when it is due.**

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

**Do not take a double dose to make up for the dose you missed.**

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

If you have missed several doses, consult your doctor.

## **If you take too much ZAN-EXTRA**

If you think that you have taken too much ZAN-EXTRA, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (Australia telephone 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.**

If you take too much ZAN-EXTRA, it may cause your blood pressure to become too low and you may feel your heart beats become irregular and faster. It may also lead to unconsciousness.

## **5. What should I know while taking ZAN-EXTRA?**

### **Things you should do**

**Take ZAN-EXTRA exactly as your doctor has prescribed.**

If you do not follow your doctor's instructions correctly, your blood pressure may not be controlled.

**Be sure to keep all of your doctor's appointments so that your progress can be checked.**

### **Tell your doctor if you:**

- become pregnant while you are taking ZAN-EXTRA
- are about to start taking any new medicine that you are taking ZAN-EXTRA



Remind any doctor, dentist or pharmacist you visit that you are taking ZAN-EXTRA.

If you have an operation, tell the anaesthetist that you are taking this medicine.

## **Things you should not do**

- Do not give ZAN-EXTRA to anyone else, even if they have the same condition as you.
- Do not use ZAN-EXTRA to treat any other complaints unless your doctor tells you to.

## **Things to be careful of**

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

**As with some medicines used to treat high blood pressure such as ZAN-EXTRA, you should avoid drinking grapefruit juice.**

Grapefruit juice may increase the effects of these medicines.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how ZAN-EXTRA affects you.**

ZAN-EXTRA generally does not cause any problems with your ability to drive a car or operate machinery. However, as with other medicines used to treat high blood pressure, a few people may feel dizzy, light-

headed or faint, especially when first taking ZAN-EXTRA or when starting to take a different amount of medicine.

## **Drinking alcohol**

### **Tell your doctor if you drink alcohol.**

Your doctor may also ask you to limit or stop your alcohol intake while taking medicines to control your blood pressure, such as ZAN-EXTRA, as alcohol may increase the effects of medicines used to treat high blood pressure.

## **Looking after your medicine**

- Keep your tablets in the blister pack until it is time to take them.
- If you take the tablets out of the blister pack, they may not keep well.

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

Store it in a cool dry place below 25°C away from moisture, heat or sunlight.

Do not store it:

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

### **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 your doctor tells you to stop taking this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

ZAN-EXTRA helps most people with high blood pressure, but it may have unwanted side effects in a few people.

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.

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
<ul style="list-style-type: none"><li>• flushing</li><li>• swelling of the ankles, feet or lower legs</li><li>• headache</li><li>• dizziness</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● gastrointestinal disturbances such as nausea, abdominal pain, taste alteration or diarrhoea</li> <li>● fatigue or sleepiness</li> <li>● dry cough</li> </ul>	<p>These effects when they occur are usually mild.</p>

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● angina (chest pain or tightness)</li> <li>● increased or irregular heart beat</li> <li>● signs of allergy such as rash, itching or hives on the skin, muscle pain, tenderness or joint pain</li> <li>● swelling of the face, lips, tongue or throat</li> <li>● difficulty in breathing</li> </ul>	<p><b>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.</b></p> <p>These side effects are usually rare but may be serious and need urgent medical attention.</p>

**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](http://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 ZAN-EXTRA contains

<b>Active ingredients (main ingredients)</b>	Lercanidipine hydrochloride 10 mg with either enalapril maleate 10 mg or 20 mg per tablet
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>● lactose monohydrate</li><li>● microcrystalline cellulose</li><li>● sodium starch glycollate Type A</li><li>● povidone</li></ul>

	<ul style="list-style-type: none"> <li>● sodium bicarbonate</li> <li>● magnesium stearate</li> <li>● hypromellose</li> <li>● titanium dioxide (E171)</li> <li>● purified talc</li> <li>● macrogol 6000</li> <li>● quinoline yellow aluminium lake (E104) for ZAN-EXTRA 10/20 tablets</li> <li>● iron oxide yellow (E172) for ZAN-EXTRA 10/20 tablets</li> </ul>
<b>Potential allergens</b>	<p>ZAN-EXTRA 10/10: sugars as lactose</p> <p>ZAN-EXTRA 10/20: lactose</p>

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

### **What ZAN-EXTRA looks like**

ZAN-EXTRA is available as tablets of two separate strengths, ZAN-EXTRA 10/10 and ZAN-EXTRA 10/20 both containing lercanidipine hydrochloride 10 mg, and either enalapril maleate 10 mg or 20 mg respectively.

ZAN-EXTRA 10/10 tablets are white, circular, biconvex, film-coated tablets, and available in packs of 28 tablets in a blister pack (AUST R 120955).

ZAN-EXTRA 10/20 tablets are yellow, circular, biconvex, film-coated tablets, and available in packs of 28 tablets in a blister pack (AUST R 120961).

## **Who distributes ZAN-EXTRA**

Viatrix Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatrix.com.au](http://www.viatrix.com.au)

Phone: 1800 274 276

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