Package leaflet: Information for the user

Zanidip® 20 mg film-coated tablets

(lercanidipine hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Zanidip 20 mg film-coated tablets but will be referred to as Zanidip throughout the remainder of this leaflet. Your medicine is also available in 10 mg strength.

What is in this leaflet:

1. What Zanidip is and what it is used for

Zanidip, lercanidipine hydrochloride, belongs to a group of medicines called Calcium Channel Blockers (dihydropyridine derivatives) that lower blood pressure.

Zanidip is used to treat high blood pressure also known as hypertension in adults over the age of 18 years (it is not recommended for children under 18 years old).

2. What you need to know before you take Zanidip

Do not take Zanidip:
- If you are allergic to lercanidipine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- If you are suffering from certain heart diseases:
  - obstruction to flow of blood from the heart
  - untreated heart failure
  - unstable angina (chest discomfort occurring at rest or progressively increasing)
  - within one month of heart attack.
- If you have severe liver problems.
- If you have severe kidney problems or you are undergoing dialysis.
- If you are taking medicines that are inhibitors of hepatic metabolism, such as:
  - antifungal medicines (such as ketoconazole or itraconazole)
  - macrolide antibiotics (such as erythromycin, troleandomycin or clarithromycin)
  - antivirals (such as ritonavir).
- If you are taking another medicine called ciclosporin or cyclosporin (used after transplants to prevent organ rejection).
- With grapefruit or grapefruit juice.

Warning and precautions

Talk to your doctor or pharmacist before taking Zanidip:
- if you have a heart problem
- if you have liver or kidney problems

You must tell your doctor if you think you are (or might become) pregnant or breast-feeding (see pregnancy, breast-feeding and fertility section).

Children and adolescents

The safety and efficacy of Zanidip in children aged up to 18 years have not been established.

Other medicines and Zanidip

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because when Zanidip is taken with other medicines the effect of Zanidip or of the other medicine may be changed or certain side effects may occur more frequently (see also section 2 “Do not take Zanidip”).

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- phenytoin, phenobarbital or carbamazepine (medicines for epilepsy)
- rifampicin (a medicine to treat tuberculosis)
- astemizole or terfenadine (medicines for allergies)
- amiodarone, quinidine or sotalol (medicines to treat a fast heart beat)
- midazolam (a medicine that helps you sleep)
- digoxin (a medicine to treat a heart problem)
- beta-blockers e.g. metoprolol (a medicine to treat high blood pressure, heart failure and abnormal heart rhythms)
- cimetidine (more than 800 mg, a medicine for ulcers, indigestion, or heartburn)
- simvastatin (a medicine to lower cholesterol in your blood)
- other medicines to treat high blood pressure

Zanidip with food, drink and alcohol
- A high fat meal significantly increases blood levels of the medicine (see section 3)
- Alcohol can increase the effect of Zanidip. Do not consume alcohol during treatment with Zanidip
- Zanidip must not be taken with grapefruit or grapefruit juice (they can increase its hypotensive effect). See section 2 “Do not take Zanidip”.

Pregnancy, breast-feeding and fertility

Zanidip is not recommended if you are pregnant, it should not be used during breast-feeding. There are no data from the use of Zanidip in pregnant women and in nursing mothers. If you are pregnant or breast-feeding, if you are not using any contraceptive method, you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

If you develop dizziness, weakness or drowsiness with this medicine, do not drive a vehicle or operate machines.

Zanidip contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.

3. How to take Zanidip

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults: The recommended dose is 10 mg once daily, at the same time each day, preferably in the morning at least 15 minutes before breakfast. Your doctor may advise you to increase the dose to one Zanidip 20 mg daily, if needed (see section 2 “Zanidip with food, drink and alcohol”). The tablets should preferably be swallowed whole with some water.

Use in children: This medicine should not be used in children under 18 years of age.

Elderly patients: No adjustment of the daily dose is required. However, special care should be exercised in starting treatment.

Patients with liver or kidney problems: Special care is needed in starting treatment in these patients and an increase in daily dose to 20 mg should be approached with caution.

If you take more Zanidip than you should
Do not exceed the prescribed dose. If you take more than the prescribed dose, talk to your doctor or go to the hospital straight away. Take the medicine pack with you. Taking more than the correct dose can cause an excessive drop in blood pressure and your heart can beat irregularly or faster.

If you forget to take Zanidip
If you forget to take your tablet simply miss that dose and then go on as before.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Zanidip
If you stop taking Zanidip your blood pressure may increase again. Please consult your doctor before stopping the treatment. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The following side effects may happen with this medicine:

Some side effects can be serious.
If any of the following happen, tell your doctor straight away:
Rare (*may affect up to 1 in 1,000 people)*: angina pectoris (e.g. chest tightness due to lack of blood to your heart), allergic reactions (symptoms include itching, rash, urticaria), fainting.

Patients with pre-existing angina pectoris may experience increased frequency, duration or severity of these attacks with the group of medicines to which Zanidip belongs. Isolated cases of heart attack may be observed.

Other possible side effects:
Common (*may affect up to 1 in 10 people*): headache, fast heart rate, feeling of fast or uneven heart beat (palpitations), sudden reddening of your face, neck or upper chest (flushing), ankle swelling.

Uncommon (*may affect up to 1 in 100 people*): dizziness, fall in blood pressure, heartburn, feeling sick, stomach pain, skin rash, itching, muscle pain, passage of large amounts of urine, feeling weak or feeling tired.

Rare (*may affect up to 1 in 1,000 people*): sleepiness, vomiting, diarrhoea, hives, increase in the usual number of times one urinates, chest pain.

Not known (*frequency cannot be estimated from the available data*): swelling of gums, changes in liver function (detected by blood tests), cloudy fluid (when performing dialysis through a tube into your abdomen), swelling of your face, lip, tongue or throat which may cause difficulty in breathing or swallowing.

Reporting of suspected adverse reactions
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store.** By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Zanidip

Keep out of the sight and reach of children.

Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton and on the blister after 'EXP'. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater of household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

If your medicine shows any signs of deterioration or discolouration, consult your doctor or pharmacist for advice. If damaged, please tell your doctor or pharmacist.

6. Contents of the pack and other information

What Zanidip contains
The active substance is lercanidipine hydrochloride. Each film-coated tablet contains 20 mg lercanidipine hydrochloride (equivalent to 18.8 mg lercanidipine).

Tablet core contains: lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate and povidone K30.

Tablet coating contains: hypromellose, talc, titanium dioxide (E171), macrogol 6000, and iron oxide (E172).

What Zanidip looks like and contents of the pack
Zanidip are pink, circular, biconvex film-coated tablets, scored on one side and plain on the other.

Zanidip tablets are available in blister packs of 28 tablets.

Manufactured by: Recordati Industria Chimica e Farmaceutica S.p.A., I-20148 Milan, Italy. Procured from within the EU. Product Licence Holder: Quadrant Pharmaceuticals Limited, Lynstock House, Lynstock Way, Lostock, Bolton, BL6 4SA. Repackaged by: Maxearn Limited, Unit 29, Oakhill Trading Estate, Devonshire Road, Worsley, Manchester, M28 3PT.

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Is this leaflet hard to see or read?
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