PACKAGE LEAFLET: INFORMATION FOR THE USER

ZANIDIP® 20MG TABLETS
(lercanidipine hydrochloride)

Zanidip Tablets are available in the following strengths: 10mg and 20mg.

Your medicine is available as Zanidip 20mg tablets but will be referred to as Zanidip throughout the leaflet. Zanidip 10mg will also be referred to in this leaflet.

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.

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 (hypersensitive) to lercanidipine hydrochloride or to any other ingredients of Zanidip.
- If you have had allergic reactions to drugs closely related to Zanidip (such as amlodipine, nicardipine, felodipine, isradipine, nifedipine or lacidipine).
- If you are suffering from certain heart diseases:
  - untreated heart failure
  - obstruction to flow of blood from the heart
  - unstable angina (angina at rest or progressively increasing)
  - within one month of heart attack
- If you have severe liver or kidney problems.
- If you are taking drugs that are inhibitors of CYP3A4 isoenzyme:
  - antifungal medicines (such as ketoconazole or itraconazole)
  - macrolide antibiotics (such as erythromycin or troleandomycin)
  - antivirals (such as ritonavir)
- If you are taking another drug called ciclosporin or cyclosporin (used after transplants to prevent organ rejection).
- With grapefruit or grapefruit juice.

Do not use if you are pregnant or breastfeeding (see section Pregnancy, breast-feeding and fertility for more information).

Warning and precautions
Talk to your doctor or pharmacist before taking Zanidip:
- if you have certain other heart conditions which have not been treated by insertion of a pacemaker or have pre-existing angina.
- if you have problems with your liver or kidneys or you are on dialysis.

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.
No data are available.

Other medicines and Zanidip
Please tell your doctor or pharmacist if:
- You are taking or have recently taken any other medicines, including medicines obtained without a prescription
- You are taking beta-blockers e.g. metoprolol, diuretics (water tablets) or ACE-inhibitors (medicines to treat high blood pressure)
- You are taking cimetidine (more than 800mg, a medicine for ulcers, indigestion, or heartburn)
- You are taking digoxin (a medicine to treat a heart problem)
- You are taking midazolam (a medicine that helps you sleep)
- You are taking rifampicin (a medicine to treat tuberculosis)
- You are taking astemizole or terfenadine (medicines for allergies)
- You are taking amiodarone or quinidine (medicines to treat a fast heart beat)
- You are taking phenytoin or carbamazepine (medicines for epilepsy). Your doctor will want to monitor your blood pressure more frequently than usual.

Zanidip with food, drink and alcohol
- Please do not consume alcohol during treatment with Zanidip since it may increase the effect of Zanidip.
- Please do not take Zanidip with grapefruit or grapefruit juice.

Pregnancy, breast-feeding and fertility
Zanidip should not be used if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby or you are not using any contraceptive method.

Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Caution should be exercised because of the possibility of dizziness, weakness, tiredness and rarely sleepiness. Do not drive or use machines until you know how Zanidip affects you.

Zanidip contains lactose monohydrate
If you have been told by your doctor that you have an intolerance to some sugars, e.g. intolerance to lactose, galactosaemia or glucose/galactose malabsorption syndrome, contact your doctor before taking this medicinal product, as the tablets contain lactose monohydrate.

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 10mg once daily at the same time each day, preferably in the morning at least 15 minutes before breakfast, because a high fat meal significantly increases blood levels of the drug. Your doctor may advise you to increase the dose to one Zanidip 20mg daily, if needed.

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 20mg should be approached with caution.

If you have any further questions on the use of this medicine ask your doctor or pharmacist.

If you take more Zanidip than you should

Do not exceed the prescribed dose.
If you take more than the prescribed dose or in the event of overdose, seek medical advice immediately and, if possible, take your tablets and/or the container with you.

Exceeding the correct dosage may cause blood pressure to become too low, and the heart to beat irregularly or faster. It may also lead to unconsciousness.

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.

Some side effects can be serious:
If you experience any of these side effects tell your doctor straight away.

Rare *(affecting less than 1 out of 1,000 patients):*
angina pectoris (chest pain due to lack of blood to your heart)

Very rare *(affecting less than 1 out of 10,000 patients):*
chest pain, fall in blood pressure, fainting and allergic reactions (symptoms include itching, rash, hives)

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

Other possible side effects:
Uncommon *(affecting less than 1 out of 100 patients)*:
headache, dizziness, faster heart beats, palpitations (heart pounding or racing), sudden reddening of the face, neck or upper chest, ankle swelling.

Rare *(affecting less than 1 out of 1,000 patients):*
sleepiness, feeling sick, vomiting, heartburn, stomach pain, diarrhoea; skin rash, muscle pain, passage of large amounts of urine, tiredness.

Very rare *(affecting less than 1 out of 10,000 patients):*
swelling of gums, changes in liver function (detected by blood tests), increase in the usual number of times one urinates.

Reporting of suspected adverse reactions
If you get any side effects, talk to your doctor or pharmacist. 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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zanidip

- Store in the original package.
- Keep out of the sight and reach of children.
- Do not use the tablets after the expiry date, which is shown on the carton and blister labels. The expiry date refers to the last day of that month.
- If your doctor tells you to stop using the medicine, please take it back to the pharmacist for safe disposal. Only keep the medicine if your doctor tells you to. Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.
- If the medicine become discoloured or shows any other signs of deterioration, you should seek the advice of pharmacist who will tell you what to do.

6. Contents of the pack and other information

What Zanidip contains

Each film-coated tablet contains 20mg of the active ingredient lercanidipine hydrochloride.

The following inactive ingredients are also included in Zanidip: Lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone K30, magnesium stearate, hypromellose, talc, titanium dioxide (E171), macrogol 6000, and iron oxide (E172).

What Zanidip looks like and contents of the pack

Zanidip tablets are pink, circular, biconvex, film-coated tablets which are plain on both sides. They are available in blister packs of 30 tablets.

Manufacturer

Laboratoires BOUCHARA-RECORDATI,
92300 LEVALLOIS-PERRET, France

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder**:**
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