PACKAGE LEAFLET: INFORMATION FOR THE USER

Zanidip® 10 mg Film-coated Tablets
Zanidip® 20 mg Film-coated Tablets

lercanidipine hydrochloride
(Zanidip is also known as Lercanidipine HCl)

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.

What is in this leaflet:

1. WHAT ZANIDIP IS AND WHAT IT IS USED FOR

Zanidip belongs to a group of medicines called Calcium Channel Blockers (dihydropyridine derivatives). 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 AND TELL YOUR DOCTOR IF:
- You are allergic (hypersensitive) to lercanidipine hydrochloride or to any other ingredients of Zanidip tablets
- You have had allergic reactions to drugs closely related to Zanidip tablets (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
- You have severe liver or kidney problems
- 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)
- You are taking another drug called ciclosporin or cyclosporin (used after transplants to prevent organ rejection).

Do not take with grapefruit or grapefruit juice.

Do not use if you are pregnant or breastfeeding (see Pregnancy and Breastfeeding section for more information).

TAKE SPECIAL CARE WITH ZANIDIP AND TELL YOUR DOCTOR IF:
- You have certain other heart conditions which have not been treated by insertion of a pacemaker or have pre-existing angina
- You have problems with your liver or kidneys or you are on dialysis.

USING OTHER MEDICINES
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 800 mg, 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.

TAKING ZANIDIP WITH FOOD AND DRINK
- Patients should not consume alcohol during treatment with Zanidip tablets since it may increase the effect of Zanidip tablets.
- Patients should not take grapefruit or grapefruit juice.

PREGNANCY AND BREAST FEEDING
Do not use Zanidip if you are pregnant or breast-feeding, or you wish to become pregnant or if you are not using any contraceptive method.
If you are taking Zanidip and think that you may be pregnant, consult your doctor.

DRIVING AND USING MACHINES
Caution should be exercised because of the possibility of dizziness, weakness and tiredness. Do not drive or use machines until you know how Zanidip affects you**.**

INFORMATION ABOUT SOME INGREDIENTS OF ZANIDIP:
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

3. HOW TO TAKE ZANIDIP

Always take Zanidip exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults: The usual dose is one 10 mg film-coated tablet 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 20 mg film-coated tablet daily, if needed.
The tablets should preferably be swallowed whole with some water.

Elderly: 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.

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

If you have any further questions on the use of this product ask your doctor.

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.

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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zanidip can cause side effects, although not everybody gets them.

SERIOUS SIDE EFFECTS:
If you experience any of the side effects listed below tell your doctor straight away.

Rare *(affecting fewer than 1 in 1000 patients):* angina pectoris (chest pain due to lack of blood to your heart)

Very rare *(affecting fewer than 1 in 10,000 patients):* fall in blood pressure (which can cause light headedness or 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 fewer than 1 in 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 fewer than 1 in 1000 patients):* sleepiness, feeling sick, vomiting, heartburn, stomach pain, diarrhoea; skin rash, muscle pain, passage of large amounts of urine, tiredness.

Very rare *(affecting fewer than 1 in 10,000 patients):* swelling of the gums, changes in liver function (detected by blood tests), increase in the usual number of times one urinates.
Reporting of side effects
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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. 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.

Do not use Zanidip after the expiry date, which is stated on the label, carton and blister. The expiry date refers to the last day of that month.
Do not store above 25° C.
Store in the original package in order to protect from light and moisture. The original package should be kept in a dry place.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

WHAT ZANIDIP CONTAINS
The active substance is: lercanidipine hydrochloride 10 mg which is equivalent to 9.4 mg of lercanidipine or lercanidipine hydrochloride 20 mg which is equivalent to 18.8 mg of lercanidipine.
The other ingredients are:
Core tablet: lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone K30, magnesium stearate
Film coating: hypromellose, talc, titanium dioxide (E171), macrogol 6000, and ferric oxide (E172).

WHAT ZANIDIP LOOKS LIKE AND CONTENTS OF THE PACK
Zanidip 10 mg: yellow, circular, biconvex, film-coated tablet scored on one side.

Zanidip 20 mg: pink, circular, biconvex, film-coated tablet scored on one side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Pack size: ZANIDIP film-coated tablets are available in blister packs of 28, 30 or 50 tablets, contained in an outer cardboard carton.

MANUFACTURER:
Zanidip Film-coated Tablets are manufactured by RECORDATI Industria Chimica e Farmaceutica S.p.A. – Via Matteo Civitali I – 20148 Milan, Italy or BERLIN-CHEMIE AG, Glienicker Weg 125, D-12489 Berlin, Germany.

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