PACKAGE LEAFLET: INFORMATION FOR THE USER

Zanidip® 10mg film-coated tablets
Zanidip® 20mg 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.

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 this medicine (listed in section 6)
- If 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
- 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 (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 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 might take any other medicines
- 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 tubercolosis)
- 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
- 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, 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 if you are not using any contraceptive method.
Ask your doctor or pharmacist for advice before taking this medicine.

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

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

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 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.

Use in 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 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Zanidip can cause side effects, although not everybody gets them.

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

Rare *(may affect up to 1 in 1000 people):* angina pectoris (chest pain due to lack of blood to your heart)

Very rare *(may affect up to 1 in 10,000 people):* 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 *(may affect up to 1 in 100 people)*: headache, dizziness, faster heart beats, palpitations (heart pounding or racing), sudden reddening of the face, neck or upper chest, ankle swelling.

Rare *(may affect up to 1 in 1000 people):* sleepiness, feeling sick, vomiting, heartburn, stomach pain, diarrhoea; skin rash, muscle pain, passage of large amounts of urine, tiredness.

Very rare *(may affect up to 1 in 10,000 people):* 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2.
Tel: +353 1 6764971, Fax: +353 1 6762517.
Website: www.hpra.ie e-mail: medsafety@hpra.ie

5. HOW TO STORE ZANIDIP

Keep this medicine out of the sight and reach of children
Do not use this medicine after the expiry date, which is stated on the label, carton and on blister. The expiry date refers to the last day of that month.
Store in the original package in order to protect from light and moisture. Do not store above 25°C.
Do not throw away any medicines via wastewater of household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment

6. CONTENTS OF THE PACK AND OTHER INFORMATION
WHAT ZANIDIP CONTAINS
Each 10mg film-coated tablet contains 9.4mg of lercanidipine (present as lercanidipine hydrochloride 10mg) as the active ingredient.
Each tablet also contains the following other ingredients; lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone K30, magnesium stearate, hypromellose, talc, titanium dioxide (E171), macrogol 6000, ferric oxide (E172).

Each 20mg film-coated tablet contains 18.8mg of lercanidipine (present as lercanidipine hydrochloride 20mg) as the active ingredient.
Each tablet also contains the following other ingredients; lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone K30, magnesium stearate, hypromellose, talc, titanium dioxide (E171), macrogol 6000, ferric oxide (E172).

WHAT ZANIDIP LOOKS LIKE AND CONTENTS OF THE PACK
Zanidip 10mg film-coated tablets are yellow, circular, biconvex tablets, scored on one side and plain on the reverse.

Zanidip 20mg film-coated tablets are pink, circular, biconvex, scored on one side and plain on the other.

Zanidip 10mg & 20mg film-coated tablets are available in blister packs of 28 tablets.

Manufacturer
Manufactured by: RECORDATI Industria Chimica e Farmaceutica S.p.A – Via Matteo Civitali 1 – 20148 Milan, Italy.

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

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

PPA No: 1151/57/1-2

Leaflet issue and revision date: 06.11.17

Zanidip® is a registered trademark of Recordati Ireland Limited, Ireland.

Blind or partially sighted?
Is this leaflet hard to see or read?
Call +44 (0) 1302 365000 (Regulatory)

Please be ready to give the following information:
Product name:
Zanidip 10mg film-coated tablets 1151/57/1
Or
Zanidip 20mg film-coated tablets 1151/57/2