

Patient Information Leaflet

Zanidip® 10 mg tablets Zanidip® 20 mg 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.
- The name of this medicine is Zanidip® 10 mg tablets or Zanidip® 20 mg tablets but will be referred to as Zanidip throughout the remainder of this leaflet.

What is in this leaflet:

- 1) What Zanidip is and what it is used for
- 2) What you need to know before you take Zanidip
- 3) How to take Zanidip
- 4) Possible side effects
- 5) How to store Zanidip
- 6) Contents of the pack and other information

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 tablets.
- If you have had allergic reactions to drugs closely related to Zanidip tablets (such as amlodipine, nifedipine, 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 breast-feeding (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 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.

Zanidip with food, drink and alcohol

- Please do not consume alcohol during treatment with Zanidip tablets since it may increase the effect of Zanidip tablets.
- Please do not take Zanidip tablets 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

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 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, 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 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 20 mg 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 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 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

- **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 on the blister.
- Keep in the original package in order to protect from light.
- Do not use any damaged or discoloured tablets, return them to your pharmacist.
- 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.

Remember: this medicine has been prescribed for you. Do not give it to anyone else under any circumstances.

6) CONTENTS OF THE PACK AND OTHER INFORMATION

What ZANIDIP contains

Zanidip 10 mg: 1 tablet contains 10 mg of lercanidipine hydrochloride, which is equivalent to 9.4 mg of lercanidipine.

Zanidip 20 mg: 1 tablet contains 20 mg of lercanidipine hydrochloride, which is equivalent to 18.8 mg of lercanidipine.

The following ingredients are also included in Zanidip tablets, but they are not medicines: lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone K30, magnesium stearate, hypromellose, talc, titanium dioxide (E171), macrogol 6000, and ferric oxide (E172).

Contents of the pack

Zanidip 10mg tablets are available in blister packs of 25, 50 and 100 tablets.

Zanidip 20mg tablets are available in blister packs of 30 and 100 tablets.

Manufactured by
BERLIN-CHEMIE AG, D-12489 Berlin, Germany.

Procured from within the EU by the Product Licence holder:
MPT Pharma Ltd., Westgate Business Park, Unit 5-7 Tintagel Way,
Aldridge, Walsall, WS9 8ER, UK.

Repackaged by xxxxxxxxxxxxxx

Zanidip 10mg tablets: PL 33532/0089

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