PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

ZANIDIP 10 mg, each film-coated tablet contains 10 mg of lercanidipine hydrochloride

Contains sugar (lactose monohydrate): 30 mg per film-coated tablet

ZANIDIP 20 mg, each film-coated tablet contains 20 mg of lercanidipine hydrochloride

Contains sugar (lactose monohydrate): 60 mg per film-coated tablet

Read all of this leaflet carefully before you start taking ZANIDIP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ZANIDIP has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ZANIDIP is and what it is used for

ZANIDIP contains a medicine called lercanidipine hydrochloride.

Lercanidipine belongs to a group of medicines called calcium channel blockers (of the dihydropyridine group) which are used to treat high blood pressure.

ZANIDIP is used to treat high blood pressure, also known as hypertension

2. What you need to know before you take ZANIDIP

Do not take ZANIDIP:

- If you are hypersensitive (allergic) to lercanidipine hydrochloride or to any of the other ingredients of ZANIDIP (listed in section 6).
- If you are pregnant or breastfeeding, or you wish to become pregnant or do not use any contraceptive method.
- If you are suffering from certain heart diseases:
  - Obstruction to flow of blood from the heart.
  - Uncontrolled heart failure.
  - Unstable angina (angina at rest or progressively increasing).
  - Within one month of a heart attack.
- With grapefruit or grapefruit juice.
- If you have severe liver problems.
- If you have severe kidney problems or you are undergoing dialysis.
- ZANIDIP is not recommended for children under 18 years old.
- If you are taking medicines that are inhibitors of CYP3A4 isoenzyme:
  - Antifungal medicines (such as ketoconazole or itraconazole).
  - Macrolide antibiotics (such as erythromycin, or troleandomycin
  - Antivirals (such as ritonavir).
  - Antidepressants (such as fluoxetine).

- At the same time as another medicine called ciclosporin (used after transplants to prevent organ rejection).

Warnings and precautions

Take special care with ZANIDIP:

Also tell your doctor or pharmacist if you have any condition in the list below:

- Certain heart conditions, or if you have a pacemaker.
- Problems with your liver or kidney, or if you are on dialysis.
- If you have a heart problem such as left ventricular dysfunction or ischaemic heart disease.
- If you think you are (or might become) pregnant or if you are breastfeeding your baby (see Pregnancy and breastfeeding).
- If you are using medicines called CYP3A4 inducers, like anticonvulsants (e.g. phenytoin, carbamazepine) or a medicine to teat tuberculosis called rifampicin.

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially ‘sodium free’.

Children and adolescents

The safety and efficacy of ZANIDIP has not been established in children under the age of 18 years.

Other medicines and ZANIDIP

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if:

- You are taking medicines that are inhibitors of CYP3A4 isoenzyme (medicines that will increase the absorption of lercanidipine):
  - Antifungal medicines (such as ketoconazole or itraconazole).
  - Macrolide antibiotics (such as erythromycin, troleandomycin or clarithromycin).
  - Antivirals (ritonavir)
  - Antidepressants (such as fluoxetine)
- You are taking beta-blockers, diuretics or ACE-inhibitors (medicines to treat high blood pressure), although these may be safely taken with ZANIDIP.
- You are taking digoxin (a medicine to treat a heart problem).
- You are taking cimetidine (a medicine for ulcers, indigestion, or heartburn).
- You are taking midazolam (a medicine that helps you sleep).
- You are taking rifampicin (a medicine to treat tuberculosis).
- You are taking astemizole.
- You are taking terfenadine (a medicine for allergies).
- You are taking amiodarone or quinidine (medicines to treat a fast heartbeat).
- You are taking phenytoin or carbamazepine (medicines for epilepsy).
- You are taking medicines which lower the body's resistance to disease (such as ciclosporin).
- You are taking grapefruit or grapefruit juice.
- You are taking simvastatin (to lower your cholesterol)
- You are taking warfarin (to thin your blood).
- You are taking other medicines to control your blood pressure.

ZANIDIP with food, drink and alcohol

High fat meals significantly increase the blood levels of ZANIDIP. You must therefore take the tablet at least 15 minutes before a meal.

Alcohol can increase the effect of ZANIDIP; therefore, alcohol should be avoided.

ZANIDIP must not be taken with grapefruit or grapefruit juice as it can increase the hypotensive effect of the medicine.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

ZANIDIP should not be used during pregnancy and breastfeeding or by women who have the ability to become pregnant and who are not using any form of contraception.

Driving and using machines

ZANIDIP may cause sleepiness, dizziness, weakness or tiredness. Do not drive a car or operate machinery until you know how ZANIDIP affects you.

ZANIDIP contains lactose

ZANIDIP contains lactose. Patients with the rare hereditary conditions of lactose, fructose or galactose intolerance should not take ZANIDIP.

ZANIDIP contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take ZANIDIP

Do not share medicines prescribed for you with any other person.

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

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.

Your doctor will tell you how long your treatment with ZANIDIP will last.

If you have the impression that the effect of ZANIDIP is too strong or too weak, tell your doctor or pharmacist.

If you take more ZANIDIP than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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

you forget to take your tablet, take it as soon as you remember, unless it is almost time for your next dose. Do not take a double dose to make up for forgotten individual doses.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you stop taking ZANIDIP

If you stop taking ZANIDIP your blood pressure may increase again. Please consult your doctor before stopping the treatment.

4. Possible side effects

ZANIDIP can have side effects.

Not all side effects reported for ZANIDIP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZANIDIP, please consult your health care provider for advice.

If any of the following happens, stop taking / using ZANIDIP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ZANIDIP. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Common

- Headache,
- Fast heart rate (tachycardia),
- A sensation that the heart is racing (palpitations),
- Flushing,
- Swelling of the lower legs or hands (peripheral oedema).

Uncommon

- Dizziness,
- Low blood pressure (hypotension),

- Stomach pain,
- Indigestion
- Feeling sick (nausea)
- Rash, itching,
- Muscle pain (myalgia),
- Excessive urination,
- Weakness (asthenia),
- Tiredness (fatigue).

Rare

- Hypersensitivity,
- Excess sleepiness (somnolence),
- Fainting or a sudden temporary loss of consciousness (syncope),
- A type of chest pain caused by reduced blood flow to the heart (angina),
- Runny tummy,
- Being sick (vomiting),
- Hives,
- Frequent urination,
- Chest pain.

Not known

- Overgrowth of gum tissue,
- Peritoneal cloudy effluent,
- Elevated liver enzymes,
- Painless swelling under the skin (angioedema),

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you/your child get/s side effects, talk to your/your child's doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Acino Pharma via email on drugsafety_ZA@acino.swiss. By reporting side effects, you can help provide more information on the safety of ZANIDIP.

5. How to store ZANIDIP

Store all medicines out of reach of children.

- Store at or below 25 °C. Protect from light.
- Keep the blisters in the outer carton until you require it.
- Do not use the tablets after the expiry date printed on the carton and blister strips.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ZANIDIP contains

- The active substance is lercanidipine hydrochloride.
- The other ingredients are ferric oxide (E172), hypromellose, lactose monohydrate, macrogol 6000, magnesium stearate, microcrystalline cellulose, povidone K30, sodium starch glycolate, talc, titanium dioxide (E171).

What ZANIDIP looks like and contents of the pack

ZANIDIP 10: Yellow, circular, biconvex film-coated tablets, scored on one side.

ZANIDIP 20: Pink, circular, biconvex film-coated tablets, scored on one side.

Aluminium / opaque PVC blisters.

Packs of 14, 28, 35, 50 and 100 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Acino Pharma (Pty) Ltd

106 16th Road

Midrand

This leaflet was last revised in

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Registration numbers

ZANIDIP 10: 33/7.1/0113

ZANIDIP 20: A40/7.1/0106

Access to the corresponding Professional Information

TBC

Registration No.:
Namibia NS3
Zanidip 10: 06/7.1/0169
Zanidip 20: 06/7.1/0001