PROPOSED CLEAN PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

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

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

Please read this leaflet carefully before you start taking ZANIDIP tablets.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **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 ZANIDIP CONTAINS

The active substance is lercanidipine hydrochloride

The inactive ingredients are ferric oxide (E172), hypromellose, lactose monohydrate, macrogol 6000, magnesium stearate, microcrystalline cellulose, povidone K30, sodium starch glycolate, talc, titanium dioxide (E171).

Contains sugar: lactose

ZANIDIP IS USED FOR

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.

BEFORE YOU TAKE ZANIDIP

Do not take ZANIDIP:

- If you are hypersensitive (allergic) to **Zanidip** or any of the other ingredients of **Zanidip**.
- If you have had allergic reactions to medicines closely related to **Zanidip** tablets (such as amlodipine, nicardipine, felodipine, isradipine nifedipine or lacidipine).
- 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:
  - Uncontrolled cardiac failure.
  - Obstruction to flow of blood from the heart.
  - Unstable angina (angina at rest or progressively increasing).
  - Within one month of heart attack.
- With grapefruit or grapefruit juice.
- If you have severe liver or kidney problems.

Zanidip is not recommended for children under 18 years old.

You should not take **Zanidip** tablets

- 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 cyclosporin used after transplants to prevent organ rejection).

Take special care with ZANIDIP

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

- Certain other heart conditions, or if you have a pacemaker.
- Problems with your liver or kidney, or you are on dialysis.

Taking ZANIDIP with food or drink

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

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

You must not use **Zanidip** if you are pregnant or breastfeeding.

Driving and using machinery

Zanidip may cause sleepiness and tiredness. Do not drive a car or operate machinery until you know how **Zanidip** affects you.

Important information about some of the ingredients of Zanidip.

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

Using other medicines with ZANIDIP

Always tell your healthcare professional if you are taking any other medicine. (This includes 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 or troleandomycin).
  - Antivirals (such as 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 heart beat).
- You are taking phenytoin or carbamazepine (medicines for epilepsy).
- You are taking medicines which lower the body's resistance to disease (such as cyclosporin).
- You are taking grapefruit or grapefruit juice.

Drinking alcohol during your treatment with **Zanidip** tablets may increase the effect of **Zanidip** tablets, you are therefore advised to cut out or strictly limit your consumption of alcoholic drinks.

HOW TO USE ZANIDIP

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

Always take **Zanidip** exactly as your doctor has instructed you. **Do not exceed the prescribed dose.** You should check with your doctor if you are unsure.

The usual dose is one **Zanidip** 10 mg film-coated tablet daily at the same time each day, preferably in the morning at least 15 minutes before breakfast. 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.

If you have the impression that the effect of **Zanidip** is too strong or too weak, talk to 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 control 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

Take your normal dose immediately and continue as prescribed the next day. If you forget to take your tablet, take it as soon as you remember, unless it is almost time for your next dose. Then go on as before. 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.

POSSIBLE SIDE EFFECTS

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

You may experience flushing, swelling of the ankles or legs, palpitations, headache, dizziness, weakness.

Sometimes you may get gastrointestinal disturbances such as heartburn, nausea, vomiting, pain in the area above your stomach and diarrhoea, increase in urinary volume or frequency, rash, tiredness, sleepiness, muscle pain. Low blood pressure may rarely occur (you may feel dizzy).

Other medicines of the dihydropyridine group have been reported on rare occasions to cause thickening of the gums. In patients with angina, these medicines have been reported to increase the frequency of severity of angina. If you experience any of these problems with **Zanidip**, please tell your doctor immediately.

STORING AND DISPOSING OF ZANIDIP

- Store at or below 25 ºC. Protect from light.
- Keep the blisters in the outer carton until you require it.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN
- 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 and sewerage systems (e.g. toilets)

PRESENTATION OF ZANIDIP

Zanidip 10 is available in blister packs of 14, 28, 35, 50 and 100 tablets.

Zanidip 20 is available in blister packs of 28 tablets.

IDENTIFICATION OF ZANIDIP

Zanidip 10 is a yellow, round scored film-coated tablet.

Zanidip 20 is a pink, round, biconvex film-coated tablet, scored on one side.

REGISTRATION NUMBERS

Zanidip 10: 33/7.1/0113

Zanidip 20: A40/7.1/0106

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Litha Pharma (Pty) Ltd

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DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Date of registration: 2 April 2004 (10 mg); 1 December 2006 (20 mg)

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