PROPOSED PATIENT INFORMATION LEAFLET

Information for the Patient about

CIPALAT RETARD TABLETS

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

CIPALAT RETARD containing 20 mg **nifedipine** (Tablets)

Read all of this leaflet carefully before you start taking **CIPALAT RETARD**:

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

The active ingredient of **CIPALAT RETARD** is nifedipine.

Each **CIPALAT RETARD** tablet contains 20 mg nifedipine.

Inactive ingredients are colloidal silicon, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, polysorbate 80, povidone,

Film coating ingredients are ferric oxide red, hypromellose, propylene glycol and purified talc.

WHAT IS CIPALAT RETARD USED FOR

CIPALAT RETARD is a medicine used to treat high blood pressure and certain types of coronary heart diseases:

- Chronic stable angina pectoris (chest pain)
- Mild to moderate hypertension (high blood pressure)

BEFORE YOU TAKE CIPALAT RETARD

Do NOT take CIPALAT RETARD

- If you are allergic (hypersensitive) to nifedipine or any other ingredients of **CIPALAT RETARD**.
- If you suffer from low blood pressure.
- If you have narrowing of the gastrointestinal tract or oesophagus.
- If you have inflammatory bowel disease which has symptoms such as diarrhea, fever and fatigue, abdominal pain, blood in your stool, reduced appetite, and unintended weight loss.
- If you are taking rifampicin (an antibiotic).
- If you have you have liver or kidney function impairment.
- If you are pregnant or feeding your baby.
- If you have been diagnosed with porphyria.

- Do not give **CIPALAT RETARD** to children.

Take special care with CIPALAT RETARD:

- If you have been diagnosed with malignant hypertension (blood pressure that continues to rise despite treatment) and irreversible kidney failure and you are a dialysis patient.
- Inform your doctor if you have impaired liver function so that careful monitoring and dose reduction can be made if necessary.
- Inform your doctor if you are a diabetic before taking **CIPALAT RETARD** as it may modify insulin and blood sugar responses because **CIPALAT RETARD** may lead to damaged kidneys.
- Pains in joints and lack of sleep may also occur.
- If you experience a steal taste in our mouth you should stop taking nifedipine.
- An increase in blood sugar levels has been observed.
- If you have been diagnosed with Kock pouch (a surgically constructed intestinal reservoir with an opening through the abdominal wall) (ileostomy after proctolectomy).
- **CIPALAT RETARD** may interfere with the results of a barium contrast X-Ray.

Taking CIPALAT RETARD with food and drink:

- Do NOT take **CIPALAT RETARD** together with grape juice as it inhibits the metabolism of **CIPALAT RETARD.** This will decrease the effect of **CIPALAT RETARD** to decrease blood pressure. If you take grape fruit regularly, wait three days before you can take **CIPALAT RETARD.**

Pregnancy and Breastfeeding:

- Do not take **CIPALAT RETARD** if you are pregnant before week 20. Nifedipine passes into breast milk.

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

Driving and using machinery:

- **CIPALAT RETARD** may make you feel drowsy/sleepy especially at the start of treatment.
- Do not drive because **CIPALAT RETARD** could interfere with your ability to drive safely.
- Do not operate any tools or machines while taking **CIPALAT RETARD** until you know how it affects you.

Important information about some of the ingredients of CIPALAT RETARD:

- **CIPALAT RETARD** contains lactose monohydrate, take special precautions if you are intolerant to any of the ingredients.
- Do not take **CIPALAT RETARD** with alcohol as it inhibits the metabolism of nifedipine.

Taking other medicines with CIPALAT RETARD:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines)

Please inform your doctor if you are taking any of the following medicines, as you may require a reduction in dose or special precautions:

- *Rifampicin* (an antibiotic): do not take rifampicin together with **CIPALAT RETARD** as it enhances the cytochrome P450 enzyme and may lead to reduced nifedipine levels in the blood.
- *Non-steroidal anti-inflammatory drugs* (medicines that are known to treat pain, fever and inflammation)*:* take special precautions when taking non-steroidal anti-inflammatory drugs especially *indomethacin* (Pain killer) with **CIPALAT RETARD** as it may enhance their ability to reduce high blood pressure.
- *Anaesthetics*: Before receiving anaethetics please tell your doctor that you are taking **CIPALAT RETARD** as it may cause low blood pressure.

- *Erythromycin* (an antibiotic) increases the concentration of **CIPALAT RETARD** in the blood when taken with other medicines.
- The following medicines may lead to increased blood concentrations of **CIPALAT RETARD,** tell your doctor if you are taking them because your blood pressure should be closely monitored and dose reduction considered:
    - *Amprenavir, Indinavir, Nelfinavir, Ritonavir, Saquinavir* (to treat HIV)
    - *Ketoconazole, Itraconazole, Fluconazole* (anti-fungal medicines)
    - *Fluoxetine, Nefazodone* (to treat depression)
    - *Quinupristin/Dalfopristin* (combination anti-biotic)
    - *Valproic acid* (to treat epilepsy)
    - *Cimetidine* (to treat stomach ulcers)
    - *Cisapride* (to treat reduced movements of gullet and stomach)
- *Alcohol* inhibits the metabolism of nifedipine and thus should not be taken together.
- *Calcium supplements* may reduce effect of **CIPALAT RETARD**. Please discuss this with your doctor.
- When *phenytoin, carbamazepine* (to treat epilepsy) and *phenobarbitone* (to treat insomnia) are taken together with **CIPALAT RETARD** may result in reduced concentrations of **CIPALAT RETARD** in the blood and thus lowered effectiveness, there might be a need to increase the dose of **CIPALAT RETARD**.

Inform you doctor before taking the following medicines as **CIPLAT RETARD** may increase the blood pressure lowering effect.

- diuretics (water tablets e.g hydrochlorothiazide)
- β-blockers (e.g propranolol, bisoprolol)
- ACE-inhibitors (e.g enatapril, lisinopril)
- AT-antagonists/Angiotensin 1 receptor blockers (e.g losartan, valsartan)
- other calcium antagonists (e.g amlodipine)
- α-adrenergic blocking agents (e.g doxazosin)
- PDE5 inhibitors (e.g sildenafil, tadalafil)
- α-methyldopa (e.g hypotone)

HOW TO TAKE CIPALAT RETARD

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

Always take CIPALAT RETARD exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Take **CIPALAT RETARD** twice a day as recommended by your doctor.

Take your tablets with fluid before meals do not take with grape juice or alcohol.

The usual dose is 20 to 40 mg twice per day.

Your doctor will tell you how long your treatment will last. If you have an impression that **CIPALAT RETARD** is too strong or too weak, tell your doctor or pharmacist.

If you take more CIPALAT RETARD than you should

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

If you experience an abnormally fast or slow heart rate and lowering of blood pressure of which symptoms are flushing, headaches, dizziness or lightheadedness, unsteadiness and fainting, inform your doctor immediately.

If you forget to take CIPALAT RETARD more than you should

Do not take double dose to make up for forgotten individual doses.

Effects when treatment with CIPALAT RETARD is stopped

Sudden withdrawal of nifedipine might be associated with severe angina (chest pain).

POSSIBLE SIDE EFFECTS

CIPALAT RETARD can have side effects.

Not all side effects reported for CIPALAT RETARD are included in this leaflet. Should your general health worsen or if you experience any

untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens stop taking **CIPALAT RETARD** and tell your doctor immediately, or go to the casualty department at your nearest hospital:

- Those that are frequent involve:
    - Flushing, abnormally low blood pressure, peripheral oedema (accumulation of fluid causing swelling).
    - Jaundice (yellowing of the skin or eyes) any skin rash with blister formation and photosensitivity reddish spots on the skin.
    - Allergic reaction, weakness, a feeling of warmth
    - A sense of whirling and loss of balance.
- Those that are less frequent involve:
    - A superficial reddening of the skin, severe itching of the skin.
    - An increase in the size of gums and rash.
- Those for which frequency is unknown:
    - Difficulty in swallowing.

These are all very serious side effects. If you have them you may have a serious allergic reaction to **CIPALAT RETARD.** You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Those that occur less frequently are:
    - Anxiety reactions and abnormal rapid heart rate.
    - Tremor, impairment of any sense especially of the sense of touch, visual disturbances, palpitations, nose bleeding, blocked nose and difficulty in breathing.
    - Muscle cramps and joint swelling, excessive urination, painful or difficult urination.
    - Erectile dysfunction.
- Those for which frequency is unknown:
    - Agranulocytosis which is a condition associated with sudden fever, sore throat, weakness in your limbs, sore mouth and gums, mouth ulcers and bleeding gums.
    - Chest pain.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice the following:

- Those that are frequent involve:
    - Headache and constipation.
- Those that are less frequent involve:
    - Tiredness
    - Sleep disorders and migraine
    - Stomach pain, nausea, indigestion, accumulation of gas, vomiting and dry mouth

- Feeling unwell, unspecific pain and chills.

- Those for which frequency is unknown:
    - Eye pain, blurred vision and mental depression
    - Joint and muscle pain.
    - Intestinal obstruction, intestinal ulcer, vomiting

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

STORING AND DISPOSING OF CIPALAT RETARD

Store all medicines out of reach of children.

Store at or below 30 ˚C.

Do not refrigerate.

Store in the original package

Protect from light/ Moisture

PRESENTATION OF CIPALAT RETARD

CIPALAT RETARD tablets are available in blister strips of 10 tablets in packs of 60 and 120 tablets.

IDENTIFICATION OF CIPALAT RETARD

Brown, circular, biconvex film-coated tablets.

REGISTRATION NUMBER

32/7.1.4/0660

NAME AND ADDRESS OF REGISTRATION HOLDER

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