Applicant/PHRC: ***Hetero Drugs South Africa (Pty) Ltd***

*Product proprietary name****: NIDEXIF 10 mg & 20 mg***

Dosage form and strength: ***Each film coated tablet contains lercanidipine hydrochloride (as hemihydrate) 10 mg and 20 mg***

APPROVED PATIENT INFORMATION LEAFLET FOR NIDEXIF

SCHEDULING STATUS

S3

NIDEXIF 10 mg film-coated tablets

NIDEXIF 20 mg film-coated tablets

Each film-coated tablets contains 10 mg of lercanidipine hydrochloride (as hemihydrate)

Each film-coated tablets contains 20 mg of lercanidipine hydrochloride (as hemihydrate)

Contains sugar “lactose monohydrate”

Each 10 mg film-coated tablets contains 29,861 mg of lactose monohydrate

Each 20 mg film-coated tablets contains 59,722 mg of lactose monohydrate

Read all of this leaflet carefully before you start taking NIDEXIF

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- NIDEXIF 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 NIDEXIF is and what it is used for

The active substance is 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. NIDEXIF is used to treat high blood pressure, also known as hypertension.

2.What you need to know before you NIDEXIF

Do not take NIDEXIF:

- If you are hypersensitive (allergic) to lercanidipine hydrochloride or any of the other ingredients of NIDEXIF (listed in section 6).
- If you are suffering from certain heart diseases:
- obstruction to flow of blood from the heart.
- untreated heart failure.
- unstable angina (chest discomfort occurring at rest or progressively increasing)
- within one month of heart attack
- With grapefruit or grapefruit juice.
- If you have severe liver or kidney problems - you are undergoing dialysis.
- If you are taking medicines that are inhibitors of the hepatic metabolism, such as:
- antifungal medicines (such as ketoconazole or itraconazole)
- macrolide antibiotics (such as erythromycin, troleandomycin or clarithromycin)
- antivirals (such as ritonavir).
- antidepressants (such as fluoxetine)
- If you are taking another medicine called ciclosporin or cyclosporin (used after transplants to prevent organ rejection).

Warnings and precautions

Take special care with NIDEXIF

- Certain other heart conditions, or if you have a pacemaker.
- Problems with your liver or kidney, or you are 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 Lercanidipine HCl in children aged up to 18 years have not been established.

Other medicines and NIDEXIF

Always tell your health care provider 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 NIDEXIF
- 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 or terfenadine (medicines for allergies).
- You are taking amiodarone, quinidine or sotalol (medicines to treat a fast heart beat).
- You are taking phenytoin, phenobarbitone 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.
- Simvastatin (a medicine to lower cholesterol in your blood)

NIDEXIF with food, drink and alcohol

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

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, 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.

You must not use NIDEXIF if you are pregnant or breastfeeding.

Driving and using machines

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

It is not always possible to predict to what extent NIDEXIF may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which NIDEXIF affects them.

NIDEXIF contains lactose

If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking NIDEXIF.

3. How to take NIDEXIF

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

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

The usual dose is one NIDEXIF 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 NIDEXIF 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 NIDEXIF is too strong or too weak, talk to your doctor or pharmacist.

If you take more NIDEXIF 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 NIDEXIF

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

4. Possible side effects

NIDEXIF can have side effects.

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

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

- 'swelling of the ankles or legs, face, lip, tongue, or throat, 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 NIDEXIF. 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:

- chest pain,
- angina
- changes in the way your heart beats, for example, if you notice it beating faster.
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Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache,
- fast heart rate
- feeling of fast or uneven heartbeat (palpitations)

Less frequent side effects:

- dizziness
- low blood pressure
- heartburn
- feeling sick
- stomach pain
- muscle pain

- passing large amounts of urine
- feeling weak or feeling tired
- sleepiness
- vomiting
- diarrhoea
- hives
- increase in the usual number of times one urinates
- changes in liver function
- cloudy fluid

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. 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 the Holder of certificate of registration through the mail: pvg.cdma@hererodrugs.com By reporting side effects, you can help provide more information on the safety of NIDEXIF.

5. How to store NIDEXIF

Store all medicines out of reach of children.

Store at or below 25 °C

Store in the original package.

Protect from light/ moisture.

Do not use after the expiry date stated on the label.

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 NIDEXIF contains

The active substance is lercanidipine hydrochloride.

The other ingredients are:

- Lactose monohydrate
- Cellulose microcrystalline
- Sodium starch glycolate
- Povidone (k-30)

Composition of Opadry II yellow 85F520410

- Polyvinyl alcohol-part hydrolyzed E1203
- Titanium dioxide E171
- Macrogol/PEG E1521
- Talc E553b
- Iron oxide yellow E172
- Iron oxide red E172

Composition of Opadry II pink 85F540460

- Polyvinyl alcohol-part hydrolyzed E1203
- Titanium dioxide E171
- Macrogol/PEG E1521
- Talc E553b
- Iron oxide red E172

What NIDEXIF looks like and contents of the pack

Yellow, film coated, round shaped, biconvex tablets debossed with “3” and “4” on either side of score line on one side of the tablet and “HL” on the other side.

10 x 10's Aclar-Alu Blister

White opaque 250 µ PVC/102 µ Aclar film with 0,025 mm Plain aluminium foil (Hard Tampered) with 7GSM HSL coating on bright side

9 x 10's Alu-Alu Blister

Form pack film with Desiccant with 20 µ Plain aluminum foils with 15GSM PE coating on bright side width 148 mm (sealable to form pack film with desiccant).

500's simulated Bulk Pack

Clear 100 µ poly bag 9 x 12 inches with triple laminated bag (9"x12") with silica gel sachet 5 gram

Holder of Certificate of Registration

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Registration numbers

NIDEXIF 10 mg: 57/7.1/0045.043

NIDEXIF 20 mg: 57/7.1/0046.044

Access to the corresponding Professional Information

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