AUROBINDO

1.3.2 Patient Information Leaflet (approved copy)

SCHEDULING STATUS

S4

PATIENT INFORMATION LEAFLET

NURADAR 600 mg (film-coated tablet)

Darunavir

Sugar free

Read all of this leaflet carefully before you start taking NURADAR.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.
- NURADAR 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 NURADAR is and what it is used for
2. What you need to know before you use NURADAR
3. How to use NURADAR
4. Possible side effects
5. How to store NURADAR
6. Contents of the pack and other information

1. What NURADAR is and what it is used for

NURADAR is an anti-retroviral medicine (ARV). It belongs to a group called protease inhibitors.

NURADAR is used in combination with ritonavir and other antiretroviral medicines for the treatment of HIV infection in adults especially for those who are resistant to more than one ARV medicine.

2. What you need to know before you take NURADAR

Do not take NURADAR:

- If you have ever had an allergic reaction to darunavir or any ingredients of the NURADAR (listed in section 6).
- If you have severe liver problems.
- If you are allergic (hypersensitive) to ritonavir.
- If you are taking a combined medicine containing lopinavir/ ritonavir.

Do not combine NURADAR with any of the following medicines:

- medicines to treat convulsions (epilepsy) (carbamazepine, phenobarbitone or phenytoin).
- medicines to treat allergy symptoms (astemizole or terfenadine).
- medicines to treat tuberculosis (rifampicin and rifabutin).
- medicines to treat high blood pressure as a result of problems with your lungs (sildenafil and bosentan)
- medicines to treat gout (colchicine)
- medicines used to treat hepatitis C (boceprevir, telaprevir, elbasvir,/ grazoprevir)
- medicines to treat prostate problems (alfuzosin).

- medicines to treat migraine and headaches (dihydroergotamine, ergonovine, ergotamine, methylergonovine).
- herbal products containing St. John's Wort (e.g. for depression).
- medicines to treat high cholesterol (lovastatin or simvastatin).
- medicines to treat psychiatric conditions such as schizophrenia (pimozide, lurasidone, quetiapine, sertindole).
- medicines to treat trouble with sleeping and/or anxiety (midazolam or triazolam).
- medicines to treat fungal infections (ketoconazole, itraconazole and voriconazole).
- medicines to treat narcotic dependence (buprenorphine/naloxone).
- medicines to treat stomach conditions (cisparide, domperidone)
- medicnes used to treat heart problems (amiodarone, bepridil, dronedarone, ivabradine, quinidine, ranolazine)
- medicines used to treat deep vein thrombosis (dabigatran)
- medicines used to prevent blood clots forming (ticagrelor)
- medicines used to treat premature ejaculation (dapoxetine)
- medicines used to treat constipation as a result of taking pain tablets (naloxegol)
- medicines used to treat erectile dysfunction (avanafil).

If you are taking any of these, ask your doctor about switching to another medicine, before you take NURADAR.

Warnings and Precautions

Take special care with NURADAR

- NURADAR must be taken together with another anti-HIV medicine called ritonavir and food. You should not alter your dose of either NURADAR or ritonavir,

discontinue ritonavir, or discontinue therapy with NURADAR without consulting your doctor.

- NURADAR is not a cure for HIV infection. NURADAR does not reduce the risk of passing HIV to others through sexual contact or blood contaminations. Therefore, you must continue to take appropriate precautions (practise safe sex, use condoms) and do not use or share dirty needles.
- People taking NURADAR may still develop infections or other illnesses associated with HIV infection. You must keep in regular contact with your doctor.
- Tell your doctor if you have an allergy towards sulpha medicines.
- Discontinue using NURADAR and tell your doctor if you develop a severe skin reaction that is accompanied by fever, fatigue, muscle or joint ache, oral lesions and a general feeling of being unwell.
- Tell your doctor if you are taking another anti-HIV medicine called Efavirenz. Your dosage of NURADAR and ritonavir may need to change.
- Tell your doctor if you are taking any oestrogen based contraceptives
- Tell your doctor if you have had problems with your liver before. Your doctor may evaluate how severe your liver disease is before deciding if you can take NURADAR.
- Tell your doctor if you have diabetes. Anti-HIV medicines such as NURADAR may increase sugar levels in the blood.
- Tell your doctor immediately if you notice any symptoms of infection.
- In some patients with advanced HIV and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started.

- Tell your doctor if you notice changes in body fat. Redistribution, accumulation or loss of body fat may occur in patients receiving a combination of antiretroviral medicines.
- Tell your doctor if you have haemophilia (bleeding disease). Anti-HIV medicines, such as NURADAR, may increase the risk of bleeding.

Other medicines and NURADAR:

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

There are some medicines that you must not combine with NURADAR. These are mentioned above under the heading “Do not take NURADAR with any of the following medicines.”

Tell your doctor if you take other anti-HIV medicines. NURADAR can be combined with some other anti-HIV medicines while other combinations are not recommended.

The effects of NURADAR might be reduced if you take any of the following products. Tell your doctor if you take:

- medicines to treat some infections such as tuberculosis (rifampicin)
- products that contain St John’s wort (hypericum perforatum)
- medicines to prevent seizures (phenobarbital, phenytoin, carbamazepine)
- steroids (dexamethasone).

The effects of other medicines might be influenced if you take NURADAR. Tell your doctor if you take:

- medicines for heart disease or high blood pressure (amiodarone, bepridil, felodipine,

lignocaine, nifedipine, nicardipine, quinidine and digoxin, bosentan).

- medicines used to reduce clotting of the blood (warfarin).
- hormonal contraceptives. NURADAR might reduce the effectiveness of hormonal contraceptives. You must combine hormonal contraceptives with other birth control methods such as a condom.
- medicines to lower cholesterol levels (e.g. simvastatin, lovastatin, pravastatin). The risk of muscle tissue disorder might be increased.
- medicines for your immune system (cyclosporin, tacrolimus, sirolimus). Your doctor might want to do some additional tests.
- medicines to control asthma (fluticasone propionate and salmeterol).

The dosage of other medicines might need to be changed. Tell your doctor if you take:

- medicines against fungal infections (ketoconazole, itraconazole, voriconazole)
- medicines against bacterial infections (rifabutin)
- medicines for erectile dysfunction (sildenafil, vardenafil, tadalafil)
- antibiotics (clarithromycin)
- medicines to treat depression and anxiety (paroxetine, sertraline, trazodone)
- methadone
- gout (colchicine)

NURADAR with food, drink and alcohol

NURADAR does not interact with food or drink but it should be taken with food (see 'How to take NURADAR below).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking NURADAR.
You should not take NURADAR when you are pregnant. You should not breastfeed your baby while taking NURADAR.
Driving and using machines NURADAR may make you feel dizzy. Do not operate machines or drive until you know how NURADAR affects you.
3. How to take NURADAR
Always take NURADAR exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.
NURADAR must be taken with food and drink NURADAR must be taken with 100 mg of ritonavir. The recommended dosage of NURADAR is 600 mg twice daily taken with ritonavir 100 mg twice daily and with food. NURADAR cannot work properly without ritonavir and food. You must eat a meal or a snack 30 minutes before you take NURADAR and ritonavir. The type of food is not important. Your doctor will tell you how long your treatment with NURADAR will last. Do not stop treatment early. Even if you feel better, do not stop taking NURADAR without talking to your doctor. If you have the impression that the effect of NURADAR is too strong or weak, tell your doctor or pharmacist.
If you take more NURADAR than you should

In the event of over dosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison control centre. Take the medicine with you.

If you forget to take NURADAR

If you notice within 6 hours, you must take the tablets immediately. Always take with ritonavir and food. If you notice after 6 hours, then take the next doses as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking NURADAR

Therapy with NURADAR and ritonavir should not be stopped without consulting your doctor.

NURADAR causes increases in your blood glucose or worsening of diabetes (see 'Possible side effects' below) and this can persist when treatment with NURADAR is stopped.

4. Possible side effects

NURADAR can have side effects.

Not all side effects reported for NURADAR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NURADAR, please consult your doctor, pharmacist or other healthcare professional for advice.

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

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

- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to NURADAR. 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:

- Severe abdominal pain which may be an indication that you are suffering from inflammation of your pancreas or liver.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- diarrhoea,
- headache,
- abdominal pain,
- nausea,
- fatigue
- gas,
- vomiting,
- uneven distribution of fat on your body,
- muscle pain,
- development of breasts in males,
- bloated stomach,
- increases in your blood glucose or worsening of diabetes
- loss of appetite,

- difficulty digesting food,
- abnormal loss of strength,
- increase in blood cholesterol,
- difficulty sleeping,
- weight loss,
- pins and needles sensation,
- dizziness,
- liver problems characterised by an increase in liver enzymes,
- breaking/ fracturing of your bones easily,

Less frequent side effects:

- abnormal dreams,
- worsening of pre-existing infectious conditions,
- herpes simplex,
- blood disorders such as a decrease in various white blood cells
- decrease in thyroid hormone , increase in blood thyroid stimulating hormone,
- gout,
- decreased appetite,
- increased weight,
- insulin resistance,
- excessive thirst,
- depression and anxiety, disorientation, increased nightmares,
- confusion, mood changes, restlessness,
- lack of energy,

- reduced sense of touch or sensation,
- memory impairment, disturbance in attention,
- excessive sleepiness,
- convulsion,
- dry eyes, visual disturbances, dilation and redness of the eye vessels,
- heart disorders such as chest pain, irregular heartbeat, heart attack,
- cough,
- nosebleeds, throat irritation,
- excessive runny nose,
- inflammation of the pancreas,
- inflammation of the stomach,
- acid reflux,
- retching,
- constipation,
- dry mouth and lips and coated tongue,
- sores inside the mouth, inflammation of the lips,
- blood in your vomit,
- liver problems: inflammation of the liver, increase in liver enzymes,
- excessive sweating,
- night sweats,
- hair loss,
- dry skin
- nail pigmentation
- acne,

- muscle spasms, muscle weakness,
- joint pain,
- weak bones,
- muscle tissue damage,
- kidney failure, protein in the urine,
- painful or difficult urination, increase in urination during the day and night,
- formation of kidney stones,
- erectile dysfunction,
- fever,
- peripheral edema (accumulation of fluid in tissues , causing swelling),
- irritability,
- feeling hot,
- pain,
- feeling unwell

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. This includes any possible side effects not listed in this leaflet. You can also report side effects via https://www.sahpra.org.za/documents/86422f1b6.04_ARF1_Jul16_v4.pdf. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store NURADAR

Store at or below 25 °C.

Keep HDPE containers tightly close.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

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 NURADAR contains

The active substance is darunavir.

Each film-coated tablet contains 600 mg of darunavir.

The other ingredients of NURADAR are cellulose microcrystalline, crospovidone, hydroxypropyl cellulose, magnesium stearate and silica colloidal anhydrous.

In addition NURADAR 600 mg contains Opadry® II complete film coating system White 85F18422.

What NURADAR looks like and contents of the pack

NURADAR 600 mg:

White to off white, oval shaped, biconvex, film-coated tablets debossed with ‘D’ on one side and ‘600’ on another side.

NURADAR 600 mg:

Tablets are packed in white opaque round 100 ml HDPE container with 38 mm neck finish closed with white opaque polypropylene 38 mm - SP 400 child resistant closure with wad having TEKNIPLEX HS 123 induction sealing liner.

Pack size: 30’s - One HDPE container contains 30 tablets.

HOLDER OF THE CERTIFICATE OF REGISTRATION

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