

Applicant/ PHCR:	Hetero Drugs South Africa (Pty) Ltd	MODULE 1 1.3.2
Product Proprietary Name:	DUNARID 400/800	
Dosage Form and Strength	Each film-coated tablet contains 400/800 mg of Darunavir	

CLEAN PATIENT INFORMATION LEAFLET FOR DUNARID 400/800

SCHEDULING STATUS: [S4]

DUNARID 400 & 800 mg (film-coated tablets)

Each film-coated tablet contains 400 & 800 mg of Darunavir

Sugar free

Read all of this leaflet carefully before you take DUNARID

- 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.
- **DUNARID** 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 **DUNARID** is and what it is used for.
2. What you need to know before you use **DUNARID**.
3. How to use **DUNARID**.
4. Possible side effects.
5. How to store **DUNARID**
6. Contents of the pack and other information

1. **What DUNARID is and what it is used for:**

DUNARID is an antiretroviral medicine. It belongs to a group called protease inhibitors. **DUNARID**

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works by reducing the amount of Human Immunodeficiency Virus (HIV) in your body. This will improve your immune system and reduce the risk of developing illnesses linked to HIV infection.

DUNARID is used in combination with ritonavir and other antiretroviral medicines to treat adults who are infected by HIV and who have developed resistance to other antiretroviral medicines. Your doctor will discuss with you on which combination of medicines is best for you.

2. What you need to know before you use **DUNARID**:

Do not take **DUNARID**:

- if you are hypersensitive (allergic) to darunavir or any of the other ingredients of **DUNARID** (listed in section 6).
- if you have severe liver problems. Ask your doctor if you are unsure about the severity of your liver disease. Some additional tests might be necessary.

Warnings and precautions

Tell your doctor or health care provider before you take **DUNARID**.

Special care should be taken with **DUNARID**:

DUNARID must be taken together with ritonavir and food. **DUNARID** is not a cure for HIV infection.

DUNARID does not reduce the risk of passing HIV to others through sexual contact or blood contaminations. Therefore, you must continue to use appropriate precautions, such as condoms.

People taking **DUNARID** may still develop infections or other illnesses associated with HIV infection. You must keep in regular contact with your doctor.

Contact your doctor immediately if the following is experienced:

- severe rash
- sulphonamide (antimicrobial used to treat certain infections) allergy.

Make sure that you check the following points and tell your doctor if any of these apply to you.

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- 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 **DUNARID**.
- Tell your doctor if you have diabetes. Anti-HIV medicines such as **DUNARID** 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 **DUNARID**, may increase the risk of bleeding.
- Tell your doctor if you experience joint aches and pain, joint stiffness or difficulty in movement.
- Tell your doctor if you are allergic to sulpha medicines.

Children and adolescents:

The **DUNARID** tablet is not for use in children younger than 3 years of age or weighing less than 40 kilograms.

Other medicines and DUNARID:

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

There are some medicines that you must not combine with **DUNARID**. These are mentioned above under the heading "Do not take **DUNARID** with any of the following medicines".

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

Tell your doctor if you take:

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- medicines to treat convulsions (epilepsy) (phenobarbitone or phenytoin)
- medicines to treat allergy symptoms (astemizole)
- medicines to treat tuberculosis (rifampicin, rifabutin)
- medicines to treat high blood pressure as a result of problems with your lungs (sildenafil, bosentan)
- medicines to treat gout if you have liver or kidney problems (colchicine)
- medicines to treat prostate problems (alfuzosin)
- medicines to treat migraine and headaches (dihydroergotamine, ergonovine, ergotamine, methylergonovine)
- medicines to treat some stomach conditions (cisapride)
- medicines to treat hepatitis C virus (boceprevir, telaprevir)
- herbal products containing St John's wort (e.g. for depression)
- medicines to treat high cholesterol (lovastatin and simvastatin)
- medicines to treat psychiatric conditions such as schizophrenia (pimozide)
- medicines to treat trouble with sleeping and/or anxiety (midazolam or triazolam)
- medicines to treat fungal infections (ketoconazole, itraconazole, voriconazole)
- medicines to treat narcotic dependence (buprenorphine/naloxone)

If you are taking any of these, discuss it with your doctor.

DUNARID with food, drink, and alcohol:

You must eat a meal or snack 30 minutes before you take your **DUNARID** and ritonavir. The type of food is not important.

Swallow the tablet with a drink such as water, milk, or any other nutritional drink.

Pregnancy and, breastfeeding, and fertility:

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.

The safe use of **DUNARID** in pregnancy and during breastfeeding has not been established.

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Mothers on **DUNARID** should not breastfeed their infants

Driving and using machines:

Do not operate machines or drive if you feel dizzy after taking **DUNARID**.

3. How to use DUNARID:

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

Always use **DUNARID** exactly as your doctor has told you. You must check with your doctor if you are not sure.

The usual dose of **DUNARID** 400 mg is two tablets once daily or PN 800 mg is one tablet once daily.

You must take **DUNARID** every day and always in combination with 100 mg of ritonavir and with food at approximately the same time of day. **DUNARID** cannot work properly without ritonavir and food.

You must eat a meal or snack 30 minutes before you take your **DUNARID** and ritonavir. The type of food is not important.

Swallow the tablet with a drink such as water, milk, or any other nutritional drink.

Even if you feel better, do not stop taking **DUNARID** without talking to your doctor.

Make sure that you always have enough **DUNARID** and ritonavir tablets available so that you don't run out. For example, in case you cannot return home, need to travel or stay in a hospital.

If you forget to take DUNARID:

If you notice within 12 hours, you must take your tablet immediately. Always take with ritonavir and food. If you notice after 12 hours, then take the next dose as usual. Do not take a double dose to make up for a forgotten dose.

If you stop using DUNARID:

Even when you feel better, do not stop taking **DUNARID**. Talk to your doctor first.

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4. Possible side effects:

DUNARID can have side effects.

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

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

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

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

- symptoms of infection or inflammation after the start of treatment (immune reconstitution inflammatory syndrome)
- inflammation of the liver or pancreas (symptoms may include abdominal pain, nausea and vomiting)
- diabetes

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- vomiting, nausea
- diarrhoea, stomach pain

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- rash
- high cholesterol and other fats in the blood
- high blood sugar

Less frequent side effects:

- changes in body fats (fat redistribution)
- loss of appetite
- abdominal swelling, indigestion, flatulence
- itching
- muscle pain
- loss of strength and energy, tiredness
- increase in pancreatic enzymes

DUNARID may change some values of your blood chemistry. These can be seen in the results of blood tests. Your doctor will explain these to you. In some patients, **DUNARID** has been reported to cause a severe or life-threatening rash. In patients taking **DUNARID** and raltegravir, rashes (generally mild or moderate) may occur more frequently than in patients taking either medicine separately. Contact your doctor if you develop a rash. Your doctor will advise you whether your symptoms can be managed on therapy or whether **DUNARID** should be stopped. **DUNARID** should not be taken if you suffer from liver problems.

Some side effects are typical for anti-HIV medicines in the same family as **DUNARID**. These include:

- raised blood sugar and worsening of diabetes.
- muscle pain, tenderness or weakness. On rare occasions, these muscle disorders have been serious.
- changes in body shape due to fat redistribution. These may include loss of fat from legs, arms and face, increased fat in the abdomen (belly) and other internal organs, breast enlargement and fatty lumps on the back of the neck (buffalo hump).

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- joint aches and pains, joint stiffness or difficulty in movement.

The cause and long-term health effects of these conditions are not known at this time.

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 or, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **DUNARID**.

5. How to store **DUNARID**:

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Store at or below 25°C
- Store in the original package / container
- Keep the container tightly closed
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton / bottle

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What **DUNARID** contains

- The active substance is Darunavir Amorphous.
- The inactive substances are:

Dry mix:

Darunavir Amorphous (Active ingredient), Silica, colloidal anhydrous (grade 200)

Wet Granulation:

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Silica, colloidal anhydrous (grade 200), Purified Water

Extra Granulation:

Silicified microcrystalline cellulose, Silica, colloidal anhydrous (grade 200), Crospovidone

Lubrication:

Magnesium stearate

Film Coating:

Opadry II Yellow 85F520012, Purified Water

What **DUNARID** looks like and contents of the pack:

Darunavir Tablets 400 mg:

60's & 56's Count HDPE Container.

10 x 10's Alu-Alu Blister Pack.

500's Stimulated Bulk pack.

Darunavir Tablets 800 mg:

60's & 56's Count HDPE Container.

10 x 10's Alu-Alu Blister Pack.

500's Stimulated Bulk pack.

HOLDER OF CERTIFICATE OF REGISTRATION

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This leaflet was last revised in:

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DUNARID 400: 56/20.2.8/0886

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