DARUNAVIR MYLAN FILM-COATED TABLETS

Darunavir (600mg)

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What DARUNAVIR MYLAN is used for

DARUNAVIR MYLAN is an antiretroviral medicine. It belongs to a group called protease inhibitors.

DARUNAVIR MYLAN is used to treat adults who are infected with HIV.

DARUNAVIR MYLAN must be taken in combination with a low dose of ritonavir and other anti-HIV medicines.

Your doctor will discuss with you which combination of medicines is best for you.

How DARUNAVIR MYLAN works

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

Before you use DARUNAVIR MYLAN

- *<u>When you must not use it</u> Do not take DARUNAVIR MYLAN:*
- if you are **allergic** (hypersensitive) to darunavir, other ingredients of DARUNAVIR MYLAN or to ritonavir.

Tell your doctor about **all** medicines you take.

Do not combine DARUNAVIR MYLAN with any of the following medicines:

- *astemizole* or *terfenadine* (to treat allergy symptoms)
- *midazolam* or *triazolam* (to treat trouble with sleeping and/or anxiety)
- *cisapride* (to treat some stomach conditions)
- *lurasidone* or *pimozide* (to treat psychiatric conditions)
- *ergot alkaloids* (to treat migraine and headaches)
- *alfuzosin* (to treat enlarged prostate gland)
- *sildenafil* (to treat pulmonary arterial hypertension)
- *colchicine* (to treat gout or familial Mediterranean fever), if you have renal/hepatic impairment
- *lovastatin, simvastatin, or lomitapide* (to lower cholesterol levels)
- *dronedarone, ivabradine, ranolazine (to treat chest pain)*
- *rifampin* (to treat some infections such as tuberculosis)
- *elbasvir/grazoprevir* (to treat hepatitis C infection)
- *St. John's wort (Hypericum perforatum)* (a herbal product used in products for depression)
- *naloxegol (to treat opioid induced constipation)*
- *dapoxetine (to treat premature ejaculation)*

If you are taking any of these, ask your doctor about switching to another medicine. This is **not** a complete list of medicines.
Therefore, tell your doctor about **all** medicines you take.

<u>Pregnancy and Breastfeeding</u>
Tell your doctor immediately if you are pregnant, planning to become pregnant or if you are breast-feeding. During pregnancy and breast-feeding, do not take DARUNAVIR MYLAN with ritonavir, unless it is specifically approved by your doctor. It is recommended that HIV infected women should not breast-feed their infants because of the possibility of your baby becoming infected with HIV through your breast milk and because of the unknown effects of the medicine on your baby.

- *<u>Before you start to use it</u>*
Take special care with DARUNAVIR MYLAN DARUNAVIR MYLAN is not a cure for HIV infection. DARUNAVIR MYLAN does not reduce the risk of passing HIV to others through sexual contact or blood contaminations. Therefore, you must continue to use appropriate precautions.
People taking DARUNAVIR MYLAN may still develop infections or other illnesses associated with HIV infection. You must keep in regular contact with your doctor.

Tell your doctor about your situation
Make sure that you check the following points and tell your doctor if any of these apply to you.
- Tell your doctor if you have had **problems with your liver** before, including hepatitis B or C infection. Your doctor may evaluate how severe your liver disease is before deciding if you can take DARUNAVIR MYLAN.
- Tell your doctor if you have **diabetes**. In general, anti-HIV medicines such as DARUNAVIR MYLAN might increase sugar levels in the blood.
- Tell your doctor immediately if you notice any **symptoms of infection or inflammation**. In some patients with advanced HIV infection, signs and symptoms of infection or inflammation may occur after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response.
- Tell your doctor if you have **hemophilia**. Anti-HIV medicines, such as DARUNAVIR MYLAN, might increase the risk of bleeding.
- Tell your doctor if you are allergic to sulfonamide medicines.

- *<u>Taking other medicines</u>*
Tell your doctor about your medicines
DARUNAVIR MYLAN might interact with other medicines. Please tell your doctor if you are taking or have recently

taken any other medicines, including medicines obtained without a prescription. There are some medicines that **you must not combine** with DARUNAVIR MYLAN. These are mentioned above under the heading 'Do not combine DARUNAVIR MYLAN with any of the following:'.
Tell your doctor if you take other anti-HIV medicines. DARUNAVIR MYLAN can be combined with some other anti-HIV medicines while other combinations are not recommended.

The effects of DARUNAVIR MYLAN might be reduced if you take any of the following products. Tell your doctor if you take:
- medicines to treat hepatitis C infection (*boceprevir*).
- medicines to prevent seizures (*phenobarbital, phenytoin*).
- corticosteroids (*dexamethasone*).
- medicines to treat some infections such as tuberculosis (*rifapentine*).

The effects of other medicines might be influenced if you take DARUNAVIR MYLAN and your doctor might want to do some additional blood tests. Tell your doctor if you take:
- medicines for heart disease (*amiodarone, amlodipine, bepridil, bosentan, carvedilol, diltiazem, felodipine, flecainide, disopyramide, lidocaine, metoprolol, mexiletine, nifedipine, nicardipine, propafenone, tadalafil, timolol, quinidine, verapamil*).
- medicines used to reduce clotting of the blood (e.g. *apixaban, dabigatran etexilate, edoxaban, rivaroxaban, warfarin),* or to prevent blood clots *(e.g. ticagrelor, clopidogrel)*
- contraceptives. DARUNAVIR MYLAN might reduce the effectiveness of hormonal contraceptives. Therefore, additional or alternative methods (non-hormonal) contraception are recommended. If you take a contraceptive containing *drosperinone,* your potassium levels might become elevated
- medicines to lower cholesterol levels (e.g. *atorvastatin, pravastatin, rosuvastatin*). The risk of muscle tissue disorder might be increased.
- *Atorvastatin, pravastatin or rosuvastatin*, at a reduced starting dose, could be used.
- medicines for your immune system (*everolimus, cyclosporin, tacrolimus, sirolimus*). Your doctor might want to do some additional tests.
- corticosteroids (*betamethasone, budesonide, fluticasone, mometasone, prednisone, triamcinolone*).
- medicines to treat asthma (*salmeterol*).
- medicines to treat gout or familial Mediterranean fever (*colchicine*).
- combination medicine to treat malaria (*artemether/lumefantrine*).
- medicines to treat cancer (*dasatinib, everolimus, irinotecan, nilotinib, vinblastine, vincristine*).
- medicine to prevent seizures (*clonazepam)*
- medicines to treat depression and anxiety (*amitriptyline, desipramine, imipramine, nortriptyline, trazodone)*.
- medicines to treat fungal infections (*clotrimazole, fluconazole, isavuconazole, posaconazole*).
- sedatives/hypnotics *(buspirone, clorazepate, diazepam, estazolam, flurazepam, zolpidem).*
- certain medicines to treat moderate or severe pain (*fentanyl, oxycodone, tramadol).*
- medicines to treat urinary disorders (fesoterodine, solifenacin)
- medicines to treat nausea and vomiting (domperidone)

The dosage of other medicines might need to be changed and your doctor might do some additional blood tests. Tell your doctor if you take:
- medicines used to reduce clotting of the blood *(dabigatran etexilate, edoxaban, warfarin)*
- medicines to treat certain heart disorders (*digoxin*)
- medicines against fungal infections (*itraconazole, ketoconazole, voriconazole*)
- medicines against bacterial infections (*rifabutin*)
- medicines for erectile dysfunction (*avanafil, sildenafil, vardenafil, tadalafil*)
- antibiotics (*clarithromycin*)
- medicines to treat depression and anxiety (*paroxetine, sertraline*).
- medicines to prevent seizures or to treat trigeminal neuralgia (*carbamazepine*)
- medicines to treat narcotic dependence (*buprenorphine/naloxone, methadone)*
- medicines to treat psychiatric conditions (*perphenazine, quetiapine, risperidone, thioridazine)*
- medicines used as sedatives (*parenteral midazolam)*

This is **not** a complete list of medicines. Tell your doctor about **all** medicines that you are taking.
Taking DARUNAVIR MYLAN with food and drink
See 'How to use DARUNAVIR MYLAN' with food and drink.

How to use DARUNAVIR MYLAN
- *How much to use*
Always use DARUNAVIR MYLAN exactly as your doctor has told you. You must check with your doctor if you are not sure.

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

Adults who have taken anti-HIV medicines before (your doctor will determine this)
The dose is 600 mg (1 tablet containing 600 mg of DARUNAVIR MYLAN) together with 100 mg ritonavir twice daily.

Instructions
You must take DARUNAVIR MYLAN every day and always in combination with 100 mg of ritonavir and with food. DARUNAVIR MYLAN cannot work properly without ritonavir and food. You must eat a meal or a snack within 30 minutes prior to taking your DARUNAVIR MYLAN and ritonavir. The type of food is not important.
Even if you feel better, do not stop taking DARUNAVIR MYLAN without talking to your doctor.

When the dose of DARUNAVIR MYLAN is 600 mg with 100 mg ritonavir twice daily

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- Take one 600 mg tablet in the morning and one 600 mg tablet in the evening.
- Take DARUNAVIR MYLAN always together with 100 mg of ritonavir.
- Take DARUNAVIR MYLAN with food.
- Swallow the tablet(s) with a drink such as water, milk, or any other nutritional drink.
- Take your other HIV medicines used in combination with DARUNAVIR MYLAN and ritonavir as recommended by your doctor.

- *When to use it*

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

- *How long to use it*

Continue taking DARUNAVIR MYLAN for as long as your doctor recommends.

- *If you forget to use it*

If your dosing regimen is DARUNAVIR MYLAN with ritonavir twice a day:

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 skip the intake and take the next doses as usual. Do not take a double dose to make up for a forgotten dose. Please refer to your doctor for instructions on missed doses of other HIV medicines used in combination with DARUNAVIR MYLAN and ritonavir.

If you vomit within 4 hours of taking the medicine, another dose of DARUNAVIR MYLAN with ritonavir should be taken with food as soon as possible. If you vomit more than 4 hours after taking the medicine, you do not need to take another dose of DARUNAVIR MYLAN with ritonavir until the next regularly scheduled time.

- *If you use too much (overdose)*

Contact your doctor or pharmacist immediately.

While you are using it

- *Things you must do*

If you have any further questions on the use of this product, ask your doctor.

- *Things you must not do*

Do not stop using DARUNAVIR MYLAN without talking to your doctor first HIV therapy may increase your sense of well-being. Even when you feel better, do not stop taking DARUNAVIR MYLAN. Talk to your doctor first.

- *Things to be careful of*

Driving and using machines

Do not operate machines or drive if you feel dizzy after taking DARUNAVIR MYLAN.

Side effects

Like all medicines, DARUNAVIR MYLAN can cause side effects, although not everybody gets them.
When treating HIV infection, it is not always easy to identify what side effects are caused by DARUNAVIR MYLAN, which are caused by other medicines you are taking, or which are caused by the HIV infection itself.

The following is not a complete list of side effects reported with DARUNAVIR MYLAN.

Liver problems that may occasionally be severe have been reported. Your doctor should do blood tests prior to initiating DARUNAVIR MYLAN. If you have chronic hepatitis B or C infection, your doctor should check your blood tests more often because you have an increased chance of developing liver problems. Talk to your doctor about the signs and symptoms of liver problems. These may include yellowing of your skin or whites of your eyes, dark (tea colored) urine, pale colored stools (bowel movements), nausea, vomiting, loss of appetite, or pain, aching, or sensitivity on your right side below your ribs.
Skin rash has been reported in 10.3% of patients receiving DARUNAVIR MYLAN. Occasionally a rash can be severe or potentially life-threatening. In patients taking DARUNAVIR MYLAN and raltegravir, rashes (generally mild or moderate) may occur more frequently than in patients taking either drug separately. It is important to consult your doctor if you develop a rash.

Your doctor will advise you how to deal with your symptoms or whether DARUNAVIR MYLAN must be stopped. Other clinically relevant severe side effects, reported at an uncommon or rare frequency were inflammation of the pancreas, increased blood fat levels, diabetes, and symptoms of infection. Darunavir crystals in the kidney causing kidney disease have been reported at a very rare frequency.

The most commonly reported side effects include abdominal pain, diarrhea, headache, nausea, rash and vomiting.

Some side effects are typical for anti-HIV medicines. These are:

- raised blood sugar and worsening of diabetes.
- immune reconstitution inflammatory syndrome. In some patients with advanced HIV infection (AIDS) and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started, including DARUNAVIR MYLAN. In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment.
- increased bleeding in patients with hemophilia.
- muscle pain, tenderness or weakness. On rare occasions, these muscle disorders have been serious.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [(*Consumers* → *Reporting Side Effects* or *Medicines (ConSERF) or Vaccines (AEFI)*].

Storage and Disposal of DARUNAVIR MYLAN

- *Storage*

Do not store above 30°C. Store in the original container. Discard 60 days after the first opening

Keep out of the reach and sight of children.

Do not use DARUNAVIR MYLAN after the expiry date, which is stated on the box and on the bottle after the letters EXP. The expiry date refers to the last day of that month.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.
These measures will help to protect the environment.

Product Description

- *What it looks like*

White to off-white, film coated, oval shaped, biconvex tablet, debossed with 'M' on one side and 'DE6' on the other side.

- *Ingredients*

Active ingredients
The active substance is darunavir. Each 600 mg tablet contains 650.46 mg of darunavir ethanolate, corresponding to 600 mg of darunavir.

Inactive ingredients
The other ingredients are
Hypromellose,
Silicified microcrystalline cellulose,
Crospovidone, Colloidal silicon dioxide,
Magnesium stearate.

The film-coating contains Polyvinyl alcohol part hydrolysed, Titanium dioxide, Macrogol/PEG, Talc

- *MAL number*

MALxxxxxx

Manufacturer

Mylan Laboratories Limited
Plot No. H12 & 13, MIDC Waluj
Industrial Area,
Chhatrapati Sambhajinagar,
Maharashtra 431136, India

Product Registration Holder

NVS Regulatory Services Sdn Bhd,
Unit 19g, 7th Floor, Block 2,
Worldwide Business Centre,
Jalan Tinju 13/50,
40675 Shah Alam, Selangor, Malaysia

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