

## DARUNAVIR MYLAN

*Darunavir film coated tablet 400 & 600 mg*



### What is in this leaflet

Please read this leaflet carefully before you start taking Darunavir Mylan.

This leaflet answers some common questions about Darunavir Mylan.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Darunavir Mylan against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

### What Darunavir Mylan is used for

Darunavir Mylan is used to treat

- Human immunodeficiency virus-1 (HIV-1) infection in adult patients.
- Human immunodeficiency virus (HIV) infection in treatment-experienced paediatric patients aged  $\geq 6$  years old and weighing at least 40 kg.

Darunavir Mylan must be taken in combination with a low dose ritonavir, and with other anti-HIV medicines.

Darunavir Mylan contains the active ingredient darunavir. It belongs to a group of medicines called protease inhibitors.

It works by reducing the amount of HIV in your body. Reducing the amount of HIV in your blood improves your immune system, and reduces the risk of developing illness as a result of HIV infection.

Your doctor may have prescribed this medicine for another reason.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

This medicine is available only with a doctor's prescription.

### Before you take Darunavir Mylan

#### **When you must not take it**

**Do not take Darunavir Mylan if you have an allergy to:**

- any medicine containing darunavir.
- any of the ingredients listed at the end of this leaflet.
- Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**Do not give this medicine to a child under the age of 6 years.**

**Do not give this medicine to children and adolescents who have never used antiretroviral medicines before.**

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.** If it has expired or is damaged,

return it to your pharmacist for disposal.

**Do not combine Darunavir Mylan with any of the following medicines:**

- Alfuzosin (to treat an enlarged prostate)
- Astemizole or terfenadine (to treat allergy symptoms)
- Amiodarone, bepridil, disopyramide, flecainide, mexiletine, propafenone, lidocaine, quinidine or dronedarone (to treat irregular heartbeat)
- Ivabradine or ranolazine (to treat heart disease)
- Apixaban (used to reduce blood clotting)
- Cisapride (to treat some stomach conditions)
- Colchicine (to treat gout) if you have renal/hepatic impairment
- Lovastatin, simvastatin or lomitapide (to lower cholesterol levels)
- Lurasidone or pimozone (to treat psychiatric conditions)
- Midazolam or triazolam (to treat trouble with sleeping and/or anxiety)
- Ergot alkaloids such as dihydroergotmine, ergonovine, ergotamine and methylergonovine (to treat migraine and headaches)
- Sildenafil (to treat pulmonary arterial hypertension)
- Rifampicin (to treat some infections such as tuberculosis)
- Elbasvir/grazoprevir (to treat hepatitis C)
- Products that contain St John's wort (*hypericum perforatum*)
- Naloxegol (to treat constipation caused by taking opioids)
- Dapoxetine (to treat premature ejaculation)

In addition, do not combine Darunavir Mylan in combination with cobicistat with any of the following medicines:

- Carbamazepine, phenobarbital, phenytoin (to treat epilepsy and prevent seizures)

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

There are other medicines that you need to be careful of when taking Darunavir Mylan (see Taking other medicines).

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

## ***Before you start to take it***

**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. Therefore, you must continue to use appropriate precautions to prevent passing HIV on to others.

People taking Darunavir Mylan can still develop infections or other illnesses associated with HIV. You should continue to keep in regular contact with your doctor and to monitor your health while taking Darunavir Mylan.

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- **Problems with your liver, including hepatitis B and C.** You doctor may need to evaluate your liver before deciding if you can take Darunavir Mylan.
- **Diabetes** Darunavir Mylan, like some other anti-HIV medicines, might increase sugar level in the blood.
- **Symptoms of infection** In some patients with advanced HIV infection and a history of opportunistic infection, signs and

symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response. This improvement enables the body to fight infections that may have been present prior to taking Darunavir Mylan, with no obvious symptoms.

- **Changes in body fat** Redistribution, accumulation or loss of body fat may occur in patients receiving a combination of antiretroviral medicines.
- **Haemophilia** Anti-HIV medicines, such as Darunavir Mylan, might increase the risk of bleeding in patients with this blood clotting disorders.
- **An allergy to sulfa medicines (sulphonamides).**

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.** Your doctor can discuss with you the risks and benefits involved.

Do not take Darunavir Mylan with cobicistat if you are pregnant or breastfeeding. During pregnancy and breast-feeding you must not take Darunavir Mylan, 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 our baby becoming infected with HIV through your breast milk and because of the unknown effects of the medicine on your baby.

**If you have not told your doctor about any of the above, tell them before you start taking Darunavir Mylan.**

## ***Taking other medicines***

**Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.**

You should also tell any health professional who is prescribing a

new medication for you that you are taking Darunavir Mylan.

Some medicines may interfere with Darunavir Mylan. These include:

**Alfuzosin, amiodarone, apixaban, astemizole, bepridil, cisapride, colchicine, dapoxetine, disopyramide, dronedarone, elbasvir/grazoprevir, ergot alkaloids, flecainide, ivabradine, lidocaine, lomitapide, lovastatin, lurasidone, mexiletine, midazolam, naloxegol, pimozone, propafenone, quinidine, ranolazine, rifampicin, sildenafil, simvastatin, products that contain St John's wort (hypericum perforatum), terfenadine or triazolam. You must not take these medicines while taking Darunavir Mylan. You must not take carbamazepine, phenobarbital or phenytoin while taking Darunavir Mylan in combination with cobicistat.**

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.

**If you take Darunavir Mylan with some other medicines, the effects of Darunavir Mylan or other medicines might be influenced. The dosage of some medicines may need to be changed. Some combinations are not recommended. Tell you doctor if you take any of the following:**

- **Contraceptives.** Darunavir Mylan might reduce the effectiveness of hormonal contraceptives. Therefore, additional or alternative (non-hormonal) methods of contraception are recommended. If you take a contraceptive containing drospirenone your potassium levels might become elevated.
- **Medicines for heart disease** (amlodipine, diltiazem, felodipine, nifedipine, nicardipine, tadalafil, verapamil).

- Medicines to treat certain heart disorders (digoxin, carvedilol, metoprolol, timolol, bosentan).
- Medicines used to reduce clotting of the blood (dabigatran, edoxaban, rivaroxaban, ticagrelor, warfarin, clopidogrel).
- Medicines to lower cholesterol levels (pravastatin, pitavastatin, atorvastatin, rosuvastatin). The risk of muscle tissue disorder might be increased. Atorvastatin, rosuvastatin, or pravastatin, at a reduced starting dose, could be used as an alternative.
- Medicines for your immune system (cyclosporin, everlimus, tacrolimus, sirolimus). Your doctor might want to do some additional test.
- Medicines to treat asthma (salmeterol).
- Steroids (betamethasone, budesonide, dexamethasone, fluticasone propionate, mometasone, prednisone, triamcinolone).
- Medicines to treat cancer (dasatinib, everolimus, irinotecan, nilotinib, vinblastine, vincristine).
- Buprenorphine, naloxone, methadone.
- Medicines to treat malaria (artemether/lumefantrine).
- Medicines to treat hepatitis C (boceprevir, glecaprevir/pibrentasvir).
- Medicines to treat urinary disorders (fesoterodine, solifenacin).
- Medicines to treat nausea and vomiting (domperidone).
- Medicines to treat fungal infections (clotrimazole, fluconazole, isavuconazole, itraconazole, ketoconazole, posaconazole, voriconazole).
- Medicines to treat some infections such as tuberculosis (rifapentine).
- Medicines against bacterial infections (rifabutin, clarithromycin).
- Medicines to treat gout (colchicine). If you have renal / hepatic impairment, do not take colchicine with Darunavir Mylan.
- Medicines for erectile dysfunction (avanafil, sildenafil, vardenafil, tadalafil).
- Medicines to treat depression and anxiety (paroxetine, sertraline, amitriptyline, desipramine, imipramine, nortriptyline, and trazodone).
- Sedatives (buspirone, clorazepate, diazepam, estazolam, flurazepam, zolpidem).
- Medicines to treat psychiatric conditions (perphenazine, risperidone, thioridazine, quetiapine).
- Medicines to prevent seizures or to treat trigeminal neuralgia (carbamazepine, clonazepam, phenobarbital, phenytoin, oxcarbamazepine).
- Certain medicines to treat moderate or severe pain (fentanyl, oxycodone, tramadol).
- Medicines to treat excessive sleepiness (armodafinil, modafinil).

These medicines may be affected by Darunavir Mylan or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

**Please refer to ritonavir or cobicistat Consumer Medicine Information for information on ritonavir or cobicistat.**

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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## How to take Darunavir Mylan

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.**

### *How much to take*

Take Darunavir Mylan exactly as directed by your doctor. Your doctor will decide which dose is right for you.

### *How to take it*

**Swallow the tablets whole with a full glass of water.**

You must take Darunavir Mylan every day and always in combination with 100 milligrams 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.

Take your other HIV medicines used in combination with Darunavir Mylan and ritonavir as recommended by your doctor.

For children 6 years of age and older, weighing at least 40 kg, who have taken anti-HIV medicines before, the doctor will work out the right dose based on the weight of the child. The doctor will inform you exactly how many Darunavir Mylan tablets and how much ritonavir (capsules or solution) your child should take.

If your child feels better, do not stop administering Darunavir Mylan without talking to the child's doctor.

### *When to take it*

**Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

## ***How long to take it***

**Continue taking your medicine for as long as your doctor tells you.**

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

**Continue taking your medicine until you finish the pack.**

## ***If you forget to take it***

**If your dosing regimen is Darunavir Mylan with ritonavir once a day:**

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

**If your dosing regimen is Darunavir Mylan with ritonavir twice a day:**

If it more than 6 hours after you missed the dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember (within 6 hours), and then go back to taking your medicine as you would normally.

**Do not take a double dose to make up for the dose that you missed.**

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist for instruction on missed doses.**

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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## **While you are taking Darunavir Mylan**

### ***Things you must do***

**If you are about to be started on any new medicine, tell your**

**doctor and pharmacist that you are taking Darunavir Mylan.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

It may affect other medicines used during surgery.

**If you become pregnant while taking this medicine, tell your doctor immediately. You must not take Darunavir Mylan with cobicistat if you are pregnant or breastfeeding.**

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.**

It may interfere with the results of some tests.

**Keep all of your doctor's appointments so that your progress can be checked.**

Your doctor may do some tests (e.g. blood, urine) from time to time to make sure the medicine is working and to prevent unwanted side effects.

Be sure to follow up your doctor's instruction about other medicines you should take, and other things you should do. Ask your doctor or pharmacist if you have any questions.

### ***Things you must not do***

**Do not take Darunavir Mylan to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

## ***Things to be careful of***

**Be careful driving or operating machinery until you know how Darunavir Mylan affects you.**

This medicine may cause dizziness, headache, fatigue or nausea in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.

**Be careful when drinking alcohol while you are taking this medicine.**

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

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## **In case of overdose**

### ***If you take too much (overdose)***

**Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Darunavir Mylan. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

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## **Side effects**

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Darunavir Mylan.**

This medicine helps most people with HIV infections, but it may have unwanted side effects in a few people.

**All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.**

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.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- Nausea
- Vomiting
- Headache
- Abdominal pain
- Diarrhoea
- Rash
- Change in body fat

The above list includes the more common side effects of your medicine.

They are usually mild and short-lived

Darunavir Mylan 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.

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 coloured) urine, pale coloured 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% 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.

**Tell your doctor as soon as possible if you notice any of the following:**

- Inflammation of the pancreas
- Increased blood fat levels
- Diabetes
- Symptoms of infection
- Changes in body fat

Some side effects are typical for anti-HIV medicines in the same family as Darunavir Mylan. These are:

- Raised blood sugar and worsening of diabetes.
- 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). The cause and long term health effects of these conditions are not known at this time.
- Immune reactivation 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 treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment.
- Increased bleeding in patients with haemophilia.
- Muscle pain, tenderness or weakness. On rare occasions, these muscles disorders have been serious.

If you experience any of these side effects and they worry you, or if you

notice any side effects not listed in this leaflet, please tell your doctor.

Tell your doctor if you notice signs of symptoms of infections, such as a fever or rashes. Some people with HIV who have had infections in the past may experience a return of symptoms soon after taking anti-HIV medicines.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- Rash, itching or hives on the skin
- Shortness of breath, wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

**Do not be alarmed by this list of possible side effects. You may not experience any of them.**

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## After taking Darunavir Mylan

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### Storage

**Keep your tablets in the pack until it is time to take it.**

If you take the tablets out of the pack they may not keep well.

**Keep your tablets in a cool dry place where the temperature stays below 25°C.**

Do not store Darunavir Mylan or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

***Disposal***

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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**Product description**

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***What it looks like***

Darunavir Mylan 400 mg – White to Off white, oval shaped, biconvex film coated tablets debossed with 'M' on one side of the tablet and 'DV4' on other side.

Darunavir Mylan 600 mg – White to Off white, oval shaped, biconvex film coated tablets debossed with 'M' on one side of the tablet and 'DV5' on other side.

***Ingredients***

Active ingredient(s):

Darunavir Mylan contains 400 or 600 mg of darunavir as the active ingredient.

Inactive ingredient(s):

Darunavir Mylan also contains:

- Colloidal silicon dioxide
- Microcrystalline cellulose
- Crospovidone
- Sodium starch glycolate
- Hypromellose
- Magnesium stearate
- Purified water
- Polyvinyl alcohol
- Titanium dioxide
- Macrogol/PEG
- Talc

This medicine does not contain lactose and gluten.

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**If you want to know more**

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Should you have any questions regarding this product, please contact your pharmacist or doctor.

***Who supplies this medicine***

Darunavir Mylan is supplied in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Ellerslie,  
Auckland  
NEW ZEALAND

Telephone: 0800 579 811

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**Date of Preparation**

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31 July 2020.

(Based on datasheet dated 31 July 2020)