Package leaflet: Information for the user

[Invented name] 75 mg film-coated tablets
[Invented name] 150 mg film-coated tablets
[Invented name] 300 mg film-coated tablets
[Invented name] 600 mg film-coated tablets
darunavir

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Invented name] is and what it is used for
2. What you need to know before you take [Invented name]
3. How to take [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

1. What [Invented name] is and what it is used for

What is [Invented name]?
[Invented name] contains the active substance darunavir. [Invented name] is an antiretroviral medicine used in the treatment of Human Immunodeficiency Virus (HIV) infection. It belongs to a group of medicines called protease inhibitors. This medicine works by reducing the amount of HIV in your body. This will improve your immune system and reduces the risk of developing illnesses linked to HIV infection.

What it is used for?
[Invented name] is used to treat adults and children of 3 years of age and above, and at least 15 kilogram body weight who are infected by HIV and who have already used other antiretroviral medicines.

[Invented name] 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.

2. What you need to know before you take [Invented name]

Do not take [Invented name]
- if you are **allergic** to darunavir or any of the other ingredients of this medicine (listed in section 6) or to ritonavir.
- 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.

Do not combine [Invented name] with any of the following medicines
If you are taking any of these, ask your doctor about switching to another medicine.

Medicine	Purpose of the medicine
Avanafil	to treat erectile dysfunction
Astemizole or *terfenadine*	to treat allergy symptoms
Triazolam and *oral* (taken by mouth) *midazolam*	to help you sleep and/or relieve anxiety
Cisapride	to treat some stomach conditions
Colchicine (if you have kidney and/or liver problems)	to treat gout or familial Mediterranean fever
Lurasidone, pimozide, quetiapine or *sertindole*	to treat psychiatric conditions
Ergot alkaloids like *ergotamine, dihydroergotamine, ergometrine* and *methylergonovine*	to treat migraine headaches
Amiodarone, bepridil, dronedarone, ivabradine, quinidine, ranolazine	to treat certain heart disorders e.g. abnormal heart beat
Lovastatin, simvastatin and *lomitapide*	to lower cholesterol levels
Rifampicin	to treat some infections such as tuberculosis
The combination product *lopinavir/ritonavir*	this anti-HIV medicine belongs to the same class as [Invented name]
Elbasvir/grazoprevir	to treat hepatitis C infection
Alfuzosin	to treat enlarged prostate
Sildenafil	to treat high blood pressure in the pulmonary circulation
Dabigatran, ticagrelor	to help stop the clumping of platelets in the treatment of patients with a history of a heart attack
Naloxegol	to treat opioid induced constipation
Dapoxetine	to treat premature ejaculation
Domperidone	to treat nausea and vomiting

Do not combine [Invented name] with products that contain St John's wort *(Hypericum perforatum)*.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking [Invented name].

[Invented name] is not a cure for HIV infection. You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your physician the precautions needed to avoid infecting other people.

People taking [Invented name] may still develop infections or other illnesses associated with HIV infection. You must keep in regular contact with your doctor.

People taking [Invented name] may develop a skin rash. Infrequently a rash may become severe or potentially life-threatening. Please contact your doctor whenever you develop a rash.

In patients taking [Invented name] and raltegravir (for HIV infection), rashes (generally mild or moderate) may occur more frequently than in patients taking either medicine separately.

Tell your doctor about your situation BEFORE and DURING your treatment
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 [Invented name].
- Tell your doctor if you have **diabetes**. [Invented name] might increase sugar levels in the blood.
- Tell your doctor immediately if you notice any **symptoms of infection** (for example enlarged lymph nodes and fever). 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, enabling the body to fight infections that may have been present with no obvious symptoms.
- 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. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.
- Tell your doctor if you have **haemophilia**. [Invented name] might increase the risk of bleeding.
- Tell your doctor if you are **allergic to sulphonamides** (e.g. used to treat certain infections).
- Tell your doctor if you notice any **musculoskeletal problems**. Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index, among others, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms please inform your doctor.

Elderly
Darunavir has only been used in limited numbers of patients 65 years or older. If you belong to this age group, please discuss with your doctor if you can use [Invented name].

Children
[Invented name] is not for use in children younger than 3 years of age or weighing less than 15 kilograms.

Other medicines and [Invented name]
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

There are some medicines that **you must not combine** with [Invented name]. These are mentioned above under the heading 'Do not combine [Invented name] with any of the following medicines:'

In most cases, [Invented name] can be combined with anti-HIV medicines belonging to another class [e.g. NRTIs (nucleoside reverse transcriptase inhibitors), NNRTIs (non-nucleoside reverse transcriptase inhibitors), CCR5 antagonists and FIs (fusion inhibitors)]. Darunavir with ritonavir has not been tested with all PIs (protease inhibitors) and must not be used with other HIV PIs. In some cases dose of other medicines might need to be changed. Therefore always tell your doctor if you take other anti-HIV medicines and follow your doctor's instruction carefully on which medicines can be combined.

The effects of [Invented name] might be reduced if you take any of the following products. Tell your doctor if you take:
- *Phenobarbital, phenytoin* (to prevent seizures)
- *Dexamethasone* (corticosteroid)
- *Efavirenz* (HIV infection)
- *Boceprevir* (hepatitis C infection)
- *Rifapentine, rifabutin* (medicines to treat some infections such as tuberculosis)
- *Saquinavir* (HIV infection).

The effects of other medicines might be influenced if you take [Invented name]. Tell your doctor if you take:

- *Amlodipine, diltiazem, disopyramide, carvedilol, felodipine, flecainide, lidocaine, metoprolol, mexiletine, nifedipine, nicardipine, propafenone, timolol, verapamil* (for heart disease) as the therapeutic effect or side effects of these medicines may be increased.
- *Apixaban, edoxaban, rivaroxaban, warfarin* (to reduce clotting of the blood) as their therapeutic effect or side effects may be altered; your doctor may have to check your blood.
- Oestrogen-based hormonal contraceptives and hormonal replacement therapy. [Invented name] might reduce its effectiveness. When used for birth control, alternative methods of non-hormonal contraception are recommended.
- *Ethinylestradiol/drospirenone*. [Invented name] might increase the risk for elevated potassium levels by drospirenone.
- *Atorvastatin, pravastatin, rosuvastatin* (to lower cholesterol levels). The risk of muscle damage might be increased. Your doctor will evaluate which cholesterol lowering regimen is best for your specific situation.
- *Clarithromycin* (antibiotic)
- *Ciclosporin, everolimus, tacrolimus, sirolimus* (for dampening down your immune system) as the therapeutic effect or side effects of these medicines might be increased. Your doctor might want to do some additional tests.
- *Corticosteroids including betamethasone, budesonide, fluticasone, mometasone, prednisone, triamcinolone.* These medicines are used to treat allergies, asthma, inflammatory bowel diseases, inflammatory conditions of the eyes, joints and muscles and other inflammatory conditions. If alternatives cannot be used, its use should only take place after medical evaluation and under close monitoring by your doctor for corticosteroid side effects.
- *Buprenorphine/naloxone* (medicines to treat opioid dependence)
- *Salmeterol* (medicine to treat asthma)
- *Artemether/lumefantrine* (a combination medicine to treat malaria)
- *Dasatinib, everolimus, irinotecan, nilotinib, vinblastine, vincristine* (to treat cancer)
- *Sildenafil, tadalafil, vardenafil* (for erectile dysfunction or to treat a heart and lung disorder called pulmonary arterial hypertension)
- *Glecaprevir/pibrentasvir, simeprevir* (to treat hepatitis C infection)
- *Fentanyl, oxycodone, tramadol* (to treat pain)
- *Fesoterodine, solifenacin* (to treat urologic disorders).

The dose of other medicines might need to be changed since either their own or [Invented name]'s therapeutic effect or side effects may be influenced when combined.
Tell your doctor if you take:
- *Alfentanil* (injectable strong and short-acting painkiller that is used for surgical procedures)
- *Digoxin* (to treat certain heart disorders)
- *Clarithromycin* (antibiotic)
- *Itraconazole, isavuconazole, fluconazole, posaconazole, clotrimazole* (to treat fungal infections). Voriconazole should only be taken after medical evaluation.
- *Rifabutin* (against bacterial infections)
- *Sildenafil, vardenafil, tadalafil* (for erectile dysfunction or high blood pressure in the pulmonary circulation)
- *Amitriptyline, desipramine, imipramine, nortriptyline, paroxetine, sertraline, trazodone* (to treat depression and anxiety)
- *Maraviroc* (to treat HIV infection)
- *Methadone* (to treat opioid dependence)
- *Carbamazepine, clonazepam* (to prevent seizures or to treat certain types of nerve pain)
- *Colchicine* (to treat gout or familial Mediterranean fever)
- *Bosentan* (to treat high blood pressure in the pulmonary circulation)
- *Buspirone, clorazepate, diazepam, estazolam, flurazepam, midazolam when used as injection, zoldipem* (sedative agents)
- *Perphenazine, risperidone, thioridazine* (to treat psychiatric conditions).

This is **not** a complete list of medicines. Tell your healthcare provider about ***all*** medicines that you are taking.

[Invented name] with food and drink
See section 3 'How to take [Invented name]'.

Pregnancy and breast-feeding
Tell your doctor immediately if you are pregnant, planning to become pregnant or if you are breast-feeding. Pregnant or breast-feeding mothers should not take [Invented name] with ritonavir unless specifically directed by the doctor. Pregnant or breast-feeding mothers should not take [Invented name] with cobicistat.

It is recommended that HIV infected women must not breast-feed their infants because of both 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.

Driving and using machines
Do not operate machines or drive if you feel dizzy after taking [Invented name].

[Invented name] 75 mg contains lactose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
[Invented name] 75 mg contains propylene glycol (E1520).
This medicine contains 10.42 mg propylene glycol (E1520) in each film-coated tablet.
If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

[Invented name] 150 mg contains lactose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
[Invented name] 150 mg contains propylene glycol (E1520).
This medicine contains 20.84 mg propylene glycol (E1520) in each film-coated tablet.
If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

[Invented name] 300 mg contains lactose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
[Invented name] 300 mg contains propylene glycol (E1520).
This medicine contains 41.66 mg propylene glycol (E1520) in each film-coated tablet.
If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.
[Invented name] 300 mg contains Sunset Yellow FCF Aluminum Lake (E110) which may cause allergic reactions.

[Invented name] 600 mg contains lactose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
[Invented name] 600 mg contains propylene glycol (E1520).
This medicine contains 83.33 mg propylene glycol (E1520) in each film-coated tablet.
If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.
[Invented name] 600 mg contains Sunset Yellow FCF Aluminum Lake (E110) which may cause allergic reactions.

3. How to take [Invented name]

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.
Even if you feel better, do not stop taking [Invented name] and ritonavir without talking to your doctor.

After therapy has been initiated, the dose or dosage form must not be changed or therapy must not be stopped without instruction of the doctor.

Dose for children of 3 years of age and above, weighing at least 15 kilograms who have not taken antiretroviral medicines before (your child's doctor will determine this)
The doctor will work out the right once daily dose based on the weight of the child (see table below). This dose must not exceed the recommended adult dose, which is 800 milligram [Invented name] together with 100 milligram ritonavir once a day.
The doctor will inform you on how many darunavir tablets and how much ritonavir (capsules, tablets or solution) the child must take. Tablets of other strengths are available and your doctor may have prescribed a certain combination of tablets to construct the appropriate dosing regimen. Darunavir oral suspension may also be available. Your doctor will determine whether darunavir tablets or oral suspension is right for the child.

Weight	One darunavir dose is	One ritonavir[a] dose is
between 15 and 30 kilograms	600 milligram	100 milligram
between 30 and 40 kilograms	675 milligram	100 milligram
more than 40 kilograms	800 milligram	100 milligram

[a] ritonavir oral solution: 80 milligram per milliliter

Dose for children of 3 years of age and above, weighing at least 15 kilograms who have taken antiretroviral medicines before (your child's doctor will determine this)
The doctor will work out the right dose based on the weight of the child (see table below). The doctor will determine if once daily dosing or twice daily dosing is appropriate for the child. This dose must not exceed the recommended adult dose, which is 600 milligram darunavir together with 100 milligram ritonavir two times per day or 800 milligram [Invented name] together with 100 milligram ritonavir once a day.
The doctor will inform you on how many darunavir tablets and how much ritonavir (capsules, tablets or solution) the child must take. Tablets of other strengths are available and your doctor may have prescribed a certain combination of tablets to construct the appropriate dosing regimen. Darunavir oral suspension may also be available. Your doctor will determine whether darunavir tablets or oral suspension is right for the child.

Twice daily dosing

Weight	One dose is
between 15 and 30 kilograms	375 milligram darunavir + 50 milligram ritonavir twice a day
between 30 and 40 kilograms	450 milligram darunavir + 60 milligram ritonavir twice a day
more than 40 kilograms *	600 milligram darunavir + 100 milligram ritonavir twice a day

***** For children aged 12 or more and weighing at least 40 kilograms, your child's doctor will determine if [Invented name] 800 milligram once daily dosing may be used. This cannot be administered with these tablets. Other strengths of darunavir are available.

Once daily dosing

Weight	One darunavir dose is	One ritonavir[a] dose is
between 15 and 30 kilograms	600 milligram	100 milligram
between 30 and 40 kilograms	675 milligram	100 milligram
more than 40 kilograms	800 milligram	100 milligram

[a] ritonavir oral solution: 80 milligram per milliliter

Instructions for children

- The child must take [Invented name] always together with ritonavir. [Invented name] cannot work properly without ritonavir.
- The child must take the appropriate doses of [Invented name] and ritonavir two times per day or once a day. If prescribed [Invented name] twice daily the child must take one dose in the morning, and one dose in the evening. Your child's doctor will determine the appropriate dosing regimen for your child.
- The child must take [Invented name] with food. [Invented name] cannot work properly without food. The type of food is not important.
- The child must swallow the tablets with a drink such as water or milk.

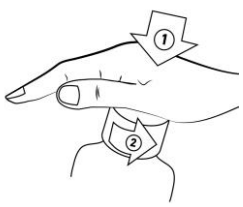
Dose for adults who have not taken antiretroviral medicines before (your doctor will determine this)
You will require a different dose of [Invented name] which cannot be administered with these tablets. Other strengths of [Invented name] are available.

Dose for adults who have taken antiretroviral medicines before (your doctor will determine this)
The dose is either:
- 600 milligram darunavir together with 100 milligram ritonavir twice daily.
  OR
- 800 milligram [Invented name] (2 tablets containing 400 milligram of [Invented name] or 1 tablet containing 800 milligram of [Invented name]) together with 100 milligram ritonavir once daily. [Invented name] 400 milligram and 800 milligram tablets are only to be used to construct the once daily 800 milligram regimen.

Please discuss with your doctor which dose is right for you.

Instructions for adults
- Take [Invented name] always together with ritonavir. [Invented name] cannot work properly without ritonavir.
- In the morning, take 600 milligram darunavir together with 100 milligram ritonavir.
- In the evening, take 600 milligram darunavir together with 100 milligram ritonavir.
- Take [Invented name] with food. [Invented name] cannot work properly without food. The type of food is not important.
- Swallow the tablets with a drink such as water or milk.
- Darunavir tablets of other strengths have been developed for use in children, but can also be used in adults in some cases. Darunavir oral suspension may also be available.

Removing the child resistant cap



The plastic bottle comes with a child resistant cap and must be opened as follows:
- Push the plastic screw cap down while turning it counter clockwise.
- Remove the unscrewed cap.

If you take more [Invented name] than you should
Contact your doctor, pharmacist or nurse immediately.

If you forget to take [Invented name]
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.

Do not stop taking [Invented name] without talking to your doctor first
Anti-HIV medicines may make you feel better. Even when you feel better, do not stop taking [Invented name]. Talk to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor if you develop any of the following side effects.

Liver problems that may occasionally be severe have been reported. Your doctor should do blood tests before you start [Invented name]. 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 pain and discomfort on your right side below your ribs.

Skin rash (more often when used in combination with raltegravir), itching. The rash is usually mild to moderate. A skin rash might also be a symptom of a rare severe situation. It is therefore important to talk to your doctor if you develop a rash. Your doctor will advise you how to deal with your symptoms or whether [Invented name] must be stopped.

Other severe side effects were diabetes (common) and inflammation of the pancreas (uncommon).

Very common side effects (may affect more than 1 in 10 people)
- diarrhoea.

Common side effects (may affect up to 1 in 10 people)
- vomiting, nausea, abdominal pain or distension, dyspepsia, flatulence
- headache, tiredness, dizziness, drowsiness, numbness, tingling or pain in hands or feet, loss of strength, difficulty falling asleep.

Uncommon side effects (may affect up to 1 in 100 people)
- chest pain, changes in electrocardiogram, rapid heart beating
- decreased or abnormal skin sensibility, pins and needles, attention disturbance, loss of memory, problems with your balance
- difficulty breathing, cough, nosebleed, throat irritation
- inflammation of the stomach or mouth, heartburn, retching, dry mouth, discomfort of the abdomen, constipation, belching
- kidney failure, kidney stones, difficult discharge of urine, frequent or excessive passage of urine, sometimes at night
- urticaria, severe swelling of the skin and other tissues (most often the lips or the eyes), eczema, excessive sweating, night sweats, hair loss, acne, scaly skin, colouration of nails
- muscle pain, muscle cramps or weakness, pain in extremity, osteoporosis
- slowing down of the thyroid gland function. This can be seen in a blood test.
- high blood pressure, flushing
- red or dry eyes
- fever, swelling of lower limbs due to fluids, malaise, irritability, pain
- symptoms of infection, herpes simplex
- erectile dysfunction, enlargement of breasts
- sleeping problems, sleepiness, depression, anxiety, abnormal dreams, decrease in sexual drive

Rare side effects (may affect up to 1 in 1,000 people)
- a reaction called DRESS [severe rash, which may be accompanied by fever, fatigue, swelling of the face or lymph glands, increase of eosinophils (type of white blood cells), effects on liver, kidney or lung]
- heart attack, slow heart beating, palpitations
- visual disturbance
- chills, feeling abnormal
- a feeling of confusion or disorientation, altered mood, restlessness
- fainting, epileptic fits, changes or loss of taste
- mouth sores, vomiting blood, inflamation of the lips, dry lips, coated tongue
- running nose
- skin lesions, dry skin
- stiffness of muscles or joints, joint pain with or without inflammation
- changes in some values of your blood cells or chemistry. These can be seen in the results of blood and/or urine tests. Your doctor will explain these to you. Examples are: increase in some white blood cells.

Some side effects are typical for anti-HIV medicines in the same family as [Invented name]. These are:
- muscle pain, tenderness or weakness. On rare occasions, these muscle disorders have been serious.

Reporting of side effects
If you get any 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 directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the bottle after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [Invented name] contains
- The active substance is darunavir.
  Each film-coated tablet of [Invented name] 75 mg contains 75 milligram of darunavir (as propylene glycolate).

  Each film-coated tablet of [Invented name] 150 mg contains 150 milligram of darunavir (as propylene glycolate).

  Each film-coated tablet of [Invented name] 300 mg contains 300 milligram of darunavir (as propylene glycolate).

  Each film-coated tablet of [Invented name] 600 mg contains 600 milligram of darunavir (as propylene glycolate).

- The other ingredients are:
  Internal Phase: Lactose monohydrate, Microcrystalline cellulose, Povidone K30, Crospovidone, Silica, colloidal anhydrous
  External Phase: Magnesium stearate

  [Invented name] 75 mg, 150 mg
  Coating (white): Polyvinyl alcohol, Titanium dioxide (E171), Macrogols, Talc

  [Invented name] 300 mg, 600 mg
  Coating (orange): Polyvinyl alcohol, Macrogols,
  Titanium dioxide (E171), Talc, Sunset Yellow FCF Aluminum Lake (E110)

What [Invented name] looks like and contents of the pack

[Invented name] 75 mg film-coated tablets
White caplet shaped tablet, debossed with "75" on one side with dimensions: Length: 9.4±0.2 mm, Width: 4.5 ± 0.2 mm and Thickness: 3.4±0.3mm.

[Invented name] 150 mg film-coated tablets
White oval shaped tablet, debossed with "150" on one side with dimensions: Length: 13.8±0.2 mm, Width: 7.0 ± 0.2 mm and Thickness: 3.6±0.3mm.

[Invented name] 300 mg film-coated tablets
Orange oval shaped tablet, debossed with "300" on one side with dimensions: Length: 16.1±0.2 mm, Width: 8.1 ± 0.2 mm and Thickness: 5.2±0.3mm.

[Invented name] 600 mg film-coated tablets
Orange oval shaped tablet, debossed with "600" on one side with dimensions: Length: 20.2±0.2 mm, Width: 10.2 ± 0.2 mm and Thickness: 6.8±0.4mm.

[Invented name] tablets are supplied in a cardboard box containing a white, opaque high density polyethylene bottle with polypropylene (PP) child resistant screw cap and induction sealing and an instruction leaflet.

Pack sizes:

[Invented name] 75 mg film-coated tablets
One bottle of 480 tablets.

[Invented name] 150 mg film-coated tablets
One bottle of 240 tablets.

[Invented name] 300 mg film-coated tablets
One bottle of 120 tablets.

[Invented name] 600 mg film-coated tablets
One bottle of 60 tablets.

Marketing Authorisation Holder

<[To be completed nationally]>

Manufacturers

Pharmathen S.A.

Dervenakion 6, Pallini 15351, Attiki Greece

Or

Pharmathen International S.A
Industrial Park Sapes,
Rodopi Prefecture, Block No 5,
Rodopi 69300,
Greece

Or

Pharmadox Healthcare Ltd.
KW20A Kordin Industrial Park,
Paola PLA 3000,
MALTA.

Or

Hormosan Pharma GmbH
Hanauer Landstraße 139-143
60314 Frankfurt am Main
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	DAVARINO
Germany	Davarino 75mg/150mg/300mg/400mg/600mg/800mg Filmtabletten
Spain	Darunavir Kern Pharma 75/150/300/600 mg comprimidos recubiertos con película EFG
United Kingdom	Darunavir 75mg/150mg/300mg/400mg/600mg/800mg film–coated tablets
Poland	Darunavir Synoptis
Greece	DAVARINO
Cyprus	DAVARINO
Romania	Darunavir Flomi 400 mg/600 mg/800 mg comprimate filmate
Austria	Darunavir Accord 75mg/150mg/400mg/600mg/800mg Filmtabletten
Czech Republic	Darunavir Accord
Slovenia	Darunavir Accord 75mg/150mg/300mg/400mg/600mg/800mg filmsko obložene tablete
Netherlands	Darunavir Accord 75mg/150mg/300mg/400mg/600mg/800mg filmomhulde tabletten
Norway	Darunavir Accord 600mg/800mg Tablett,filmdrasjert
Italy	Darunavir Accord 600mg/800mg compresse rivestite con film
Ireland	Darunavir Accord 600mg/800mg Film–coated tablets
Malta	Darunavir Accord 600mg Film–coated tablets
Bulgaria	Darunavir Accord 800mg Филмирани таблетки
Croatia	Darunavir Accord 800mg filmom obložene tablete
Finland	Darunavir Accord 400mg/600mg/800mg kalvopäällysteiset tabletit
Sweden	Darunavir Accord 400mg/600mg/800mg filmdragerade tabletter
Portugal	Darunavir Accord 400mg/600mg/800mg Comprimidos revestidos por película
France	Darunavir Accord 75mg/150mg/300mg/400mg/600mg/800mg comprimé pelliculé

This leaflet was last revised in

<[To be completed nationally]>