PACKAGE LEAFLET

Package leaflet: Information for the patient

Dailiport 0.5 mg Prolonged-release capsules, hard
Dailiport 1 mg Prolonged-release capsules, hard
Dailiport 2 mg Prolonged-release capsules, hard
Dailiport 3 mg Prolonged-release capsules, hard
Dailiport 5 mg Prolonged-release capsules, hard

tacrolimus

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dailiport is and what it is used for

Dailiport contains the active substance tacrolimus. It is an immunosuppressant. Following your organ transplant (liver, kidney), your body's immune system will try to reject the new organ. Dailiport is used to control your body's immune response, enabling your body to accept the transplanted organ.

You may also be given Dailiport for an ongoing rejection of your transplanted liver, kidney, heart or other organ when any previous treatment you were taking was unable to control this immune response after your transplantation.

Dailiport is used in adults.

2. What you need to know before you take Dailiport

Do not take Dailiport:

- if you are allergic to tacrolimus or any of the other ingredients of this medicine (listed in section 6).

- if you are allergic to sirolimus or to any macrolide-antibiotic (e.g. erythromycin, clarithromycin, josamycin)
- if you are allergic to peanut or soya.

Warnings and precautions
Tacrolimus immediate release capsules and Dailiport both contain the active substance, tacrolimus. However, Dailiport Prolonged-release capsules, hard are taken once daily, whereas Tacrolimus immediate release capsules are taken twice daily. This is because Dailiport Prolonged-release capsules allow for a prolonged release (more slow release over a longer period) of tacrolimus. Dailiport Prolonged-release capsules, hard and Tacrolimus immediate release capsules are not interchangeable.

Talk to your doctor or pharmacist before taking Dailiport:
- if you are taking any medicines mentioned below under 'Other medicines and Dailiport'
- if you have or have had liver problems
- if you have diarrhoea for more than one day
- if you feel strong abdominal pain accompanied or not with other symptoms, such as chills, fever, nausea or vomiting
- if you have an alteration of the electrical activity of your heart called "QT prolongation".

Tell your doctor immediately if during treatment you suffer from:
- problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.

Your doctor may need to adjust your dose of Dailiport.

You should keep in regular contact with your doctor. From time to time, your doctor may need to do blood, urine, heart, eye tests, to set the right dose of Dailiport.

You should limit your exposure to the sun and UV (ultraviolet) light whilst taking Dailiport. This is because immunosuppressants could increase the risk of skin cancer. Wear appropriate protective clothing and use a sunscreen with a high sun protection factor.

Children and adolescents
The use of Dailiport is not recommended in children and adolescents under 18 years.

Other medicines and Dailiport
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription and herbal preparations.

It is not recommended that Dailiport is taken with ciclosporin (another medicine used for the prevention of transplant organ rejection).

Dailiport blood levels can be affected by other medicines you take, and blood levels of other medicines can be affected by taking Dailiport, which may require interruption, an increase or a decrease in Dailiport dose. In particular, you should tell your doctor if you are taking or have recently taken medicines like:

- antifungal medicines and antibiotics, particularly so-called macrolide antibiotics, used to treat infections e.g. ketoconazole, fluconazole, itraconazole, voriconazole, clotrimazole, and isavuconazole, erythromycin, clarithromycin, josamycin, and rifampicin
- HIV protease inhibitors (e.g. ritonavir, nelfinavir, saquinavir), the booster medicine cobicistat, and combination tablets, used to treat HIV infection
- HCV protease inhibitors (e.g. telaprevir, boceprevir and the combination ombitasvir/paritaprevir/ritonavir with or without dasabuvir), used to treat hepatitis C infection
- nilotinib and imatinib (used to treat certain cancers)
- mycophenolic acid, used to suppress the immune system to prevent transplant rejection
- medicines for stomach ulcer and acid reflux (e.g. omeprazole, lansoprazole or cimetidine)
- antiemetics, used to treat nausea and vomiting (e.g. metoclopramide)
- cisapride or the antacid magnesium-aluminium-hydroxide, used to treat heartburn
- the contraceptive pill or other hormone treatments with ethinylestradiol, hormone treatments with danazol
- medicines used to treat high blood pressure or heart problems (e.g. nifedipine, nicardipine, diltiazem and verapamil)
- anti-arrhythmic drugs (amiodarone) used to control arrhythmia (uneven beating of the heart)
- medicines known as "statins" used to treat elevated cholesterol and triglycerides
- phenytoin or phenobarbital, used to treat epilepsy
- the corticosteroids prednisolone and methylprednisolone, belonging to the class of corticosteroids used to treat inflammations or suppress the immune system (e.g. in transplant rejection)
- nefazodone, used to treat depression
- herbal preparations containing St. John's Wort (*Hypericum perforatum*) or extracts of *Schisandra sphenanthera*.

Tell your doctor if you are taking or need to take ibuprofen (used to treat fever, inflammation and pain), amphotericin B (used to treat bacterial infections) or antivirals (used to treat viral infections e.g. aciclovir). These may worsen kidney or nervous system problems when taken together with Dailiport.

Your doctor also needs to know if you are taking potassium supplements or certain diuretics used for heart failure, hypertension and kidney disease, (e.g. amiloride, triamterene, or spironolactone), nonsteroidal anti-inflammatory drugs (NSAIDs, e.g. ibuprofen) used for fever, inflammation and pain, anticoagulants (blood thinners), or oral medicines for diabetes, while you take Dailiport.

If you need to have any vaccinations, please tell your doctor before.

Dailiport with food and drink
Avoid grapefruit (also as juice) while on treatment with Dailiport, since it can affect its levels in the blood.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Dailiport passes into breast milk. Therefore, you should not breast-feed whilst using Dailiport.

Driving and using machines
Do not drive or use any tools or machines if you feel dizzy or sleepy, or have problems seeing clearly after taking Dailiport. These effects are more frequent if you also drink alcohol.

Dailiport contains lactose, Sunset yellow FCF (E110), Allura red AC (E129) and soya.
Dailiport contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
Dailiport contains Sunset yellow FCF (E110), Allura red AC (E129), which may cause allergic reactions.
The printing ink used to mark Dailiport capsules contains soya lecithin. If you are allergic to peanut or soya, do not use this medicinal product.

Dailiport 0.5 mg contains tartrazine (E102).
Dailiport contains tartrazine (E102), which may cause allergic reactions.

Dailiport 2 mg contains tartrazine (E102).
Dailiport contains tartrazine (E102), which may cause allergic reactions.

3. How to take Dailiport

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. This medicine should only be prescribed to you by a doctor with experience in the treatment of transplant patients.

Make sure that you receive the same tacrolimus medicine every time you collect your prescription, unless your transplant specialist has agreed to change to a different tacrolimus medicine. This medicine should be taken once a day. If the appearance of this medicine is not the same as usual, or if dosage instructions have changed, speak to your doctor or pharmacist as soon as possible to make sure that you have the right medicine.

The starting dose to prevent the rejection of your transplanted organ will be determined by your doctor calculated according to your body weight. Initial daily doses just after transplantation will generally be in the range of 0.10 – 0.30 mg per kg body weight per day depending on the transplanted organ. When treating rejection, these same doses may be used.

Your dose depends on your general condition and on which other immunosuppressive medication you are taking.

Following the initiation of your treatment with Dailiport, frequent blood tests will be taken by your doctor to define the correct dose. Afterwards regular blood tests by your doctor will be required to define the correct dose and to adjust the dose from time to time. Your doctor will usually reduce your Dailiport dose once your condition has stabilised. Your doctor will tell you exactly how many capsules to take.

You will need to take Dailiport every day as long as you need immunosuppression to prevent rejection of your transplanted organ. You should keep in regular contact with your doctor.

Dailiport is taken orally once daily in the morning. Take Dailiport on an empty stomach or 2 to 3 hours after a meal. Wait at least 1 hour until the next meal. Take the capsules immediately following removal from the blister. The capsules should be swallowed **whole** with a glass of water. Do not swallow the desiccant contained in the aluminum bag.

If you take more Dailiport than you should
If you have accidentally taken too much Dailiport, contact your doctor or nearest hospital emergency department immediately.

If you forget to take Dailiport
If you have forgotten to take your Dailiport capsules in the morning, take them as soon as possible on the same day. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Dailiport
Stopping your treatment with Dailiport may increase the risk of rejection of your transplanted organ. Do not stop your treatment unless your doctor tells you to do so.

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

4. Possible side effects

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

Dailiport reduces your body's defence mechanism (immune system), which will not be as good at fighting infections. Therefore, you may be more prone to infections while you are taking Dailiport. Severe effects may occur, including allergic and anaphylactic reactions. Benign and malignant tumours have been reported following Dailiport treatment.

Cases of pure red cell aplasia (a very severe reduction in red blood cell counts), agranulocytosis (a severely lowered number of white blood cells) and haemolytic anaemia (decreased number of red blood cells due to abnormal breakdown) have been reported.

Very common side effects (may affect more than 1 in 10 people):
- Increased blood sugar, diabetes mellitus, increased potassium in the blood
- Difficulty in sleeping
- Trembling, headache
- Increased blood pressure
- Liver function tests abnormal
- Diarrhoea, nausea
- Kidney problems.

Common side effects (may affect up to 1 in 10 people):
- Reduction in blood cell counts (platelets, red or white blood cells), increase in white blood cell counts, changes in red blood cell counts (seen in blood tests)

- Reduced magnesium, phosphate, potassium, calcium or sodium in the blood, fluid overload, increased uric acid or lipids in the blood, decreased appetite, increased acidity of the blood, other changes in the blood salts (seen in blood tests)
- Anxiety symptoms, confusion and disorientation, depression, mood changes, nightmare, hallucination, mental disorders
- Fits, disturbances in consciousness, tingling and numbness (sometimes painful) in the hands and feet, dizziness, impaired writing ability, nervous system disorders
- Blurred vision, increased sensitivity to light, eye disorders
- Ringing sound in your ears
- Reduced blood flow in the heart vessels, faster heartbeat
- Bleeding, partial or complete blocking of blood vessels, reduced blood pressure
- Shortness in breath, disorders of the respiratory tissues in the lung, collection of liquid around the lung, inflammation of the pharynx, cough, flu-like symptoms
- Stomach problems such as inflammation or ulcer causing abdominal pain or diarrhoea, bleeding in the stomach, inflammation or ulcer in the mouth, collection of fluid in the belly, vomiting, abdominal pain, indigestion, constipation, passing wind, bloating, loose stools
- Bile duct disorders, yellowing of the skin due to liver problems, liver tissue damage and inflammation of the liver
- Itching, rash, hair loss, acne, increased sweating
- Pain in joints, limbs, back and feet, muscle spasms
- Insufficient function of the kidneys, reduced production of urine, impaired or painful urination
- General weakness, fever, collection of fluid in your body, pain and discomfort, increase of the enzyme alkaline phosphatase in your blood, weight gain, feeling of temperature disturbed
- Insufficient function of your transplanted organ.

Uncommon side effects (may affect up to 1 in 100 people):
- Changes in blood clotting, reduction in the number of all types of blood cells (seen in blood tests)
- Dehydration, inability to urinate
- Abnormal blood test results: reduced protein or sugar, increased phosphate, increase of the enzyme lactate dehydrogenase
- Coma, bleeding in the brain, stroke, paralysis, brain disorder, speech and language abnormalities, memory problems
- Clouding of the eye lens, impaired hearing
- Irregular heartbeat, stop of heartbeat, reduced performance of your heart, disorder of the heart muscle, enlargement of the heart muscle, stronger heartbeat, abnormal ECG, heart rate and pulse abnormal
- Blood clot in a vein of a limb, shock
- Difficulties in breathing, respiratory tract disorders, asthma
- Obstruction of the gut, increased blood level of the enzyme amylase, reflux of stomach content in your throat, delayed emptying of the stomach
- Inflammation of the skin, burning sensation in the sunlight
- Joint disorders
- Painful menstruation and abnormal menstrual bleeding
- Multiple organ failure, flu-like illness, increased sensitivity to heat and cold, feeling of pressure on your chest, jittery or abnormal feeling, weight loss.

Rare side effects (may affect up to 1 in 1,000 people):
- Small bleedings in your skin due to blood clots
- Increased muscle stiffness
- Blindness, deafness
- Collection of fluid around the heart
- Acute breathlessness
- Cyst formation in your pancreas
- Problems with blood flow in the liver
- Serious illness with blistering of skin, mouth, eyes and genitals; increased hairiness
- Thirst, fall, feeling of tightness in your chest, decreased mobility, ulcer.

Very rare side effects (may affect up to 1 in 10,000 people):
- Muscular weakness
- Abnormal heart scan
- Liver failure
- Painful urination with blood in the urine
- Increase of fat tissue.

Not known (frequency cannot be estimated from the available data):
- Abnormality of the optic nerve (optic neuropathy)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971;
Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dailiport

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 blister and bag after "EXP". The expiry date refers to the last day of that month. Use all the capsules within 1 year of opening the aluminium bag and before the expiry date.

Store in the original package (aluminium bag) in order to protect from light and moisture.

Take the capsule immediately after removing from the blister.

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 Dailiport contains

- The active substance is tacrolimus. Each capsule contains 0.5 mg, 1 mg, 2 mg, 3 mg or 5 mg of tacrolimus (as monohydrate).
- The other ingredients are:
  Capsule content: ethylcellulose, hypromellose, lactose, magnesium stearate.
  Capsule shell:
  Dailiport 0.5 mg Prolonged-release capsules, hard
  Brilliant blue FCF (E133), Allura red AC (E129), titanium dioxide (E171), Sunset yellow FCF (E110), gelatin, tartrazine (E102).

  Dailiport 1 mg Prolonged-release capsules, hard
  Brilliant blue FCF (E133), Allura red AC (E129), titanium dioxide (E171), Sunset yellow FCF (E110), gelatin.

  Dailiport 2 mg Prolonged-release capsules, hard
  Brilliant blue FCF (E133), Allura red AC (E129), titanium dioxide (E171), Sunset yellow FCF (E110), gelatin, tartrazine (E102).

  Dailiport 3 mg Prolonged-release capsules, hard
  Brilliant blue FCF (E133), Allura red AC (E129), titanium dioxide (E171), Sunset yellow FCF (E110), gelatin.

  Dailiport 5 mg Prolonged-release capsules, hard
  Brilliant blue FCF (E133), Allura red AC (E129), titanium dioxide (E171), Sunset yellow FCF (E110), gelatin, erythrosin (E127).

  Printing ink
  Shellac Glaze, Allura Red AC Aluminum Lake (E129), Brilliant blue FCF Aluminum Lake (E133), Sunset Yellow FCF Aluminum Lake (E110), propylene glycol (E1520), lecithin (soya), simeticone
  See section 2 "Dailiport contains lactose, Sunset yellow FCF (E110), Allura red AC (E129) and soya.".
  See section 2 "Dailiport 0.5 mg contains tartrazine (E102)."
  See section 2 "Dailiport 2 mg contains tartrazine (E102)."

What Dailiport looks like and contents of the pack
Dailiport 0.5 mg Prolonged-release capsules, hard
Gelatine capsule size 5 with a light brown body and a light yellow cap, imprinted in black with "0.5 mg", containing white to yellowish powder or compacted powder (length 10.7 – 11.5 mm).

Dailiport 1 mg Prolonged-release capsules, hard
Gelatine capsule size 4 with a light brown body and a white cap, imprinted in black with "1 mg", containing white to yellowish powder or compacted powder (length 14.0 – 14.6 mm).

Dailiport 2 mg Prolonged-release capsules, hard
Gelatine capsule size 3 with a light brown body and a dark green cap, imprinted in black with "2 mg", containing white to yellowish powder or compacted powder (length 15.6 – 16.2 mm).

Dailiport 3 mg Prolonged-release capsules, hard
Gelatine capsule size 2 with a light brown body and a light orange cap, imprinted in black with “3 mg”, containing white to yellowish powder or compacted powder (length 17.7 – 18.3 mm).

Dailiport 5 mg Prolonged-release capsules, hard
Gelatine capsule size 0 with a light brown body and a pink cap, imprinted in black with “5 mg”, containing white to yellowish powder or compacted powder (length 21.4 – 22.0 mm).

PVC/PVDC // aluminium blister with desiccant sealed in aluminium bag. The desiccant should not be swallowed.

Packs sizes: 30, 50, 60 and 100 capsules in blister and 30x1, 50x1, 60x1 and 100x1 capsules in unit-dose perforated blisters.

Number of capsules per aluminium bag:
30 capsules per 1 bag
50 capsules per 1 bag
60 capsules per 2 bags (2x30 capsules)
100 capsules per 2 bags (2x50 capsules)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturer
Lek Pharmaceuticals d.d., Trimlini 2D, Lendava 9220, Slovenia.

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

Austria	Dailiport 0,5 mg - Hartkapsel, retardiert
	Dailiport 1 mg - Hartkapsel, retardiert
	Dailiport 2 mg - Hartkapsel, retardiert
	Dailiport 3 mg - Hartkapsel, retardiert
	Dailiport 5 mg - Hartkapsel, retardiert
Belgium	Dailiport 0,5 mg capsules met verlengde afgifte
	Dailiport 1 mg capsules met verlengde afgifte
	Dailiport 3 mg capsules met verlengde afgifte
	Dailiport 5 mg capsules met verlengde afgifte
	Dailiport 2 mg capsules met verlengde afgifte
Czech Republic	Dailiport
Denmark	Dailiport
Estonia	Dailiport
Finland	Dailiport 0,5 mg depotkapseli, kova
	Dailiport 1 mg depotkapseli, kova
	Dailiport 2 mg depotkapseli, kova

	Dailiport 3 mg depotkapseli, kova
	Dailiport 5 mg depotkapseli, kova
Germany	Dailiport 0,5 mg Hartkapseln, retardiert
	Dailiport 1 mg Hartkapseln, retardiert
	Dailiport 2 mg Hartkapseln, retardiert
	Dailiport 3 mg Hartkapseln, retardiert
	Dailiport 5 mg Hartkapseln, retardiert
Iceland	Dailiport 0,5 mg forðahylki, hörð
	Dailiport 1 mg forðahylki, hörð
	Dailiport 2 mg forðahylki, hörð
	Dailiport 3 mg forðahylki, hörð
	Dailiport 5 mg forðahylki, hörð
Ireland	Dailiport 0.5 mg Prolonged-release capsules, hard
	Dailiport 1 mg Prolonged-release capsules, hard
	Dailiport 2 mg Prolonged-release capsules, hard
	Dailiport 3 mg Prolonged-release capsules, hard
	Dailiport 5 mg Prolonged-release capsules, hard
Latvia	Dailiport 0,5 mg ilgstošās darbības cietās kapsulas
	Dailiport 1 mg ilgstošās darbības cietās kapsulas
	Dailiport 2 mg ilgstošās darbības cietās kapsulas
	Dailiport 3 mg ilgstošās darbības cietās kapsulas
	Dailiport 5 mg ilgstošās darbības cietās kapsulas
Lithuania	Dailiport 0,5 mg pailginto atpalaidavimo kietosios kapsulės
	Dailiport 1 mg pailginto atpalaidavimo kietosios kapsulės
	Dailiport 2 mg pailginto atpalaidavimo kietosios kapsulės
	Dailiport 3 mg pailginto atpalaidavimo kietosios kapsulės
	Dailiport 5 mg pailginto atpalaidavimo kietosios kapsulės
Netherlands	Dailiport 0,5 mg, harde capsules met verlengde afgifte
	Dailiport 1 mg, harde capsules met verlengde afgifte
	Dailiport 2 mg, harde capsules met verlengde afgifte
	Dailiport 3 mg, harde capsules met verlengde afgifte
	Dailiport 5 mg, harde capsules met verlengde afgifte
Norway	Dailiport
Poland	Dailiport
Portugal	Dailiport
Romania	Dailiport 0,5 mg capsule cu eliberare prelungită
	Dailiport 1 mg capsule cu eliberare prelungită
	Dailiport 2 mg capsule cu eliberare prelungită
	Dailiport 3 mg capsule cu eliberare prelungită
	Dailiport 5 mg capsule cu eliberare prelungită
Slovenia	Dailiport 0,5 mg trde kapsule s podaljšanim sproščanjem
	Dailiport 1 mg trde kapsule s podaljšanim sproščanjem
	Dailiport 2 mg trde kapsule s podaljšanim sproščanjem
	Dailiport 3 mg trde kapsule s podaljšanim sproščanjem
	Dailiport 5 mg trde kapsule s podaljšanim sproščanjem
Slovakia	Dailiport 0,5 mg
	Dailiport 1 mg

	Dailiport 3 mg
	Dailiport 5 mg
Sweden	Dailiport
United Kingdom	Dailiport 0.5 mg prolonged-release hard capsules
	Dailiport 1 mg prolonged-release hard capsules
	Dailiport 2 mg prolonged-release hard capsules
	Dailiport 3 mg prolonged-release hard capsules
	Dailiport 5 mg prolonged-release hard capsules

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