Package leaflet: Information for the user

Tacni 0.5 mg hard capsules
Tacni 1 mg hard capsules
Tacni 5 mg hard capsules
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 Tacni is and what it is used for

Tacni is an immunosuppressant. Following your organ transplant (e.g. liver, kidney, heart), your body's immune system will try to reject the new organ.

Tacni is used to control your body's immune response enabling your body to accept the transplanted organ.

Tacni is often used in combination with other medicines that also suppress the immune system.

You may also be given Tacni 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.

2. What you need to know before you take Tacni

Do not take Tacni
- 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).

Warnings and precautions
Talk to your doctor before taking Tacni
- if you are taking any medicines mentioned below under 'Other medicines and Tacni'.
- if you have or have had liver problems
- if you have diarrhoea for more than one day
- if you need to receive any vaccinations

Your doctor may need to adjust your dose of Tacni.

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 Tacni.
You should limit your exposure to the sun and UV (ultraviolet) light whilst taking Tacni. 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.

Other medicines and Tacni
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tacni must not be taken with cyclosporine.

Tacni blood levels can be affected by other medicines you take, and blood levels of other medicines can be affected by taking Tacni which may require an increase or decrease in 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, such as ketoconazole, fluconazole, itraconazole, voriconazole, clotrimazole, erythromycin, clarithromycin, josamycin, and rifampicin
- HIV medicines (e.g. ritonavir), used to treat HIV infection
- medicines for stomach ulcer and acid reflux (e.g. omeprazole, lansoprazol 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)
- 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 other herbal preparations.

Tell your doctor if you are taking or need to take ibuprofen, amphotericin B or antivirals (e.g. aciclovir). These may worsen kidney or nervous system problems when taken together with Tacni.

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), non-steroidal anti-inflammatory drugs (NSAIDs, e.g. ibuprofen) used for fever, inflammation and pain, anticoagulants (blood thinners), or oral medicines for diabetes, while you take Tacni.

If you need vaccinations, tell your doctor in advance that you are taking this medicine.

Tacni with food and drink
Take Tacni on an empty stomach or 2 to 3 hours after a meal. Wait at least 1 hour until the next meal. Avoid grapefruit (also as juice) while on treatment with Tacni since it can affect its levels.

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 or pharmacist for advice before taking this medicine. Tacrolimus passes into breast milk. Therefore you should not breast-feed whilst using Tacni.

Driving and using machines
Tacrolimus may have a minor influence on the ability to drive and use machines. Do not drive or use any tools or machines if you feel dizzy or sleepy, or have problems seeing clearly after taking this medicine. These effects are more frequently observed if you also drink alcohol.

Tacni contains lactose
Tacni 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.

3. How to take Tacni

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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 twice 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 doses just after transplantation will generally be in the range of 0.075 – 0.30 mg per kg body weight per day depending on the transplanted organ.

Your dose depends on your general condition and on which other immunosuppressive medication you are taking. 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 tacrolimus capsules dose once your condition has stabilised. Your doctor will tell you exactly how many capsules to take and how often.

Tacni is taken orally twice daily, usually in the morning and evening. You should generally take Tacrolimus capsules on an empty stomach or at least 1 hour before or 2 to 3 hours after the meal. The capsules should be swallowed whole with a glass of water. Avoid grapefruit and grapefruit juice while taking Tacrolimus capsules. Do not swallow the desiccant contained in the foil wrapper.

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

If you forget to take Tacni
Do not take a double dose to make up for forgotten individual doses.
If you have forgotten to take your capsules, wait until it is time for the next dose, and then continue as before.

If you stop taking Tacni
Stopping your treatment 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.

Tacni reduces your body's own defence mechanism to stop you rejecting your transplanted organ. Consequently, your body will not be as good as usual at fighting infections. So if you are taking Tacni you may therefore catch more infections than usual such as infections of the skin, mouth, stomach and intestines, lungs and urinary tract.

Severe effects may occur, including allergic and anaphylactic reactions (you may experience: a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in

swallowing or breathing), and you may feel you are going to faint). It may be fatal. An uncommon side effect is Haemolytic Uraemic Syndrome, a disease characterised by acute kidney insufficiency (low urine output /or no urine output), microangiopathic haemolytic anaemia (decreased number of red blood cells with extreme tiredness, yellowing of the skin or eyes (jaudince) and a low platelet count with abnormal bruising or bleeding and signs of infection. It may be fatal. A rare side effect is Thrombotic Thrombocytopenic Purpura (or TTP) which is characterised by fever and bruising under the skin that may appear as red pinpoint dots, with or without unexplained extreme tiredness, confusion, yellowing of the skin or eyes (jaundice), with symptoms of acute renal failure (low urine output/or no urine output). It may be fatal. Benign and malignant tumours have been reported following treatment as a result of immunosuppression.

Possible side effects are listed according to the following categories:
Very common side effects are experienced in more than one in ten patients.
Common side effects are experienced in less than one in ten patients but in more than one per one hundred patients.
Uncommon side effects are experienced in less than one in one hundred patients but more than one per one thousand patients.
Rare side effects are experienced in less than one per one thousand patients but more than one per ten thousand patients.
Very rare side effects are experienced in less than one per ten thousand patients.

Very common side effects: affects more than 1 user in 10

- increased blood sugar, diabetes mellitus, increased potassium in the blood
- difficulty in sleeping
- trembling, headache
- increased blood pressure
- diarrhoea, nausea
- kidney problems

Common side effects: affects 1 to 10 users in 100

- reduction in blood cell counts (platelets, red or white blood cells), increase in white blood cell counts, changes in red blood cell counts
- 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, changes in the lung tissue, collection of liquid around the lung, inflammation of the throat, cough, flu-like symptoms
- inflammations or ulcers causing abdominal pain or diarrhoea, bleedings in the stomach, inflammations or ulcers in the mouth, collection of fluid in the belly, vomiting, abdominal pains, indigestion, constipation, passing wind, bloating, loose stools, stomach problems
- changes in liver enzymes and function, 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 or back, muscle cramps
- 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 feverish
- insufficient function of your transplanted organ

Uncommon side effects: affects 1 to 10 users in 1,000

- changes in blood clotting, reduction in the number of all types of blood cells
- dehydration, reduced protein or sugar in the blood, increased phosphate in the blood.
- 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
- dermatitis, burning sensation in the sunlight
- joint disorders
- inability to urinate, painful menstruation and abnormal menstrual bleedings
- failure of some organs, influenza like illness, increased sensitivity to heat and cold, feeling of pressure on your chest, jittery or abnormal feeling, increase of the enzyme lactate dehydrogenase in your blood, weight loss

Rare side effects: affects 1 to 10 users in 10,000
- 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: affects less than 1 user in 10,000
- muscular weakness
- abnormal heart scan
- liver failure, narrowing of the bile vessel
- painful urination with blood in the urine
- increase of fat tissue

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.

Reporting of side effects
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

5. How to store Tacni

- Keep this medicine out of the sight and reach of children.
- Store below 30°C
- Store in the original package (within the foil pouch) in order to protect from moisture & light.
- Do not use this medicine after the expiry date which is stated on the carton and blister after {EXP}. The expiry date refers to the last day of that month. Once the foil pouch is opened, the product should be used within 1 year.

- 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 Tacni contains
Tacni 0.5 mg hard capsules
The active substance is tacrolimus.
For 0.5mg: Each capsule contains 0.5mg of tacrolimus
The other ingredients are:
- Capsule content: Povidone K-30, Croscarmellose Sodium (E 468), Lactose anhydrous, Magnesium stearate.
- Capsule shell: Titanium dioxide (E-171), Yellow Iron Opxide (E-172), Gelatin

Tacni 1 mg hard capsules
The active substance is tacrolimus.
For 1 mg: Each capsule contains 1mg of tacrolimus
The other ingredients are:
- Capsule content: Povidone K-30, Croscarmellose Sodium (E 468), Lactose anhydrous, Magnesium stearate.
- Capsule shell: Titanium dioxide (E-171), Gelatin

Tacni 5 mg hard capsules
The active substance is tacrolimus.
For 5mg: Each capsule contains 5mg of tacrolimus
The other ingredients are:
- Capsule content: Povidone K-30, Croscarmellose Sodium (E 468), Lactose anhydrous, Magnesium stearate.
- Capsule shell: Titanium dioxide (E-171), Red Iron Oxide (E-172), Gelatin

What Tacni looks like and contents of the pack
Tacni 0.5 mg hard capsules
Ivory cap and ivory body hard shell capsules with white powder.
Tacni 0.5 mg hard capsules are supplied as blister strips containing 10 capsules within a protective foil wrapper, including a desiccant protecting the capsules from moisture. The desiccant should not be swallowed.

Tacni 1 mg hard capsules
White cap and white body hard shell capsules with white powder.
Tacni 1 mg hard capsules are supplied as blister strips containing 10 capsules within a protective foil wrapper, including a desiccant protecting the capsules from moisture. The desiccant should not be swallowed.

Tacni 5 mg hard capsules
Red cap and red body hard shell capsules with white powder.
Tacni 5 mg hard capsules are supplied as blister strips containing 10 capsules within a protective foil wrapper, including a desiccant protecting the capsules from moisture. The desiccant should not be swallowed.

Tacni is available in blister packs containing blister strips of 10 capsules each.

20, 30, 50, 50*1, 60, 90 and 100 capsules

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorization Holder
Teva Pharma B.V.
Computerweg 10,
3542 DR Utrecht
The Netherlands

Manufacturers
Laboratorios Cinfa, S.A.,
Olaz-Chipi, 10-Políg Areta 31620 Huarte-Pamplona, Navarra, Spain

Pharmachemie B.V.,
Swensweg 5, 2031 GA Haarlem, The Netherlands

Teva Pharma B.V.,
Swensweg 5, 2031 GA Haarlem, The Netherlands

Teva Operations Poland Sp. z o.o.,
Ul. Mogilska 80
31-546 Kraków
Poland

This medicinal product is authorized in the Member States of the EEA under the following names :
United Kingdom Tacni 0.5, 1 & 5 mg Hard Capsules
Austria Tacni transplant 0.5, 1 & 5 mg Hartkapseln
Belgium Tacni 0.5, 1 & 5 mg, capsules, hard
Bulgaria Такни 0.5, 1 & 5 mg капсули, твърди
Cyprus Tacni, καψάκια σκληρά
Czech Republic Tacni 0.5, 1 & 5 mg, tvrdé tobolky
Germany Tacni, Hartkapsel
Denmark Tacniteva 0.5, 1 & 5 mg
Estonia Tacni kõvakapsel 0.5, 1 & 5 mg
Greece Tacni 0.5, 1 & 5 mg καψάκια σκληρά
Spain Tacni 0.5, 1 & 5 mg cápsulas duras EFG
Finland Tacni, 0.5, 1 & 5 mg kapseli, kova
Hungary Tacni 0.5, 1 & 5 mg kemény kapszula
Ireland Tacni 0.5, 1 & 5 mg Hard Capsules
Italy Tacni 0.5, 1 & 5 mg Capsule rigide
Lithuania Tacni, 0.5, 1 & 5 mg kietos kapsulės
Luxembourg Tacni, Gélules
Latvia Tacni, Cietās kapsulas
The Netherlands Tacni 0.5, 1 & 5 mg, capsules, hard
Norway Tacni, 0.5, 1 & 5 mg kapsler, harde
Poland Tacni
Portugal Tacni 0.5, 1 & 5 mg Cápsulas
Romania Tacni, Capsule
Sweden Tacni, 0.5, 1 & 5 mg kapsel, hard
Slovenia Tacni 0.5, 1 & 5 mg trde kapsule
Slovakia Tacni 0.5, 1 & 5 mg

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