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P-3880-02

Package leaflet: Information for the patient

Lupkynis 7.9 mg soft capsules

voclosporin

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

1. What Lupkynis is and what it is used for

Lupkynis contains the active substance voclosporin. It is used for the treatment of adults from 18 years of age with lupus nephritis (inflammation of the kidney caused by lupus).

The active ingredient in Lupkynis is one of a group of medicines known as calcineurin inhibitors that can be used to control your body's immune response (immunosuppressants). In lupus, the immune system (the body's natural defences) mistakenly attacks parts of your own body, including the kidneys (lupus nephritis). By reducing the response of the immune system, the medicine reduces inflammation of your kidneys and lessens symptoms such as swelling of the legs, ankles or feet, high blood pressure, tiredness, as well as improving your kidney function.

2. What you need to know before you take Lupkynis

Do not take Lupkynis
- If you are allergic to voclosporin or any of the other ingredients of this medicine (listed in section 6).
- If you are taking other medicines such as ketoconazole tablets (used to treat Cushing's syndrome when the body produces an excess of cortisol), itraconazole or clarithromycin (used to treat certain fungal and bacterial infections).

Warnings and precautions
Talk to your doctor or pharmacist before taking Lupkynis if any of the following applies to you:
- if your kidney disease gets worse, your dose of this medicine may need to be changed. Your doctor will regularly check how well your kidneys are working.
- if you have risk factors for pure red cell aplasia (PRCA) – a rare disorder in which the bone marrow does not make enough red blood cells. Such risk factors are a former infection with parvovirus B19 or other treatments in the past that may cause PRCA.
- if you suffer from or develop high blood pressure. Your doctor will check your blood pressure every two weeks for the first month and then regularly. He/she may give you a medicine to lower your blood pressure or tell you to stop taking this medicine.
- This medicine can increase the risk of conditions of the nervous system, such as headache, shaking, changes in vision, seizures, confusion or weakness in one or more limbs. If you experience any of these new symptoms or worsening of existing symptoms, your doctor may consider stopping or lowering the dose of this medicine (see section 4).
- if you are planning to have a vaccination or have had a vaccination within the last 30 days. This medicine may affect the response to vaccination, and vaccination during treatment with this medicine may be less effective.
- if you have previously experienced sudden life-threatening allergic reactions (anaphylactic reactions) to soya or peanut, do not take this medicine.

This medicine can increase the potassium levels in your blood, which may be serious and require treatment. Your doctor will check your potassium levels periodically during treatment.

This medicine has not been studied in patients with severe liver problems and is therefore not recommended in these patients.

This medicine may influence the electrical activity of your heart (QT prolongation). This can result in serious heart rhythm disorder. Early symptoms are dizziness and fainting.

Sunlight and UV light
This medicine can increase the risk of developing certain types of cancer, particularly of the skin. You should avoid or limit your exposure to sunlight and UV light by wearing appropriate protective clothing and frequently applying sunscreen with a high protection factor.

Infections
This medicine can increase your risk of developing infections, some of which may be serious or even fatal. Contact your doctor if you have any signs of infection, such as fever, chills or sore throat. Your doctor will decide whether you need to stop taking this medicine (see section 4).

Children and adolescents
Do not take this medicine if you are under the age of 18 years because it has not been studied in this age group.

Elderly
This medicine is not recommended if you are over the age of 75 years because it has not been studied in this age group.

Other medicines and Lupkynis
Tell your doctor or pharmacist if you are taking or have recently taken or are planning to take any other medicines.

In particular, tell your doctor if you take:
- Medicines used to treat fungal infection such as itraconazole and fluconazole.
- Medicines used to treat Cushing's syndrome (when the body produces an excess of cortisol), such as ketoconazole tablets.
- Medicines used to treat high blood pressure or heart problems such as digoxin, diltiazem and verapamil.
- Medicines to prevent the formation of blood clots such as dabigatran etexilate.
- Medicines used to treat epilepsy such as carbamazepine and phenobarbital.
- Herbal preparations containing St. John's Wort, used to treat mild depression.
- Medicines for the relief of symptoms associated with seasonal allergic rhinitis such as fexofenadine.
- Antibiotic medicines used to treat bacterial infections such as rifampicin, clarithromycin and erythromycin.
- Medicines that lower cholesterol such as simvastatin, atorvastatin, rosuvastatin and pravastatin.
- Medicines used to treat HIV infections, such as the antiretroviral efavirenz.

Lupkynis with food and drink
This medicine can be taken with or without food. Avoid eating grapefruit and drinking grapefruit juice during treatment with this medicine, since these can affect how the medicine works.

Pregnancy, breast-feeding and fertility
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.

This medicine is not recommended during pregnancy and in women of childbearing potential not using contraception.

Tell your doctor if you are breast-feeding. This medicine can pass into breast milk and it is not known if this medicine can affect your baby. Your doctor will discuss with you whether to stop treatment with this medicine while you are breast-feeding, or to stop breast-feeding.

There are no data on the effect of this medicine on human fertility.

Driving and using machines
Lupkynis is not expected to have any effect on your ability to drive and use machines.

Lupkynis contains alcohol
This medicine contains 21.6 mg of alcohol (ethanol) in each capsule. Therefore, a dose of 3 capsules of Lupkynis contains 64.8 mg ethanol, which is equivalent to less than 2 mL beer or 1 mL wine. This small amount of alcohol in this medicine will not have any noticeable effects.

Lupkynis contains sorbitol
This medicine contains 28.7 mg of sorbitol in each capsule.

Lupkynis may contain soya lecithin
This medicine may contain trace amounts of soya lecithin. If you experience anaphylactic reactions to soya or peanut, you must not use this medicine.

3. How to take Lupkynis

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

The recommended dose of Lupkynis is three capsules twice daily, taken by mouth.

The capsules must be swallowed whole and can be taken with or without food.

Take the daily doses at around the same time each day, at least 8 hours apart and ideally as close to 12 hours apart as possible (for example, at 8:00 am in the morning and 8:00 pm in the evening).

This medicine should be used in combination with another immunosuppressant medicine, mycophenolate mofetil.

If you take more Lupkynis than you should
If you have accidentally taken too many capsules, contact your doctor or nearest hospital emergency department immediately. Symptoms of overdose may include a fast heartbeat and tremors (uncontrolled shaking or trembling in one or more parts of the body).

If you forget to take Lupkynis
If a dose is missed, take it as soon as possible and within 4 hours of missing the dose. If more than 4 hours have passed since the time you normally take the medicine, just skip that dose and take the next regular dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Lupkynis
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. The following side effects may happen with this medicine:

Serious side effects

If any of these occur, seek immediate medical advice as your doctor may advise you to stop taking this medicine or reduce the dose.

Very common (may affect more than 1 in 10 people)
- Symptoms of infection (such as fever, body aches, feeling tired, coughing or sneezing, nausea, vomiting or diarrhoea)

Common (may affect up to 1 in 10 people)
- Newly developing symptoms of nerve or brain problems, such as seizures

Other side effects

Very common (may affect more than 1 in 10 people)
- Upper chest infection
- Reduction in red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia)
- Headache
- Increased blood pressure
- Cough
- Diarrhoea
- Pain in the abdomen (belly)
- Changes in your kidney function which could reduce the amount of urine you produce and may cause new or worsening swelling in your legs or feet

Common (may affect up to 1 in 10 people)
- Fever, cough, difficult or painful breathing, wheezing, pain in chest when breathing (possible symptoms of pneumonia)
- Infections, that can either be bacterial such as urinary tract infections or viral such as shingles
- Inflammation of the stomach and intestines
- Flu
- Increased levels of potassium seen in blood test
- Decreased appetite
- Tremors
- Feeling sick
- Abnormal swelling, bleeding and/or inflammation of the gums
- Ulcers of mouth
- Indigestion
- Hair loss
- Excessive and/or abnormal hair growth on any part of the body
- Tiredness

Not known (frequency cannot be estimated from the available data)
- Hypersensitivity

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Lupkynis

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 blister after “EXP”. The expiry date refers to the last day of that month.
Store in the original blister in order to protect from moisture.
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 Lupkynis contains
- The active substance is voclosporin. Each soft capsule of Lupkynis contains 7.9 mg of voclosporin.
- The other ingredients are:
  Capsule content: ethanol, vitamin E (E307) polyethylene glycol succinate (tocofersolan), polysorbate 40 and medium-chain triglycerides
  Capsule shell: gelatin, sorbitol, glycerin, purified water, titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172)
  Processing aid: soya lecithin

What Lupkynis looks like and contents of the pack
Lupkynis 7.9 mg pink/orange, soft capsules measuring approximately 13 mm × 6 mm packed in blisters. Each blister contains 18 soft capsules.
One carton contains 180 or 576 soft capsules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Otsuka Pharmaceutical Netherlands B.V.
Herikerbergweg 292
1101 CT Amsterdam
Netherlands

Manufacturer
Millmount Healthcare Limited
Block-7, City North Business Campus, Stamullen, Co. Meath, K32 YD60,
Ireland

For any information about this medicine, please contact:
Otsuka Pharmaceuticals (UK) Ltd.
Tel: +44 203 747 5300

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