EMA/681545/2022
EMEA/H/C/005256

Lupkynis (*voclosporin*)

An overview of Lupkynis and why it is authorised in the EU

What is Lupkynis and what is it used for?

Lupkynis is a medicine used to treat lupus nephritis, a manifestation of a disease called systemic lupus erythematosus. In lupus nephritis, the immune system (the body's natural defences) attacks the kidneys, causing inflammation and kidney damage.

Lupkynis is used together with another medicine called mycophenolate mofetil in adults with active class III, IV or V lupus nephritis, which are severe forms of the condition.

Lupkynis contains the active substance voclosporin.

How is Lupkynis used?

The medicine can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in diagnosing and treating lupus nephritis.

Lupkynis is available as a 7.9 mg capsule to be taken by mouth. The recommended dose is 23.7 mg (equivalent to three soft capsules) twice a day, with a minimum of 8 hours between each dose. The doctor should evaluate treatment effectiveness after about 24 weeks and weigh it against the risks to decide whether to continue treatment.

For more information about using Lupkynis, see the package leaflet or contact your doctor or pharmacist.

How does Lupkynis work?

The active substance in Lupkynis, voclosporin, is an immunosuppressant (a medicine that reduces the activity of the immune system) known as a calcineurin inhibitor. This means that it blocks the action of calcineurin, an enzyme involved in activating T-lymphocytes (white blood cells that are part of the immune system and play a role in inflammation). By blocking the action of calcineurin, voclosporin reduces inflammation and other symptoms of lupus nephritis.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What benefits of Lupkynis have been shown in studies?

Lupkynis was shown to be more effective than placebo (a dummy treatment) in achieving stable kidney function in adults with active lupus nephritis. A main study involving 357 adults found that after 52 weeks, 41% (73 out of 179) of patients taking Lupkynis had acceptable measures of both kidney function and protein in the urine (a sign of kidney damage) compared with 23% (40 out of 178) of patients receiving placebo. All patients received mycophenolate mofetil (another immunosuppressant medicine) in addition to Lupkynis or placebo.

What are the risks associated with Lupkynis?

The most common side effects with Lupkynis (which may affect more than 1 in 10 people) are decreased glomerular filtration rate (a sign of kidney damage) and hypertension (high blood pressure).

The most common serious side effects with Lupkynis are infections, acute kidney injury and high blood pressure.

Lupkynis must not be used together with certain medicines called 'strong CYP3A4 inhibitors', including the antifungal medicines ketoconazole and itraconazole and the antibiotic medicine clarithromycin, as these may affect the levels of voclosporin in the blood.

For the full list of side effects and restrictions with Lupkynis, see the package leaflet.

Why is Lupkynis authorised in the EU?

When used in combination with mycophenolate mofetil, Lupkynis has been shown to be effective in achieving stable kidney function in adults with active lupus nephritis. The medicine's side effect profile is serious and requires extensive monitoring of kidney function; adequate information on the risks and recommendations for monitoring is included in the product information. The European Medicines Agency therefore decided that Lupkynis's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Lupkynis?

The company will carry out a study to provide more information on the long-term safety of Lupkynis.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Lupkynis have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Lupkynis are continuously monitored. Suspected side effects reported with Lupkynis are carefully evaluated and any necessary action taken to protect patients.

Other information about Lupkynis

Lupkynis received a marketing authorisation valid throughout the EU on 15 September 2022.

Further information on Lupkynis can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/lupkynis.

This overview was last updated in 09-2022.