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Lupkynis® (active substance: voclosporin)

First authorisation in Switzerland: 24 April 2023

Medicinal product (soft capsule) for the treatment of adult patients with severe forms of lupus nephritis

About the medicinal product

The medicinal product Lupkynis, containing the active substance voclosporin, is used to treat adult patients with severe forms of lupus nephritis (LN).

Systemic lupus erythematosus (SLE) is a relapsing-remitting autoimmune disease in which the body's defence system (the immune system) attacks its own cells and tissues. This results in inflammation and organ damage. The disease is incurable and typically affects women between 20 and 40 years of age. The most common serious complication of SLE is inflammation of the kidney tissue (lupus nephritis). It affects around 50-60% of all SLE patients. In almost one third of cases this ultimately results in end-stage kidney disease with a chronic need for dialysis. The International Society of Nephrology and the Renal Pathology Society distinguish between six classes of LN (I to VI) which are relevant for the prognosis of the disease. Lupkynis is used to treat patients with LN in classes III-V.

Since this is a rare and life-threatening disease, the medicine has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Mode of action

Voclosporin, the active substance in Lupkynis, is an immunosuppressant (calcineurin inhibitor). Immunosuppressants suppress the patient's own immune system. Calcineurin is an enzyme[1] involved in the activation of white blood cells (T-cells). Voclosporin blocks (inhibits) calcineurin, which reduces inflammation in the kidney and elsewhere and prevents kidney function from deteriorating further.

[1] Enzyme: enzymes are proteins that act as biocatalysts, controlling and accelerating biochemical reactions in the body.

Administration

Lupkynis, containing the active substance voclosporin, is a prescription-only medicine. It is available as 7.9 mg soft capsules in blister packs. The recommended dose is 23.7 mg (3 x 7.9 mg soft capsules), twice daily. Wherever possible, Lupkynis should always be taken at the same time of day with an interval of at least 8 hours between doses. The capsules should be swallowed whole and do not have to be taken at mealtimes.

Efficacy

The efficacy of Lupkynis was investigated in 2 studies (AURORA 1 and AURORA 2) involving 357 and 216 patients with LN.

The AURORA 1 study compared the efficacy of Lupkynis in adult patients with LN in classes III-V versus placebo (dummy drug) over a treatment period of 52 weeks. The patients had already received background therapy of mycophenolate-mofetil[2] and corticosteroids (powerful inhibitors of inflammation). The primary efficacy endpoint[3] was complete renal response (stable kidney function) in Week 52. The proportion of patients who achieved a complete renal response in Week 52 was significantly higher in patients treated with Lupkynis than in patients treated with placebo (40.8% versus 22.5%). The other analyses supported the results obtained for the primary endpoint.

The AURORA 2 study was an extension of the AURORA 1 study performed so that treatment in comparison with placebo could continue to be observed. This study demonstrated a sustained – and compared to placebo statistically significantly greater – clinical response in LN patients treated with Lupkynis for up to 36 months in total.

Precautions, undesirable effects, & risks

Lupkynis must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects (affecting more than 1 in 10 of those treated) are upper respiratory tract infections, anaemia (deficiency of red blood cells), headache, hypertension, cough, diarrhoea, abdominal pain, and changes in kidney function which can result in the body producing less urine and, consequently, in difficulty or pain on urination.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

LN is a life-threatening autoimmune disease which is still incurable. The results obtained with the current standard treatment are unsatisfactory and there is a major medical

[2] Mycophenolate-mofetil: a conventional medicine which suppresses the body's immune system.

[3] Primary efficacy endpoint: The primary endpoint is the main objective of the trial determined before the trial starts. If the primary endpoint is reached or exceeded, the trial proves that a treatment is effective. Secondary endpoints, on the other hand, refer to other effects that do not clearly prove efficacy or that do not allow any clear conclusions to be drawn about the actual target criterion (primary endpoint).

need for effective and safe treatment options for patients with LN.

The AURORA 1 study showed that a large proportion of the adult patients who were treated with Lupkynis in addition to a background therapy achieved stable kidney function after Week 52 compared with placebo. The AURORA 2 continuation study demonstrated the sustainability of the treatment advantage over a follow-up period of 2 years.

Taking all the risks and precautions into account, and based on the available data, the benefits of Lupkynis outweigh the risks. Swissmedic has therefore authorised the medicinal product Lupkynis, containing the active substance voclosporin, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Lupkynis®

Information for patients (package leaflet): Information for patients Lupkynis®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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