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Jayempi (*azathioprine*)

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

What is Jayempi and what is it used for?

Jayempi is an immunosuppressant medicine (a medicine that reduces the activity of the immune system) that is used, on its own or with other medicines, to:

- prevent the body from rejecting a transplanted kidney, liver, heart, lung or pancreas;
- treat relapsing multiple sclerosis, a disease of the brain and spinal cord in which inflammation attacks the protective covering (sheath) around nerves and damages the nerves themselves;
- treat generalised myasthenia gravis (a disease that affects nerves and causes muscle weakness).
- treat the following autoimmune diseases (caused by the body's own defence system attacking normal tissue) in patients for whom corticosteroid medicines are not suitable:
  - severe rheumatoid arthritis or chronic polyarthritis (long-term damage and inflammation of multiple joints) which cannot be controlled by other medicines;
  - chronic inflammatory bowel diseases (diseases of the gut such as Crohn’s disease and ulcerative colitis);
  - autoimmune hepatitis, a liver disease;
  - systemic lupus erythematosus (a condition causing swollen joints, tiredness and rashes);
  - dermatomyositis (worsening muscle inflammation and weakness together with skin rash);
  - polyarteritis nodosa (inflammation of blood vessels);
  - pemphigus vulgaris and bullous pemphigoid (diseases causing blistering of the skin and mucous membranes, moist body surfaces such as the lining of the mouth);
  - Behçet’s disease (a disease in which the immune system attacks its own blood vessels causing recurrent inflammation, especially of the eyes and the mouth and genital mucous membranes);
  - refractory autoimmune haemolytic anaemia (a disease in which the red blood cells are destroyed);

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- refractory idiopathic thrombocytopenic purpura (bleeding under the skin due to damage to the platelets and reduction of their numbers);

Jayempi is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance, but is given in a different way. The reference medicine for Jayempi is Imurek and is available as tablets, while Jayempi is available as a liquid to be taken by mouth.

Jayempi contains the active substance azathioprine.

How is Jayempi used?

Jayempi should be started by a doctor experienced in the use and monitoring of immunosuppressants. The medicine can only be obtained with a prescription.

Jayempi is taken by mouth, using the syringe provided in the pack, at least 1 hour before or 2 hours after a meal or milk. The dose depends on the disease Jayempi is being used to prevent or treat and on whether it is used alone or with other medicines, and is calculated on the basis of the patient's weight.

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

How does Jayempi work?

The active substance in Jayempi, azathioprine, is a pro-drug of 6-mercaptopurine, which means it is converted into 6-mercaptopurine in the body. It acts by blocking the production of purines, molecules that are needed by the body cells to produce DNA and RNA (genetic material). This prevents the production of genetic material in the cells (such as B and T lymphocytes) involved in the immune response, thereby suppressing the immune system.

The reference medicine, Imurek, and other medicines containing mercaptopurine in tablet form have been used in the EU for several years to treat patients with autoimmune diseases.

What benefits of Jayempi have been shown in studies?

Because azathioprine has been used for the treatment of autoimmune diseases in the EU for a number of years in tablet form, the company that markets Jayempi presented results from studies previously carried out with azathioprine tablets published in the scientific literature.

As for every medicine, the company provided studies on the quality of Jayempi. A study was also carried out to show that Jayempi is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect. Although Jayempi did not show bioequivalence to Imurek, there was no real difference in the blood concentration of 6-mercaptopurine between the two formulations. Therefore, it was concluded that no clinically relevant difference in terms of safety and effectiveness is expected between the liquid and the tablet formulation

What are the risks associated with Jayempi?

The most important side effects with Jayempi include bone marrow depression (a condition in which the bone marrow cannot make enough blood cells) that most frequently manifests as leucopenia (low white blood cell counts) and thrombocytopenia (low blood platelet counts); viral, fungal and bacterial infections; life-threatening liver injury; hypersensitivity (allergic reaction), Stevens-Johnson syndrome

and toxic epidermal necrolysis (life-threatening reactions with flu-like symptoms and painful rash and blistering in the skin, mouth, eyes and genitals).

Jayempi must not be used in people allergic to the active substance azathioprine, to 6-mercaptopurine or to any of the other ingredients. Patients must not be given any live vaccine, especially the BCG, smallpox and yellow fever vaccines, until at least 3 months after the end of treatment with azathioprine. Jayempi must not be used in breastfeeding women.

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

Why is Jayempi authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Jayempi has been shown to have comparable quality to Imurek, and that the two medicines are expected to have the same effect. The Agency also noted that the risks of using the medicine are well known.

The European Medicines Agency therefore decided that Jayempi'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 Jayempi?

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

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

Other information about Jayempi

Jayempi received a marketing authorisation valid throughout the EU on 21 June 2021.

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

This overview was last updated in 06-2021.