22 April 2021
EMA/CHMP/213654/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Jayempi

azathioprine

On 22 April 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Jayempi, intended for prophylaxis against transplant rejection and as immunosuppressive antimetabolite either alone or in combination with other agents to influence the immune response in a variety of diseases.

The applicant for this medicinal product is Nova Laboratories Ireland Limited.

Jayempi will be available as 10 mg/ml oral suspension. The active substance of Jayempi is azathioprine, an immunosuppressant (ATC code: L04AX01). Azathioprine is an inactive pro-drug of 6-mercaptopurine (6-MP), which acts as a purine antagonist.

Jayempi is a hybrid medicine[2] of Imurek 50mg film coated tablets which has been authorised in the EU since 30 November 2004. Jayempi contains the same active substance as Imurek but is presented as an oral suspension.

Studies have demonstrated the satisfactory quality of Jayempi. Jayempi did not show bioequivalence to the reference product Imurek but considering the high inter and intra-subject variability the result from the bioequivalence study was not expected to indicate any real difference with the tablet formulation in clinical practice. This was also acceptable since Jayempi and Imurek are different formulations and no strict bioequivalence was required.

The full indication is:

> Jayempi is indicated in combination with other immunosuppressive agents for the prophylaxis of transplant rejection in patients receiving allogenic kidney, liver, heart, lung or pancreas transplants. Azathioprine is indicated in immunosuppressive regimens as an adjunct to immunosuppressive agents that form the mainstay of treatment (basis immunosuppression). Jayempi is used as an immunosuppressant antimetabolite either alone or, more commonly, in combination with other agents (usually corticosteroids) and/ or procedures which influence the

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

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immune response. Jayempi is indicated in patients who are intolerant to glucocorticosteroids or if the therapeutic response is inadequate despite treatment with high doses of glucocorticosteroids, in the following diseases:

- severe active rheumatoid arthritis (chronic polyarthritis) that cannot be kept under control by less toxic agents (disease-modifying anti-rheumatic -medicinal products – DMARDs)
- auto-immune hepatitis
- systemic lupus erythematosus
- dermatomyositis
- polyarteritis nodosa
- pemphigus vulgaris and bullous pemphigoid
- Behçet's disease
- refractory auto-immune haemolytic anaemia, caused by warm IgG antibodies
- chronic refractory idiopathic thrombocytopenic purpura

Jayempi is used for the treatment of moderately severe to severe forms of chronic inflammatory bowel disease (IBD) (Crohn's disease or ulcerative colitis) in patients in whom glucocorticosteroid therapy is necessary, but where glucocorticosteroids are not tolerated, or in whom the disease is untreatable with other common means of first choice.

It is also indicated in adult patients in relapsing multiple sclerosis, if an immunomodulatory therapy is indicated but beta interferon therapy is not possible, or a stable course has been achieved with previous treatment with azathioprine.

Jayempi is indicated for the treatment of generalised myasthenia gravis. Depending on the severity of the disease, Jayempi should be given in combination with glucocorticosteroids because of slow onset of action at the beginning of treatment and the glucocorticosteroid dose should be gradually reduced after several months of treatment.

Therapy with Jayempi should be initiated by a physician experienced in the administration and monitoring of immunosuppressive medicinal products.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.