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EPAR summary for the public

Imlygic

talimogene laherparepvec

This is a summary of the European public assessment report (EPAR) for Imlygic. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Imlygic.

For practical information about using Imlygic, patients should read the package leaflet or contact their doctor or pharmacist.

What is Imlygic and what is it used for?

Imlygic is a cancer medicine used to treat adults with melanoma (a type of skin cancer) that cannot be surgically removed and that has spread to other parts of the body (but not to bone, lung, brain and other internal organs).

Imlygic is a type of advanced therapy medicine called a 'gene therapy product'. This is a type of medicine that works by delivering genes into the cells of the body. It contains the active substance talimogene laherparepvec.

How is Imlygic used?

Treatment with Imlygic should be started and given under the supervision of a doctor with expertise in the treatment of cancer.

Imlygic is available as a solution for injection in two different strengths. It is given as an injection into melanoma tumours. The first dose is given using the lower strength of Imlygic, but subsequent doses use the higher strength. The second dose is given three weeks after the first dose and treatment is continued every two weeks for at least six months, unless the doctor considers that the patient is not benefiting from the medicine. The volume to be injected depends on the size of the tumour and the

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number of tumours to be injected. For more information, see the summary of product characteristics (also part of the EPAR).

How does Imlygic work?

The active substance in Imlygic, talimogene laherparepvec, is a type of gene therapy called 'oncolytic virus'. It is derived from a weakened herpes simplex virus 1 (the cold sore virus). This virus has been modified so it can infect and multiply inside melanoma cells. Imlygic uses the melanoma cells' own machinery to multiply, eventually overwhelming melanoma cells and killing them. Although Imlygic can enter healthy cells, it is not designed to multiply inside them.

In addition, Imlygic makes the infected melanoma cells produce a protein called GM-CSF. This protein stimulates the patient's immune system (the body's natural defences) to recognise and destroy melanoma cells.

What benefits of Imlygic have been shown in studies?

Imlygic has been studied in one main study involving 436 patients with inoperable melanoma that had spread to other parts of the body (but not to bone and brain). The study, which lasted 24 months, compared Imlygic with GM-CSF injected under the skin. The main measure of effectiveness was the proportion of patients who responded to treatment and for whom the response lasted for at least six months before the patients' health declined or they required another therapy. Response to treatment was defined as reduction by at least 50% in the signs of melanoma.

When looking at the subset of patients in the study (249 patients) whose disease had not spread to the lung or other internal organs, 25% (41 out of 163) of patients treated with Imlygic had a sustained response to treatment, compared with around 1% (1 out of 86) of patients treated with GM-CSF.

What are the risks associated with Imlygic?

The most common side effects with Imlygic (which may affect more than 1 in 4 people) are tiredness, chills, pyrexia (fever), nausea (feeling sick), flu-like illness and pain at the injection site. Most of these side effects were mild or moderate in severity. The most common serious side effect (affecting around 2 in 100 people) was cellulitis (infection of the upper layers of the skin). Because Imlygic contains a herpes virus, it may reactivate at a later time causing herpes infections such as cold sores. In patients whose immune system is weak (e.g. patients with HIV), Imlygic may cause more widespread disease. Imlygic must not be used in patients with a severely impaired immune system because if the virus gets reactivated, the herpes infection could spread to other parts of the body. For the full list of all side effects and restrictions reported with Imlygic, see the package leaflet.

Why is Imlygic approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) noted that Imlygic is a therapy with a novel mechanism of action which can be a valuable addition to existing therapies for advanced inoperable melanoma, an area of unmet medical need. Patients with inoperable melanoma which had spread to other parts of the body (but not to bone, brain or lung) showed a prolonged reduction in their melanoma tumours when treated with Imlygic, although it is still not known whether this will translate into longer survival. Regarding safety, Imlygic was relatively well tolerated and most side effects were mild or moderate in severity. Thus, CHMP decided that Imlygic's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

A risk management plan has been developed to ensure that Imlygic is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Imlygic, including the appropriate precautions to be followed by healthcare professionals and patients.

The company has put in place a controlled distribution programme to qualified centres to ensure that the cold storage and handling requirements are observed and to control the distribution to the patients. As part of this programme, the medicine will only be supplied to doctors who have received appropriate educational materials on the risk of herpes infection, particularly in patients with an impaired immune system, on the risk of transmission of the virus to healthcare professionals or other close contacts of the patient (accidental exposure), and on the necessary precautions to be taken when administering and disposing of the product. Patients will also be provided with educational materials and a patient alert card informing on the risks with the medicine and how to avoid accidental exposure to Imlygic.

The company will also carry out three studies to further characterise the benefits and risks of Imlygic, including a study of Imlygic in patients with advanced melanoma that can be surgically removed.

Further information can be found in the summary of the risk management plan.

Other information about Imlygic

The European Commission granted a marketing authorisation valid throughout the European Union for Imlygic on 16 December 2015.

The full EPAR and risk management plan summary for Imlygic can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Imlygic, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2015.