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EPAR summary for the public

Vargatef

nintedanib

This is a summary of the European public assessment report (EPAR) for Vargatef. 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 Vargatef.

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

What is Vargatef and what is it used for?

Vargatef is a cancer medicine used to treat adults with a type of lung cancer known as non-small cell lung cancer.

Vargatef is used to treat a type of non-small cell lung cancer called 'adenocarcinoma', when the cancer is locally advanced, metastatic (when cancer cells have spread from the original site to other parts of the body) or locally recurrent (when the cancer has come back in the same area).

The medicine is used in combination with a chemotherapy medicine called docetaxel in patients who have already received previous treatment with chemotherapy.

Vargatef contains the active substance nintedanib.

How is Vargatef used?

Vargatef can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in the use of cancer medicines.

Vargatef is available as capsules (100 and 150 mg) to be taken by mouth, preferably with food. The recommended dose is 200 mg taken twice a day (around 12 hours apart). Because Vargatef must not be given on the same day as docetaxel and because docetaxel is given on day 1 of a 21-day treatment

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cycle, Vargatef is given on days 2 to 21 with docetaxel being given on day 1. Treatment with Vargatef may continue after stopping docetaxel, for as long as the disease improves or remains stable and the side effects are tolerable.

If severe side effects develop, the doctor may decide to interrupt treatment with Vargatef and resume it at a lower dose. If severe side effects persist, treatment should be permanently discontinued.

For further information, see the package leaflet.

How does Vargatef work?

The active substance in Vargatef, nintedanib, blocks the activity of some enzymes known as tyrosine kinases. These enzymes can be found in certain receptors (such as VEGF, FGF and PDGF receptors) on the surface of cancer cells and on the cells of the surrounding tissue (e.g. blood vessel), where they activate several processes including cell division and the growth of new blood vessels. By blocking these enzymes, nintedanib helps to reduce the growth and spread of the cancer and to cut off the blood supply that keeps cancer cells growing.

What benefits of Vargatef have been shown in studies?

In a main study involving 1,314 patients with advanced or recurrent non-small cell lung cancer that did not respond to a previous treatment, Vargatef taken in combination with docetaxel was shown to be more effective than docetaxel alone at delaying progression of the cancer. Progression-free survival (the time patients lived without their disease getting worse) was 3.5 months in patients receiving Vargatef plus docetaxel, compared with 2.7 months in patients receiving docetaxel alone. In addition, Vargatef led to an improvement in overall survival (how long patients lived) in the subgroup of patients with non-small cell lung cancer of the adenocarcinoma type: overall survival was 12.6 months in patients treated with Vargatef plus docetaxel, compared with 10.3 months in patients treated with docetaxel alone.

What are the risks associated with Vargatef?

The most common side effects with Vargatef (which may affect more than 1 in 10 people) include diarrhoea, vomiting and increased blood levels of certain liver enzymes (a sign of possible liver problems).

Vargatef must not be used in patients who are hypersensitive (allergic) to nintedanib, peanut or soya, or any of the other ingredients.

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

Why is Vargatef approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Vargatef's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP noted that Vargatef was effective at slowing down disease progression and prolonging life in the subgroup of patients with non-small cell lung cancer of the adenocarcinoma type. Regarding its safety, although more side effects were reported in patients treated with Vargatef plus docetaxel than in those treated with docetaxel alone, the side effects were considered manageable with dose reductions, supportive treatments and treatment interruptions.

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

A risk management plan has been developed to ensure that Vargatef 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 Vargatef, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Vargatef will conduct studies to find ways to identify those patients who are most likely to benefit from treatment with the medicine.

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

Other information about Vargatef

The European Commission granted a marketing authorisation valid throughout the European Union for Vargatef on 21 November 2014.

The full EPAR and risk management plan summary for Vargatef 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 Vargatef, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2014.