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# Lenvima (*lenvatinib*)

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

## What is Lenvima and what is it used for?

Lenvima is a cancer medicine used to treat adults with:

- differentiated thyroid carcinoma, a type of cancer originating from the follicular cells of the thyroid gland. Lenvima is used on its own when the cancer has progressed or spread locally or to other parts of the body, and does not respond to treatment with radioactive iodine;
- hepatocellular carcinoma (a type of liver cancer). It is used on its own in patients who did not previously receive a cancer medicine by mouth or by injection and whose cancer is advanced or cannot be removed by surgery;
- endometrial carcinoma (cancer of the lining of the womb). It is used together with another cancer medicine, pembrolizumab, in patients whose disease is advanced or has come back after previous treatment involving platinum-based cancer medicines, when surgery or radiation to cure the cancer is not possible.

Lenvima contains the active substance lenvatinib.

## How is Lenvima used?

Lenvima can only be obtained with a prescription and treatment must be started and supervised by a doctor who is experienced in using cancer medicines.

The medicine is available as capsules to be taken by mouth once daily. The recommended dose depends on the condition being treated. Treatment is continued as long as the patient continues to benefit from it without too many side effects.

To manage side effects, the doctor may decide to reduce the dose or stop treatment temporarily. In certain cases treatment should be permanently stopped.

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

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands

**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

## How does Lenvima work?

The active substance in Lenvima, lenvatinib, is a tyrosine-kinase inhibitor. This means that it blocks the activity of enzymes known as tyrosine kinases. These enzymes can be found in certain receptors (such as VEGF, FGFR and RET receptors) in cancer cells, where they activate several processes including cell division and the growth of new blood vessels. By blocking these enzymes, lenvatinib can block the formation of new blood vessels and hence cut off the blood supply that keeps cancer cells growing, and reduce their growth. Lenvatinib may also alter the activity of the immune system (the body's natural defences).

## What benefits of Lenvima have been shown in studies?

### Differentiated thyroid carcinoma

Lenvima has been shown to be more effective than placebo (a dummy treatment) at slowing down disease progression in one main study. The study involved 392 adult patients with differentiated thyroid carcinoma that had shown signs of getting worse in the previous year and did not respond to treatment with radioactive iodine. The main measure of effectiveness was how long the patients lived without their disease getting worse: in the patients taking Lenvima this was an average of 18.3 months, compared with 3.6 months in those taking placebo.

### Hepatocellular carcinoma

Lenvima has been shown to be at least as effective as the cancer medicine sorafenib at prolonging the time patients lived in one main study. The study involved 954 patients with hepatocellular carcinoma who had not previously been treated for their cancer and whose cancer could not be removed by surgery. Patients given Lenvima lived on average 13.6 months compared with 12.3 months in patients on sorafenib.

### Endometrial carcinoma

Lenvima combined with pembrolizumab has been shown to be more effective than standard treatment in a main study involving 827 patients whose cancer had got worse after platinum-based treatments. Patients lived on average 18.3 months with Lenvima plus pembrolizumab and 11.4 months with standard treatment; the time patients lived without their disease getting worse again was an average 7.2 months and 3.8 months respectively.

## What are the risks associated with Lenvima?

The most common side effects with Lenvima (which may affect more than 3 in 10 people) are hypertension (high blood pressure), diarrhoea, decreased appetite and weight, tiredness, nausea (feeling sick), proteinuria (protein in the urine), stomatitis (inflammation of the lining of the mouth), vomiting, dysphonia (hoarse voice), headache and palmar-plantar erythrodysaesthesia syndrome (PPE - rash and numbness on the palms and soles). When used in combination with pembrolizumab the most common side effects, which may affect more than 2 in 10 people, also include hypothyroidism (reduced thyroid function), arthralgia (joint pain), constipation, urinary tract infection, abdominal (belly) pain, weakness, anaemia (low red blood cell levels) and hypomagnesaemia (low levels of magnesium in the blood).

The most common serious side effects include kidney failure and impairment; problems with the heart and circulation such as heart failure, blood clots in the arteries leading to stroke or heart attack, bleeding in the brain or from swollen blood vessels in the passage from mouth to stomach, a syndrome

known as 'posterior reversible encephalopathy syndrome' characterised by headache, confusion, fits and loss of vision, liver failure, hepatic encephalopathy (brain damage due to liver failure), stroke and heart attack. For the full list of side effects with Lenvima, see the package leaflet.

Lenvima must not be taken by breastfeeding women. For the full list of restrictions, see the package leaflet.

## Why is Lenvima authorised in the EU?

The European Medicines Agency decided that Lenvima's benefits are greater than its risks and it can be authorised for use in the EU. In patients with differentiated thyroid carcinoma, the medicine showed a clinically relevant improvement in the time patients lived without their disease getting worse. In patients with advanced hepatocellular carcinoma who have a poor prognosis and few treatment options, Lenvima was as effective as sorafenib in prolonging their life. Similarly, in patients with endometrial cancer that does not respond to or comes back after platinum-based treatment, prognosis is poor, and Lenvima plus pembrolizumab offers a valuable treatment option. Regarding safety, the Agency considered that the majority of side effects with Lenvima can be adequately managed by reducing the dose or temporarily interrupting treatment; there are no unexpected safety concerns when used together with pembrolizumab.

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

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

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

## Other information about Lenvima

Lenvima received a marketing authorisation valid throughout the EU on 28 May 2015.

Further information on Lenvima can be found on the Agency's website: ema.europa.eu/medicines/human/lenvima.

This overview was last updated in 11-2021.