EMA/372914/2025
EMEA/H/C/006184

Inluriyo (*imlunestrant*)

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

What is Inluriyo and what is it used for?

Inluriyo is an anti-hormonal cancer medicine used on its own in adults to treat breast cancer that is locally advanced (has spread nearby) or metastatic (has spread to other parts of the body).

It can only be used when the cancer cells have receptors (targets) for the hormone oestrogen on their surface (oestrogen receptor-positive; ER-positive) and do not have large quantities of a receptor for human epidermal growth factor called HER2 (HER2-negative). The cancer cells must also have been shown to have a specific mutation (change) in the gene called *ESR1*.

Inluriyo is used in adults whose cancer has progressed further following previous treatment with hormone-based medicines. When the medicine is used in women who have not yet reached the menopause (pre-menopausal or perimenopausal) and men, it should be given with a luteinising hormone-releasing hormone (LHRH) agonist (a medicine that lowers blood levels of the hormones oestrogen and progesterone).

Inluriyo contains the active substance imlunestrant.

How is Inluriyo used?

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

Inluriyo is available as tablets to be taken by mouth once a day. Treatment should continue as long as the patient benefits from it or until they develop unacceptable side effects.

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

How does Inluriyo work?

ER-positive breast cancer is stimulated to grow when the hormone oestrogen attaches to ER receptors on cancer cells. The active substance in Inluriyo, imlunestrant, blocks and destroys these receptors; as a result, oestrogen no longer stimulates these cancer cells to grow which slows down the growth of the cancer.

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

What benefits of Inluriyo have been shown in studies?

A main study showed that Inluriyo increased the time adults with ER-positive, HER2-negative breast cancer with an *ESR1* mutation lived without their cancer getting worse compared with standard of care (hormone-based treatment that medical experts consider most appropriate).

The study involved 874 adults with ER-positive, HER2-negative breast cancer that was locally advanced or had started to spread, and whose cancer had come back or did not respond following previous treatment with a hormone-based medicine. The study involved participants with and without an *ESR1* mutation.

Participants were given either Inluriyo on its own, standard of care or Inluriyo given with abemaciclib, another cancer medicine. Those given Inluriyo (331 people) and standard of care (330 people) both lived on average for around 5.5 months without their cancer getting worse. However, those with an *ESR1* mutation given Inluriyo on its own (138 people) lived on average for around 5.5 months without their cancer getting worse compared with around 3.8 months for those with an *ESR1* mutation given standard of care (118 people).

What are the risks associated with Inluriyo?

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

The most common side effects with Inluriyo (which may affect more than 1 in 10 people) include increased liver enzymes (proteins) which can be a sign of liver problems, tiredness, diarrhoea, nausea (feeling sick) and vomiting.

Inluriyo must not be used in women who are breast-feeding.

Why is Inluriyo authorised in the EU?

Inluriyo was shown to be effective at increasing the time before the disease got worse in adults with ER-positive, HER2-negative breast cancer with an *ESR1* mutation that was locally advanced or had started to spread, and whose cancer did not respond following treatment with a hormone-based medicine. However, there were some limitations with the main study including a limited number of patients with an *ESR1* mutation included in the study. Furthermore, there was only a small difference between the benefits observed with Inluriyo and those achieved with standard of care.

Overall, the safety profile of Inluriyo was considered similar to that of hormone-based cancer treatments; the main difference is that more side effects affecting the stomach and gut were observed with Inluriyo compared with hormone-based treatments.

The European Medicines Agency therefore decided that Inluriyo's benefits are greater than its risks and that it can be authorised for use in the EU.

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

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

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

Other information about Inluriyo

Inluriyo received a marketing authorisation valid throughout the EU on 9 January 2026.

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

This overview was last updated in 01-2026.