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Itovebi (*inavolisib*)

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

What is Itovebi and what is it used for?

Itovebi is a medicine used in combination with two other medicines (palbociclib and fulvestrant) to treat breast cancer when the cancer cells are ER positive and HER2-negative and have a mutation in a gene called *PIK3CA*. ER-positive means that cancer cells have receptors for oestrogen hormones on their surface and HER2-negative means that they do not have large quantities of a receptor called HER2.

Itovebi is used for cancer that is locally advanced (has spread nearby) or metastatic (has spread to other parts of the body) when the cancer has come back during or within 12 months of adjuvant hormonal treatment. An adjuvant treatment is an additional treatment given after the main treatment to lower the risk of cancer coming back.

Patients previously given a type of cancer medicine called CDK 4/6 inhibitor can be given Itovebi, in combination with palbociclib and fulvestrant, only if the cancer has come back after at least 12 months since stopping treatment with the CDK 4/6 inhibitor.

Women who have not yet reached the menopause (pre-menopausal or perimenopausal) and men should also be given a luteinising hormone-releasing hormone (LHRH) agonist (a medicine that lowers blood levels of the hormones oestrogen and progesterone).

Itovebi contains the active substance inavolisib.

How is Itovebi used?

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

Itovebi is available as tablets to be taken once a day. Treatment with Itovebi should continue for as long as the patient benefits from it; treatment may be stopped or the dose reduced if the patient has unacceptable side effects.

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

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How does Itovebi work?

In patients with breast cancer whose cancer cells have a *PIK3CA* mutation, an abnormal form of the enzyme PI3K is produced that stimulates cancer cells to divide and grow in an uncontrolled way. The active substance in Itovebi, inavolisib, works by blocking the activity of the abnormal PI3K, thereby reducing the growth and spread of the cancer. Inavolisib also helps the cells to break down the abnormal PI3K protein.

What benefits of Itovebi have been shown in studies?

A main study involved 325 adults with locally advanced or metastatic hormone receptor (HR)-positive HER2-negative breast cancer with *PIK3CA* mutations, whose cancer had come back during adjuvant hormonal treatment or within 12 months of completing this treatment.

The study compared the effectiveness of inavolisib plus palbociclib and fulvestrant with that of placebo (a dummy treatment) plus palbociclib and fulvestrant. Patients given the Itovebi combination lived on average 15 months without their cancer getting worse (progression-free survival) compared with around 7 months for those given the placebo combination.

In addition, patients receiving the Itovebi combination lived for an average of 34 months (overall survival) compared with 27 months for those receiving the placebo combination.

What are the risks associated with Itovebi?

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

The most common side effects with Itovebi (which may affect more than 1 in 10 people) include hyperglycaemia (high blood sugar), stomatitis (inflammation of the lining of the mouth), diarrhoea, thrombocytopenia (low levels of blood platelets), tiredness, anaemia (low levels of red blood cells), nausea, decreased appetite, rash, headache, weight loss, vomiting and urinary tract infection (infection of the parts of the body that collect and pass out urine).

Some side effects with Itovebi can be serious. The most frequent serious side effects (which may affect up to 1 in 10 people) include anaemia, diarrhoea and urinary tract infection.

Why is Itovebi authorised in the EU?

In patients with ER-positive, HER2-negative locally advanced or metastatic *PIK3CA*-mutated breast cancer, the addition of Itovebi to palbociclib and fulvestrant increased the time patients lived until the cancer got worse and the time patients lived overall. The European Medicines Agency considered the medicine's side effects manageable, providing appropriate measures are taken to minimise the risks. The Agency therefore decided that Itovebi'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 Itovebi?

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

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

Other information about Itovebi

Itovebi received a marketing authorisation valid throughout the EU on 18 July 2025.

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

This overview was last updated in 07-2025.