Package leaflet: Information for the patient

Itovebi 3 mg film-coated tablets
Itovebi 9 mg film-coated tablets
inavolisib

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Itovebi is and what it is used for

What Itovebi is

Itovebi contains the active substance inavolisib, which belongs to a group of medicines called PI3K inhibitors.

What Itovebi is used for

Itovebi is used to treat adults with a type of breast cancer called:
- ER-positive (oestrogen receptor-positive)
- HER2-negative (human epidermal growth factor receptor 2-negative)

It is used in patients whose cancer has returned whilst receiving hormonal anti-cancer therapy or within 12 months of completing hormonal anti-cancer therapy. Itovebi is used when a patient's cancer:
- has a change (mutation) in a gene called '*PIK3CA*', and
- has spread to nearby tissue or lymph nodes or to other parts of the body ('metastatic').

In patients who have previously received treatment with a 'CDK 4/6 inhibitor' medicine, there should be at least 12 months since stopping treatment with the 'CDK 4/6 inhibitor' medicine and when the breast cancer has come back.

Before starting treatment with Itovebi, your doctor will test your cancer for a *PIK3CA* mutation.

How Itovebi works

Itovebi works by blocking the effects of a protein called 'p110 alpha'. This protein is produced by the *PIK3CA* gene. A mutation in this gene may cause cancer cells to grow and multiply more rapidly. By blocking the protein, Itovebi can reduce growth and spread of the cancer and help to destroy cancer cells.

What other medicines Itovebi is given with

Itovebi is used in combination with 'palbociclib' and 'fulvestrant', which are medicines used to treat breast cancer.

In women who have not reached menopause and in men, treatment with Itovebi will also be combined with a medicine called a luteinising hormone-releasing hormone (LHRH) agonist.

Please read the Package Leaflet for these medicines for further information.

2. What you need to know before you take Itovebi

Do not take Itovebi

- if you are allergic to inavolisib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Itovebi if you have ever had:
- high levels of sugar in your blood, diabetes, or signs of high blood sugar levels (hyperglycaemia), such as feeling very thirsty and dry mouth, needing to pass urine more often than usual, producing greater amounts of urine than usual, feeling tired, feeling sick (nausea), increased appetite with weight loss, blurred vision, and/or feeling lightheaded
- kidney problems

Tell your doctor straight away if you develop symptoms of any of the following side effects while taking Itovebi (see 'Serious side effects' in section 4 for more information):
- High blood sugar levels (hyperglycaemia) – your doctor may tell you to drink more water during treatment with Itovebi
- Inflammation of the lining of the mouth (stomatitis)

Your doctor may need to treat these symptoms, pause your treatment, reduce your dose, or permanently stop your treatment with Itovebi.

Monitoring during your treatment with Itovebi

Your doctor will do blood tests before and regularly during treatment with Itovebi. This is to monitor your blood sugar levels.

Your doctor may also ask you to monitor your blood sugar at home during treatment with Itovebi.
- Your doctor will tell you exactly when to test your blood sugar.
- This will be needed more often in the first 4 weeks of treatment. If you are not sure how to test your blood sugar, talk to a doctor, pharmacist, or nurse.

Based on the results, your doctor will take any necessary actions - such as prescribing a medicine to lower blood sugar levels. If necessary, your doctor may decide to pause treatment with Itovebi - or reduce your Itovebi dose to decrease your blood sugar levels. Your doctor may also decide to stop Itovebi treatment permanently.

Children and adolescents

This medicine should not be given to children and adolescents below 18 years of age. This is because Itovebi has not been studied in this age group.

Other medicines and Itovebi

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Itovebi may increase or reduce the effectiveness of some medicines. This includes medicines obtained without a prescription and herbal medicines.

In particular, tell your doctor or pharmacist if you are taking:
- alfentanil (medicine to treat pain and for anaesthesia)
- astemizole (medicine to treat allergies)
- cisapride (medicine to treat heartburn and acid reflux)
- paclitaxel (medicine to treat various cancers)
- quinidine (medicine to treat certain types of irregular heartbeats)
- warfarin (medicine to treat or prevent blood clots)
- medicines to prevent seizures or fits (such as phenytoin and S-mephenytoin)
- medicines that affect the immune system (cyclosporine, sirolimus, and tacrolimus)

The medicines listed here may not be the only ones that could interact with Itovebi. Ask your doctor or pharmacist if you are not sure whether your medicine is one of the medicines listed above.

Pregnancy

- You should not take Itovebi if you are pregnant. This is because it is possible that Itovebi could harm your unborn baby.
- If you are able to become pregnant, your doctor will check you are not already pregnant before starting you on treatment with Itovebi. This may include having a pregnancy test.
- If you become pregnant while taking the medicine, tell your doctor right away.
- If you or your partner are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Contraception for men and women

- If you are a woman who is able to become pregnant, you should use a non-hormonal method of birth control during treatment and for 1 week after stopping Itovebi. Ask your doctor or pharmacist about suitable methods.
- If you are male and have a female partner who are or can become pregnant, you should use a condom during treatment and for 1 week after stopping Itovebi.

Breast-feeding

- You should not breast-feed while taking Itovebi and for 1 week after stopping Itovebi. This is because it is not known if this medicine can pass into breast milk and harm your baby.

Driving and using machines

Itovebi may affect your ability to drive and use machines. If you feel tired while taking Itovebi, take special care when driving or using tools or machines. You should not drive or use machines until you are sure that your ability to perform such activities is not affected.

Itovebi contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Itovebi

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much Itovebi to take

The usual starting dose of Itovebi is 9 mg taken once a day.

Your doctor will decide on the right dose for you. However, you may be prescribed:
- 6 mg once a day, or
- 3 mg once a day

Depending on how you respond to the treatment with Itovebi, your doctor may adjust your Itovebi dose. If you have certain side effects, your doctor may ask you to change to a lower dose, to pause treatment for a time, or to stop treatment.

How to take Itovebi

Take Itovebi once a day with or without food. Taking Itovebi at the same time each day will help you to remember when to take your medicine.

Itovebi tablets should be swallowed whole; they should not be chewed, crushed or split before swallowing. You should not swallow any tablet that is broken, cracked or otherwise damaged as you may not be taking the full dose.

How long to take Itovebi

Keep taking Itovebi every day for as long as your doctor tells you.

This is a long-term treatment - possibly lasting for months or years. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If you have questions about how long to take Itovebi, talk to your doctor or to your pharmacist.

If you take more Itovebi than you should

If you take more Itovebi than you should, talk to your doctor or go to the hospital straight away. Take the medicine pack and the package leaflet with you.

If you forget to take Itovebi

If you miss a dose of Itovebi, you may still take it up to 9 hours after the time you should have taken it.
- If it has been more than 9 hours from the time you should have taken it, skip the dose for that day.
- The next day, take the dose at your usual time.

Do not take a double dose to make up for a forgotten dose.

If you vomit right after taking a dose of Itovebi

If you vomit after taking a dose of Itovebi, do not take an extra dose on that day. Take your regular dose of Itovebi at your usual time the next day.

If you stop taking Itovebi

Do not stop taking Itovebi unless your doctor tells you to stop or you have serious side effects (see section 4 'Possible side effects'). This is because stopping treatment may make your illness worse.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Talk to your doctor if you experience the following side effects during treatment with Itovebi. Your doctor may need to treat these symptoms, temporarily pause your treatment, reduce your dose, or permanently stop your treatment with Itovebi.

Serious side effects

If you have any of these side effects, stop taking this medicine and tell your doctor straight away:

- High blood sugar (hyperglycaemia) (very common; may affect more than 1 in 10 people), symptoms include:
    - difficulty breathing
    - nausea and vomiting (lasting more than 2 hours)
    - stomach pain, feeling very thirsty or dry mouth
    - passing urine more often than usual or passing greater amounts of urine than usual,
    - blurred vision
    - unusually increased appetite
    - weight loss, fruity-smelling breath
    - flushed face and dry skin, and feeling unusually sleepy or tired
- Inflammation of the lining of the mouth (stomatitis) (very common; may affect more than 1 in 10 people), symptoms include:
    - pain
    - redness
    - swelling
    - ulcers in the mouth
- A serious complication of high blood sugar that involves high blood levels of ketones that can make blood more acidic (ketoacidosis) (uncommon; may affect up to 1 in 100 people), symptoms may include:
    - difficulty breathing
    - headache
    - nausea
    - vomiting

Other side effects

Tell your doctor or pharmacist if you notice any of the following side effects or if they get worse:

Very common (may affect more than 1 in 10 people)

- diarrhoea

- low levels of platelets (helps the blood to clot), which may cause unusual bruising or bleeding (thrombocytopenia)
- tiredness
- low levels of red blood cells (anaemia), which may cause tiredness, feeling unwell, and pale skin
- feeling sick (nausea)
- rash
- loss of appetite
- headache
- hair loss or hair thinning (alopecia)
- weight loss
- increased levels of alanine aminotransferase (a type of liver enzyme) seen in blood test
- low levels of potassium seen in blood test
- abdominal pain
- vomiting
- dry skin
- urinary tract infection

Common (may affect up to 1 in 10 people)

- low levels of calcium seen in blood test
- dry eye
- indigestion (dyspepsia)
- high levels of insulin (a hormone that helps the body use sugar for energy) seen in blood test
- disturbed sense of taste (dysgeusia)
- skin inflammation with rash (dermatitis)
- infection or inflammation of hair follicles (folliculitis)

Tell your doctor or pharmacist if you notice any of these side effects or if they get worse.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Itovebi

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use this medicine if you notice any damage to the packaging or if there are any signs of tampering, or if the tablet is broken, cracked, or otherwise not intact.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Itovebi contains

- The active substance is inavolisib.
- Each 3 mg film-coated tablet contains 3 mg inavolisib.
- Each 9 mg film-coated tablet contains 9 mg inavolisib.

The other ingredients are:
- Tablet core (3 mg and 9 mg film-coated tablets): lactose monohydrate, magnesium stearate (E 470b), microcrystalline cellulose (E 460), sodium starch glycolate (see section 2 'Itovebi contains lactose and sodium').
- Film-coating (3 mg film-coated tablets): polyvinyl alcohol, partially hydrolysed; titanium dioxide (E 171); macrogol; talc (E 553b); and iron oxide red (E 172).
- Film-coating (9 mg film-coated tablets): polyvinyl alcohol, partially hydrolysed; titanium dioxide (E 171); macrogol; talc (E 553b); iron oxide red (E 172); and iron oxide yellow (E 172).

What Itovebi looks like and contents of the pack

Itovebi 3 mg film-coated tablets (tablets) are red and round convex-shaped with an "INA 3" debossing on one side. Approximate diameter: 6 mm.

Itovebi 9 mg film-coated tablets (tablets) are pink and oval-shaped with an "INA 9" debossing on one side. Approximate size: 13 mm (length), 6 mm (width).

The Itovebi film-coated tablets are provided in cartons containing 28 × 1 film-coated tablets in perforated unit-dose blisters.

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