

PATIENT INFORMATION
ITOVEBI™ (eye-TOVE-bee)
(inavolisib)
tablets, for oral use

Important: ITOVEBI is used with palbociclib and fulvestrant. You should also read the Patient Information that comes with palbociclib and fulvestrant.

What is ITOVEBI?

ITOVEBI is a prescription medicine used in combination with the medicines palbociclib and fulvestrant to treat adults who have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer that has an abnormal phosphatidylinositol-3-kinase catalytic subunit alpha (*PIK3CA*) gene, and has spread to nearby tissue or lymph nodes (locally advanced), or to other parts of the body (metastatic), and has come back after hormone (endocrine) therapy.

Your healthcare provider will test your cancer for abnormal *PIK3CA* genes to make sure that ITOVEBI is right for you. It is not known if ITOVEBI is safe and effective in children.

Before you take ITOVEBI, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of diabetes or high blood sugar.
- have kidney problems.
- are pregnant or plan to become pregnant. ITOVEBI can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider will check to see if you are pregnant before you start treatment with ITOVEBI.
- You should use effective non-hormonal birth control (contraception) during treatment with ITOVEBI and for 1 week after your last dose. Talk to your healthcare provider about what birth control method is right for you during this time.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with ITOVEBI.

Males with female partners who are able to become pregnant:

- You should use effective birth control (contraception) during treatment with ITOVEBI and for 1 week after your last dose.
- are breastfeeding or plan to breastfeed. It is not known if ITOVEBI passes into your breastmilk. Do not breastfeed during treatment with ITOVEBI and for 1 week after your last dose. Talk to your healthcare provider about the best way to feed your baby during treatment with ITOVEBI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take ITOVEBI?

- Take ITOVEBI exactly as your healthcare provider tells you to take it.
- Do not change your dose or stop taking ITOVEBI unless your healthcare provider tells you.
- Take ITOVEBI 1 time each day, at about the same time each day.
- Take ITOVEBI with or without food.
- Swallow ITOVEBI tablet(s) whole. Do not chew, crush, or split the tablet(s).
- If you miss a dose of ITOVEBI, you may still take your missed dose within 9 hours from the time you usually take it. If it has been more than 9 hours after you usually take your dose, skip the dose for that day. The next day, take the dose at your usual time.
- 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.
- For women who have not reached menopause or are just starting menopause, your healthcare provider will prescribe a medicine called luteinizing hormone-releasing hormone (LHRH) agonist. For men, your healthcare provider may prescribe a LHRH agonist.

What are the possible side effects of ITOVEBI?

ITOVEBI may cause serious side effects, including:

- **High blood sugar levels (hyperglycemia).** High blood sugar is common with ITOVEBI and may be severe. Your healthcare provider will monitor your blood sugar levels before you start and during treatment with ITOVEBI. Your blood sugar levels may be monitored more often if you have a history of Type 2 diabetes. Your healthcare provider may also ask you to self-monitor and report your blood sugar levels at home. This will be required more frequently in the first 4 weeks of treatment. If you are not sure how to test your blood sugar levels, talk to your healthcare provider. You should stay well-hydrated during treatment with ITOVEBI.

Tell your healthcare provider right away if you develop symptoms of high blood sugar, including:

- difficulty breathing
- nausea and vomiting (lasting more than 2 hours)
- stomach pain
- excessive thirst
- dry mouth
- more frequent urination than usual or a higher amount of urine than normal
- blurred vision
- unusually increased appetite
- weight loss
- fruity-smelling breath
- flushed face and dry skin
- feeling unusually sleepy or tired
- confusion

• **Mouth sores (stomatitis).** Mouth sores are common with ITOVEBI and may be severe. Tell your healthcare provider if you develop any of the following in your mouth:

- pain
- redness
- swelling
- ulcers

• **Diarrhea.** Diarrhea is common with ITOVEBI and may be severe. Severe diarrhea can lead to the loss of too much body water (dehydration) and kidney injury. Tell your healthcare provider right away if you develop diarrhea, stomach-area (abdominal) pain, or see mucus or blood in your stool during treatment with ITOVEBI. Your healthcare provider may tell you to drink more fluids or take medicines to treat your diarrhea.

Your healthcare provider may tell you to decrease your dose, temporarily stop your treatment, or completely stop your treatment with ITOVEBI if you develop certain serious side effects.

The most common side effects and abnormal blood test results of ITOVEBI when used in combination with palbociclib and fulvestrant include:

- decreased white blood cell counts, red blood cell counts, and platelet counts
- decreased blood levels of calcium, potassium, sodium, and magnesium
- increased creatine blood levels
- tiredness
- increased blood levels of the liver enzyme alanine transaminase (ALT)
- nausea
- rash
- loss of appetite
- COVID-19 infection
- headache

ITOVEBI may affect fertility in males and in females who are able to become pregnant. Talk to your healthcare provider if this is a concern for you.

These are not all the possible side effects of ITOVEBI.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ITOVEBI?

- Store ITOVEBI at room temperature between 68°F to 77°F (20°C to 25°C).

Keep ITOVEBI and all medicines out of the reach of children.

General information about the safe and effective use of ITOVEBI.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ITOVEBI for a condition for which it was not prescribed. Do not give ITOVEBI to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ITOVEBI that is written for health professionals.

What are the ingredients in ITOVEBI?

Active ingredient: inavolisib

Inactive ingredients: lactose, magnesium stearate, microcrystalline cellulose, and sodium starch glycolate. The tablet film-coating contains iron oxide red, and iron oxide yellow (in the 9 mg tablet only), macrogol/polyethylene glycol, polyvinyl alcohol (partially hydrolyzed), talc, and titanium dioxide.

Distributed by: **Genentech USA, Inc.**, A Member of the Roche Group, 1 DNA Way, South San Francisco, CA 94080-4990

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For more information, go to www.ITOVEBI.com or call 1-877-436-3683.