

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:

