

Inavolisib (Itovebi) Palbociclib (Ibrance) Fulvestrant (Faslodex)

Oral Targeted Therapy Teaching

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What is Oral Targeted Cancer Therapy?

- Oral targeted therapy is oral cancer therapy that is taken by mouth and comes in a tablet or capsule form.
- It may be prescribed along with other types of cancer therapies such as chemotherapy or hormone therapy.
- Oral targeted therapy “targets” the changes in cells that cause cancer.
- It can identify and attack certain types of cancer cells and can impact the environment in which a cancer cell grows, or it can target and alter cells that help cancer grow.

What are Inavolisib, Palbociclib, and Fulvestrant?

- They are three separate medications that are used together as a treatment regimen.
- You may hear them referred to by their brand names:
 - Inavolisib (Itovebi)
 - Palbociclib (Ibrance)
 - Fulvestrant (Faslodex)
- **Fulvestrant** will be given in clinic intramuscularly (into the muscle)
- **Inavolisib** and **palbociclib** are taken by mouth at home

Inavolisib (Itovebi)

- Inavolisib belongs to a class of medications called phosphatidylinositol-3-kinase (PIK3CA) inhibitors and is a type of oral targeted therapy.
- It works by blocking the PIK3CA pathway, causing cancer cells to stop growing and die.
- **How to take inavolisib:**
 - **Take the tablet(s) by mouth once daily, with or without food**
 - Take tablets at the same time each day. Swallow the tablets whole with water. Do not break, chew, or crush the tablets.
 - If you miss a dose, take it as soon as you remember. You can take the missed dose up to **9 hours** after the regularly scheduled dose time. After >9 hours, skip the missed dose and take the next dose at the normal scheduled time. Do not take 2 doses at the same time to make up for a missed dose. Do not take another dose if vomiting occurs.
 - You can take this medication at the same time as palbociclib

Palbociclib (Ibrance)

- Palbociclib belongs to a class of medications called CDK4/6 inhibitors and is a type of oral targeted therapy.
- It works by blocking a protein called cyclin-dependent kinase 4 & 6 (CDK4/6) to disrupt breast cancer cell growth and slow tumor progression
- **How to take palbociclib:**
 - **Take the tablet by mouth once daily, with or without food, for 21 days, followed by a 7-day break to complete a 28-day cycle**
 - Take tablets at the same time each day. Swallow the tablets whole with water. Do not break, chew, or crush the tablets.
 - If you miss a dose, skip the dose and continue your regular dosing schedule. **Do not** take 2 doses at the same time to make up for the missed dose.
 - For more info: <https://www.massgeneral.org/assets/mgh/pdf/cancer-center/breast-cancer/palbociclib.pdf>

Fulvestrant (Faslodex)

- Fulvestrant is a hormonal therapy that binds to estrogen receptors on breast cancer cells and blocks estrogen. This causes the cancer to stop growing or shrink.
- This medication works with inavolisib and palbociclib to have an even greater effect on stopping growth of cancer cells.
- This medication will be given to you in clinic— you do not need a prescription for this medication
- **Fulvestrant will be given intramuscularly (into the muscle) once every 2 weeks for the first 3 doses, and then monthly thereafter**

How to Keep Track of Your Oral Targeted Therapy Schedule

- Create a medicine calendar either on paper or in your tablet or phone to keep track of your doses.
- Share the calendar with your cancer treatment team at visits.
- Pill boxes can be used to keep track of your oral chemotherapy doses. Do not mix other pills in the box you use for your oral chemotherapy.

Side Effects of Inavolisib, Palbociclib, and Fulvestrant

Inavolisib

- Diarrhea
- High blood sugar
- Mouth sores
- Fatigue
- Nausea
- Rash
- Decreased appetite
- Headache
- Low blood counts
 - Decrease in white blood cells that fight infection
 - Decrease in red blood cells that deliver oxygen throughout the body

Palbociclib

- Fatigue
- Nausea
- Diarrhea
- Headache
- Hair thinning
- Rash
- Cough
- Infections
- Low blood counts – including white blood cells, red blood cells, and platelets (which help blood to clot)

Fulvestrant

- Redness or irritation at the injection site
- Hot flashes
- Mild upset stomach
- Tiredness
- Muscle, joint, or bone pain

Drug Interactions

- Some drugs or supplements should not be taken at the same time as other drugs because they can cause side effects or cause the drug to not work well. This is called a drug interaction.
- Tell your treatment team of **ALL** prescription and over-the-counter medications (this includes vitamins and herbal products)
- Some common interactions include:
 - ☐ Black Cohosh
 - ☐ Ginseng supplements
 - ☐ Red Clover
 - ☐ St John's Wort
 - ☐ Grapefruit, grapefruit juice, pomegranate juice
- Talk with your treatment team or pharmacist before starting any new medications or supplements

Managing High Blood Sugar (Hyperglycemia)

- Inavolisib can cause new or worsening high blood sugar. Tell your doctor if you have a history of high blood sugar or diabetes.
- Your blood sugar levels will be closely monitored by your treatment team.
 - *Typically, this may occur once every 3 days for the first week, then once every week for the next 3 weeks, then once every 2 weeks for the next 8 weeks, then once every 4 weeks thereafter.*
- You may be asked to check your blood sugar at home as well. Your treatment team will let you know if this is necessary.
- Some patients need to start medication, such as metformin, to help lower their blood sugar while taking inavolisib. Your treatment team will let you know if this is necessary.
- Consuming a diet low in carbohydrates is helpful to maintain control of your blood sugar while taking inavolisib.

Treating Diarrhea

Diet:

- Eat a bland diet that is easy to digest until diarrhea resolves
- BRAT diet: bananas, rice, applesauce, toast
- Do not eat high fiber foods (raw vegetables/fruits, whole grains, nuts, seeds, beans)
- Do not have dairy, alcohol, caffeine, spicy and fried foods

Stay Hydrated:

- Drink 8-10 glasses (64-80 ounces) of non-caffeinated, non-carbonated beverages daily
- Gatorade, Pedialyte, or other beverages with electrolytes may be recommended with severe diarrhea

Medication for Treating Diarrhea

- Imodium (loperamide) is the medication of choice to treat diarrhea. It is available over the counter.
- **Instructions for use:**
 - **Take 2 tablets (4mg) with your first loose/watery stool**
 - **Then take 1 tablet (2mg) every 2-4 hours thereafter**
 - **Do not take more than 8 tablets (16mg) in 24 hours without contacting your doctor**
- Contact your care team if you continue to experience diarrhea after taking Imodium for 24 hours
- Refer to <https://www.massgeneral.org/assets/mgh/pdf/cancer-center/breast-cancer/bowel-management.pdf> for more information.

Preventing Mouth Sores

- Perform good mouth care. Brush your teeth gently with a soft toothbrush after meals and before bed.
- Avoid mouthwashes that contain alcohol
- Drink water (at least 8 glasses per day) or spray your mouth with water throughout the day
- Suck on sugar-free candy or chew sugar-free gum
- Moisten lips with plain, non-medicated lip balm (avoid menthol)

Medication to Prevent Mouth Sores

- Dexamethasone mouthwash will also be prescribed to prevent mouth sores.
- **Instructions for use:**
 - **Swish 1 mg (10 mL) for 2 minutes and then spit, four times daily**
 - **Avoid food or drink within 1 hour after using the mouthwash**
- Medication management
 - If you develop severe mouth pain or mouth pain that interferes with eating, drinking, or swallowing, we may prescribe a numbing mouth rinse or oral pain medication
 - Refer to <https://www.massgeneral.org/assets/mgh/pdf/cancer-center/breast-cancer/mouth-care.pdf> for more information

Preventing Infection

Important steps to prevent infection:

- Practice hand hygiene: wash hands frequently especially before eating, after use of the bathroom and after contact with high touch surfaces under warm water with soap, towel dry
- Wipe down high touch with moist cleaning wipes
- Stay away from large crowds and gatherings
- Do not go near anyone who is sick
- Do not clean up animal droppings, animal cages, and tanks

Supportive Care Resources

- Yoga
- Acupuncture / Acupressure
- Massage
- Support groups
- Survivorship programs
- Workshops
- Music therapy, Art therapy
- To learn more about all our Supportive Care offerings log onto cancercenterpx.org

Storage and Handling

- Keep these medicines in their original bottle or separate pill box – do not mix other medications into the pill box.
- Store at room temperature in a dry location away from direct light.
- Keep these medicines out of reach from children and pets.
- Wash your hands before and after handling these medicines.

Disposal

- If you have unused medication, do not throw it in the trash and do not flush it down the sink/toilet.
- You may dispose of this medication by:
 1. Calling your city or county's trash and recycling service for information on hazardous drug take-back programs in your community.
 2. Bringing unused oral targeted therapy to MGH Boston and disposing in the blue drug take-back receptacles located outside of the Main Lobby Yawkey elevators or near the retail pharmacy in the Wang building.
 3. Asking your treatment team or pharmacist for more information.

Sexuality and Birth Control

- It is fine to be sexually active while receiving inavolisib and palbociclib.
- **Inavolisib and palbociclib can harm a developing baby.** You should not get pregnant or get someone pregnant while on inavolisib or palbociclib.
- Use a reliable birth control during treatment and for at least 3 weeks after receiving the last dose of palbociclib and 1 week after receiving the last dose of inavolisib.
- Use a protective barrier such as a condom throughout palbociclib and inavolisib treatment. This is also to protect your partner from exposure through body fluids.

Fertility

- Infertility means you cannot become pregnant or make someone pregnant. Infertility can be temporary or permanent.
- **Palbociclib** may affect fertility in men. Palbociclib has not been shown to affect fertility in women.
- There isn't enough information to know if **inavolisib** affects fertility. No studies have been conducted to evaluate the potential effects of fertility with inavolisib in humans.
- Do not breastfeed during treatment and for at least 3 weeks after receiving the last dose of palbociclib and 1 week after the last dose of inavolisib. This is to protect your infant from exposure through breast milk.
- Before starting treatment, talk with your treatment team about your fertility and what you can do.
 - Sperm banking for men and egg harvesting for women may be options before starting treatment.
 - Women can still get pregnant even if their menstrual period changes or stops. **Always use a reliable form of birth control.**

Your Breast Cancer Team

- Oncologist
- Nurse Practitioner
- Pharmacist
- Oncology Social Worker
- Practice Nurse
- Infusion Nurse

When to call?

If experiencing:

- Fever of 100.4F (38C) or higher
- Chills
- Bleeding/unusual bruising
- Sore throat or trouble swallowing
- Dizziness
- Problems with urination
- Uncontrolled nausea, vomiting
- Uncontrolled diarrhea
- Flu-like symptoms
- Extreme fatigue or weakness
- Cough or shortness of breath
- Confusion or agitation
- Rapid heartbeat
- New swelling in arms/legs, face
- Uncontrolled pain or new pain
- Fasting blood sugar >160 mg/dL or signs of high blood sugar (excessive thirst, dry mouth, increased appetite with weight loss, and increased urination)
- COVID-19 or other infectious disease exposures

Contact Information

- For urgent matters, please call. For all other non-urgent matters, please use the patient portal
- **Phone Numbers:**
 - Boston: 617-726-6500
 - Waltham: 781-487-6100
 - Danvers: 978-882-6060
- **Patient Portal:**
 - patientgateway.org



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