

# ITOVEBI

Inavolisib (3mg, 9mg)

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## What ITOVEBI is used for

ITOVEBI contains the active ingredient inavolisib. ITOVEBI is an anti-cancer medicine used in combination with medicines called palbociclib and fulvestrant.

ITOVEBI is used to treat adults with a type of breast cancer called hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer, where, following surgery, that cancer:

- has spread to nearby tissue or lymph nodes (locally advanced), or to other parts of the body (metastatic), and
- is currently being treated with a category of medicines called endocrine therapy, or it is within 12 months of completing endocrine therapy, and
- has a change in a gene called 'PIK3CA.'

## How ITOVEBI works

ITOVEBI works by blocking the action of a protein called "p110 alpha". p110 alpha is encoded by the *PIK3CA* gene (the *PIK3CA* gene contains the blueprint for the production of the p110 alpha protein).

- *PIK3CA* is a gene that controls a pathway that is commonly disturbed in cancer. This pathway is called the PI3K cancer signalling pathway.
- When changed (mutated) due to a mutation in *PIK3CA*, the p110 alpha protein causes cancer cells to grow and multiply faster.
- By blocking the action of p110 alpha protein, ITOVEBI can reduce

the growth and spread of the cancer and help to destroy cancer cells. ITOVEBI is given on a prescription by a doctor.

## Before you use ITOVEBI

### - When you must not use it

Do not take ITOVEBI if you are allergic (hypersensitive) to inavolisib or any of the other ingredients of ITOVEBI (see section "Product Description").

If you are not sure, ask your doctor or pharmacist.

## Pregnancy

- You must not take ITOVEBI if you are pregnant, as ITOVEBI may be harmful to your unborn child.
- If you are able to become pregnant, your doctor will make sure that you are not already pregnant before starting treatment with ITOVEBI. This could mean that a pregnancy test will be conducted.
- If you do become pregnant during treatment with ITOVEBI, tell your doctor straight away.
- If you are planning to become pregnant, ask your doctor or pharmacist for advice before taking this medicinal product.

## Contraception in women

Women of childbearing potential should use non-hormonal contraception during treatment and for 1 week after stopping ITOVEBI. Ask your doctor or pharmacist which methods are suitable. If you think that you may have become pregnant after starting treatment with ITOVEBI, tell your doctor immediately.

## Breast-feeding

You must not breast-feed during treatment with ITOVEBI and for 1 week after taking the last dose of ITOVEBI, as it is not known if this medicine product passes into breast milk and could therefore cause harm to the baby.

### - Before you start to use it

Tell your doctor or pharmacist before you start using ITOVEBI if you have diabetes or signs of high blood sugar, such as:

- Strong thirst and dry mouth
- Need to urinate more often than usual
- Larger amounts of urine than usual
- Tiredness
- Nausea
- Increased appetite with weight loss
- Blurred vision
- Dizziness

## Excipients

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

This medicinal product contains less than 1 mmol sodium (23 mg) per daily dose (9 mg film-coated tablet), that is to say essentially "sodium-free".

### - Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes prescription medicines as well as over-the-counter medicines, vitamins or herbal supplements.

## How to use ITOVEBI

### - How much to use

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

## Dosage of ITOVEBI

The usual starting dose of ITOVEBI is 9 mg once a day (one 9 mg film-coated tablet).

Your doctor will determine the right dose for you. However, he or she could prescribe you the following dose:

- 6 mg (two 3 mg film-coated tablets) once daily, or
- 3 mg (one 3 mg film-coated tablet) once daily

Your doctor may adjust your dose of ITOVEBI depending on how you respond to treatment with ITOVEBI. If you get certain side effects, your doctor may ask you to use a lower dose, to

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stop treatment for a time, or to stop it altogether.

### **Elderly patients**

If you are 65 years of age or older, you can use ITOVEBI at the same dose as for adults in other age groups.

### **Paediatric population**

ITOVEBI should not be used in children and adolescents under 18 years of age because ITOVEBI has not been studied in this age group.

#### **- When to use it**

You can take ITOVEBI with or without food. Try to take ITOVEBI at the same time each day.

Swallow the entire ITOVEBI film-coated tablet. Do not chew, crush or split the film-coated tablet.

#### **- How long to use it**

Keep taking ITOVEBI once every day for as long as your doctor tells you to.

This is a long-term treatment and can last for months or years. Your doctor will check your condition regularly to see if the treatment is having the desired effect.

Ask your doctor or pharmacist if you have any questions about how long to take ITOVEBI.

#### **- If you forget to use it**

If you miss a dose of ITOVEBI, you can still take it up to 9 hours after the time you should have taken it.

- If it has been more than 9 hours since you should have taken it, skip the dose that day.
- The next day you will then take the dose at the usual time.

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

### **If you vomit right after taking a dose of ITOVEBI**

If you vomit after taking a dose of ITOVEBI, do not take another dose on that day. Instead, take your usual dose of ITOVEBI at the usual time the next day.

#### **- If you use too much (overdose)**

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

### **While you are using ITOVEBI**

#### **- Things you must do**

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using ITOVEBI.

Take ITOVEBI only with a doctor's prescription.

#### **- Things you must not do**

Do not stop taking ITOVEBI without the advice of your doctor (exception: see "Side effects"). This is because stopping treatment could lead to a worsening of your disease.

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

Do not change the prescribed dosage yourself. Tell your doctor or pharmacist if you think the effect is too weak or too strong.

#### **- Things to be careful of**

High blood sugar (hyperglycaemia) is an important side effect of ITOVEBI (see "Side effects").

You should ensure that you drink enough fluids during treatment with ITOVEBI.

### **How will you be monitored while you are taking ITOVEBI?**

Your doctor will carry out blood tests before and regularly during treatment with ITOVEBI. This is to monitor your blood glucose level.

Your doctor may also ask you to monitor your blood glucose at home during treatment with ITOVEBI.

- Your doctor will tell you exactly when you should measure your blood glucose.
- This will be required more frequently in the first 4 weeks of treatment. If you are not sure how to test your blood glucose, ask your doctor or pharmacist.

Based on the values, your doctor will take the necessary measures, e.g. prescribe a medication to lower blood glucose levels. If necessary, your doctor may decide to interrupt treatment with ITOVEBI or reduce your dose of ITOVEBI to help your blood glucose drop. Your doctor may also decide to permanently stop treatment with ITOVEBI.

### **Driving and using machines**

ITOVEBI is unlikely to affect your ability to drive or use machines.

### **Drug abuse and dependence**

ITOVEBI does not cause dependency.

Inform your doctor or pharmacist if you

- suffer from other illnesses,
- have any allergies or
- are taking any other medicines (including those bought over the counter).

### **Side effects**

Like all medicines, ITOVEBI can cause side effects, although not everybody gets them. The following side effects have been reported with the use of ITOVEBI:

#### **Serious side effects**

If you get these side effects, stop taking this medicine and tell your doctor immediately.

- High blood sugar (hyperglycaemia) and related complications such as ketoacidosis (a serious metabolic acidity requiring immediate intensive care treatment): Symptoms include nausea and vomiting (lasting more than 2 hours), stomach pain, feeling very thirsty or dry mouth, breathing difficulties, passing urine more often or more frequently than

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usual, blurred vision, unusually increased appetite, weight loss, fruity-smelling breath, red face and dry skin, and feeling unusually sleepy or tired.

- Inflammation of the lining of the mouth (stomatitis): Symptoms include pain, redness, swelling and sores in the mouth.

### Other side effects

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

### Very common (affects more than 1 in 10 people)

#### Infections

- Urinary tract infection
- COVID-19

#### Blood and lymphatic system disorders

- Anaemia (lack of red blood cells, which can cause tiredness)
- Neutrophils decreased (a reduced number of neutrophils, a type of white blood cell)
- Haemoglobin decreased (a low level of haemoglobin, the protein in red blood cells that carries oxygen)
- Platelets decreased (a low number of platelets in the blood, which may cause minor bleeding or bruising)
- Lymphocytes decreased (a reduced number of lymphocytes, a type of white blood cell)

#### Metabolism and nutrition disorders

- Hyperglycaemia (elevated blood sugar)
- Decreased appetite
- Change in laboratory values (calcium, potassium, sodium, magnesium, albumin, lipase, creatinine)
- Weight loss

#### Nervous system disorders

- Headache

#### Gastrointestinal disorders

- Diarrhoea
- Nausea
- Abdominal pain
- Vomiting
- Dyspepsia (indigestion)

- Dysgeusia (change in the sense of taste)

#### Diseases of the skin and subcutaneous tissues

- Rash
- Hair loss
- Dry skin

#### General disorders

- Fatigue

#### Liver diseases

- Blood alanine aminotransferase (an enzyme found in the liver and present in the blood when liver cells are damaged) increased

### Common (affects 1 to 10 people in 100)

#### Metabolism and nutrition disorders

- Low level of calcium in the blood, which may cause muscle cramps and weakness
- A low blood sugar level when fasting
- Insulin (a hormone that helps the body use sugar for energy) in the blood increased

#### Eye discomfort

- Dry eyes

### Rare (affects 1 to 10 people in 10,000)

- Ketoacidosis (serious metabolic acidosis)

If you get any side effects, talk to your doctor or pharmacist. This particularly includes any possible side effects not listed in this leaflet.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

### Storage and Disposal of ITOVEBI

#### - Storage

- Do not store above 30°C.
- Keep out of the sight and reach of children.

- Do not use this medicine after the expiry date marked as "EXP" on the pack.

#### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Your doctor or pharmacist, who has detailed professional information, can give you further information.

### Product Description

#### - What it looks like

ITOVEBI 3 mg film-coated tablets are red, round and convex with "INA3" engraved on one side.

ITOVEBI 9 mg film-coated tablets are pink and oval, with "INA9" engraved on one side.

#### - Ingredients

- Active ingredient  
Inavolisib

- Inactive ingredients
- Microcrystalline cellulose
- Lactose
- Sodium starch glycolate
- Magnesium stearate
- Film-coating mixture (3mg): Polyvinyl alcohol, Titanium dioxide, Macrogol/Polyethylene glycol, Talc and Iron Oxide Red
- Film-coating mixture (9mg): Polyvinyl alcohol, Titanium dioxide, Macrogol/Polyethylene glycol, Talc, Iron Oxide Red and Iron Oxide Yellow

#### - MAL number(s):

3mg: MAL\*\*\*\*\*

9mg: MAL\*\*\*\*\*

### Manufacturer

F. Hoffmann-La Roche AG,  
Wurmisweg, 4303 Kaiseraugst,  
Switzerland.

### Product Registration Holder

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