

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Itovebi?

Itovebi contains the active ingredient inavolisib. Itovebi is used to treat a certain type of breast cancer where, following surgery, that cancer:

- has spread to nearby tissue or lymph nodes, or to other parts of the body, and
- was recently, or is currently, being treated with a category of medicines called endocrine therapy, and
- has a change in a gene called 'PIK3CA.'

For more information, see Section [1. Why am I using Itovebi?](#) in the full CMI.

2. What should I know before I use Itovebi?

Do not use if you have ever had an allergic reaction to inavolisib or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have a history of diabetes or high blood sugar, including during a previous pregnancy (gestational diabetes). Tell your doctor if you are pregnant or plan to become pregnant, or you are breastfeeding or planning to breastfeed, as Itovebi can harm your baby. Tell your doctor if you have other medical conditions or use other medicines.

For more information, see Section [2. What should I know before I use Itovebi?](#) in the full CMI.

3. What if I am using other medicines?

Some medicines may interfere with Itovebi and affect how it works. See [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Itovebi?

The usual dose of Itovebi is 9 mg per day. Use Itovebi once daily, at about the same time each day. Itovebi can be used with or without food. More instructions can be found in Section [4. How do I use Itovebi?](#) in the full CMI.

5. What should I know while using Itovebi?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Itovebi. • Your doctor may ask you to monitor your blood sugar at home during treatment with Itovebi. Tell your doctor, nurse or pharmacist right away if you develop symptoms of high blood sugar levels (hyperglycaemia) such as a fruity smelling on the breath, difficulty breathing, feeling very thirsty, passing urine more often than usual or in higher amounts than usual, blurred vision. • Tell your doctor, nurse or pharmacist as soon as you notice any signs or symptoms of inflammation of the lining of the mouth, or diarrhoea • You should stay well-hydrated during treatment with Itovebi
Things you should not do	• Do not change your dose or stop using Itovebi unless your doctor tells you to.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how Itovebi affects you.
Looking after your medicine	• Store Itovebi at room temperature (below 30°C).

For more information, see Section [5. What should I know while using Itovebi?](#) in the full CMI.

6. Are there any side effects?

Itovebi can cause side effects. Speak to your doctor if you have any of these side effects and they concern you: stomach problems such as pain, nausea; skin problems; painful urination or urinary tract infection; abnormal laboratory tests; tiredness, loss of appetite; weight loss; general unwell feeling. Tell your doctor, nurse or pharmacist straight away if you notice symptoms of high blood sugar levels (hyperglycaemia), inflammation of the lining of the mouth (stomatitis), or diarrhoea. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Itovebi®

Active ingredient: inavolisib

Consumer Medicine Information (CMI)

This leaflet provides important information about using Itovebi. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Itovebi.**

Where to find information in this leaflet:

1. [Why am I using Itovebi?](#)
2. [What should I know before I use Itovebi?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Itovebi?](#)
5. [What should I know while using Itovebi?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Itovebi?

Itovebi contains the active ingredient inavolisib. Itovebi is an anti-cancer medicine used in combination with medicines called palbociclib (tradenam 'Ibrance®') and fulvestrant (of various tradenames).

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.'

2. What should I know before I use Itovebi?

Warnings

Do not use Itovebi if:

- you are allergic to inavolisib, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have a history of diabetes or high blood sugar, including during a previous pregnancy (gestational diabetes)
 - o Tell your doctor or pharmacist before using Itovebi if you have ever had diabetes or signs of increased sugar levels in your blood, such as:

- feeling very thirsty
 - 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
 - a fruity smelling on the breath
 - blurred vision
 - feeling lightheaded
- are pregnant or plan to become pregnant, or you are breastfeeding or plan to breastfeed. See 'Pregnancy and breastfeeding' below.
 - have other medical conditions
 - use medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you:

- are pregnant or plan to become pregnant. Itovebi can harm your unborn baby.
 - o Females who are able to become pregnant:
 - Your healthcare provider will do a pregnancy test before you start treatment with Itovebi.
 - You should use non-hormonal birth control (contraception) during treatment and for 2 weeks after your last dose of Itovebi. 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.
 - If you or your partner are planning to have a baby, ask your doctor for advice before using this medicine.
 - o Males with female partners who are able to become pregnant, or who are currently pregnant, should use condoms during treatment with Itovebi and for 2 weeks after the 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 or until 1 week has passed since completing treatment with

Itovebi. Talk to your doctor if you are breastfeeding or intend to breastfeed.

How Itovebi works

Itovebi works by blocking the effects of a protein called 'p110 alpha', which is produced by the PIK3CA gene.

PIK3CA is a gene that controls a pathway that is often disrupted in cancer. This pathway is called the PI3K cancer pathway.

The p110 alpha protein, when changed (mutated) due to a mutation in PIK3CA, causes cancer cells to grow and multiply more rapidly.

By blocking its action, Itovebi can reduce growth and spread of the cancer and help to destroy cancer cells.

Prior to starting treatment with Itovebi, your healthcare provider may take a sample of your blood and/or tumour tissue to test for changes in the PIK3CA gene.

3. What if I am using other medicines?

Tell your doctor or pharmacist if you are using any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are using and if these affect Itovebi.

4. How do I use Itovebi?

How much to use

- Use Itovebi exactly as your doctor tells you to.
- The usual dose of Itovebi is 9 mg per day.
- If you are a woman experiencing pre-menopause or perimenopause, your doctor may add an additional medicine called a luteinising hormone-releasing hormone (LHRH) agonist to your treatment plan.
- If you are a male, your doctor may also add an LHRH agonist medicine to your treatment plan.
- It is recommended that you continue using Itovebi until your cancer progresses or until any side effects become unacceptable (see section [6. Are there any side effects?](#), below)
- Itovebi is not addictive

When to use Itovebi

- Use Itovebi once daily, at about the same time each day.
- Itovebi can be used with or without food.
- If you vomit after using a dose of Itovebi, do not use an extra dose on that day. Use your regular dose of Itovebi at your usual time the next day.

If you forget to use Itovebi

Itovebi should be used regularly at the same time each day. If you miss your dose at the usual time, you may still use it up to 9 hours after the time you should have used it.

If it has been more than 9 hours from the time you should have used it, skip the dose you missed and use your next

dose when you are meant to the next day. Do not use a double dose to make up for the dose you missed.

If you use too much Itovebi

If you think that you have used too much Itovebi, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Itovebi?

High blood sugar levels (hyperglycaemia)

Hyperglycaemia is common with Itovebi and may be severe.

Monitoring hyperglycaemia during your treatment with Itovebi

- Your doctor may 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 your doctor or pharmacist.
- 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 let your blood sugar go down. Your doctor may also decide to stop Itovebi treatment permanently.

Inflammation of the lining of the mouth (stomatitis)

Stomatitis is very common with Itovebi and may be severe.

Your doctor may advise you to start an alcohol-free corticosteroid mouthwash and to avoid alcohol- or peroxide-containing mouthwashes as they may worsen the inflammation.

Your doctor or pharmacist may also give you dietary advice (e.g. to avoid spicy foods) to help you manage this side effect.

Diarrhoea

Diarrhoea is very common with Itovebi and may be severe.

If not managed properly, severe diarrhoea can lead to dehydration and can damage your kidneys.

Things you should do

Tell your doctor, nurse or pharmacist right away if you develop symptoms of hyperglycaemia or its complications, 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

Tell your doctor, nurse or pharmacist as soon as you notice any signs or symptoms of stomatitis inside the mouth, such as:

- pain
- redness
- swelling
- mouth ulcers

Tell your doctor, nurse or pharmacist as soon as you notice any signs or symptoms of diarrhoea (liquid or watery poo, often with tummy pain and gas).

You should stay well-hydrated during treatment with Itovebi. Your doctor, nurse or pharmacist will advise you to drink plenty of (non-alcoholic) fluids and may advise you to use a medicine which reduces diarrhoea. Your doctor may also reduce, or cease, your dose of Itovebi.

Things you should not do

- Do not change your dose or stop using Itovebi unless your doctor tells you to.

Older people (≥ 65 years)

You can use Itovebi if you are aged 65 years or over at the same dose as for other adults.

Children and adolescents (< 18 years)

Itovebi should not be used in children or adolescents below 18 years of age. This is because Itovebi has not been studied in this age group

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Itovebi affects you.

Looking after your medicine

Store Itovebi at room temperature (below 30°C). Store it in a cool dry place away from moisture or heat; for example, do not store it:

- In the bathroom or near a sink, or
- In the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are likely to be minor and temporary. However, some side effects may need medical attention.

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 side effects.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Side effects	What to do
Stomach problems: • stomach pain • nausea (feeling sick) • vomiting Mouth problems: • disturbed sense of taste Eye problems: • dry eye Skin problems: • rash • dry skin • pale skin • unusual bruising or bleeding Urinary problems: • pain when weeing (urinating) General: • tiredness • headache • loss of appetite • weight loss • hair thinning or hair loss • general unwell feeling	Speak to your doctor if you have any of these less serious side effects and they worry you. If these side effects become severe, call your doctor straight away, or go straight to the Emergency Department at your nearest hospital.

Serious side effects

Serious side effects	What to do
High blood sugar levels (hyperglycaemia) Signs and symptoms of high blood sugar levels and their complications include: • finding it hard to breathe • nausea (feeling sick) and vomiting (being sick) which lasts more than 2 hours • stomach pain • feeling very thirsty or dry mouth • weeing 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 • feeling unusually sleepy or tired Inflammation of the lining of the mouth (stomatitis) Signs and symptoms inside the mouth include: • pain • redness • swelling • ulcers Diarrhoea • Signs and symptoms include: • loose or watery poo • tummy pain • gas	Tell your doctor, nurse or pharmacist straight away, or go straight to the Emergency Department at your nearest hospital, if you notice any of these serious side effects.

Tell your doctor, nurse or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. Some side effects will only be identified when your doctor orders tests to monitor your treatment.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop using any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Itovebi contains

Active ingredient (main ingredient)	inavolisib
Other ingredients (inactive ingredients)	Microcrystalline cellulose Lactose Sodium starch glycollate Magnesium stearate Polyvinyl alcohol Titanium dioxide Macrogol/polyethylene glycol Purified talc Iron oxide red Iron oxide yellow (9 mg tablet only)
Potential allergens	Nil

Do not use this medicine if you are allergic to any of these ingredients.

What Itovebi looks like

Itovebi 3 mg film-coated tablet is red and round, convex-shaped with an "INA 3" embossing on one side. (AUST R 446750)

Itovebi 9 mg film-coated tablet is pink and oval-shaped with an "INA 9" embossing on one side. (AUST R 446751)

Itovebi 3 mg and 9 mg film-coated tablets are supplied in cartons of 28 tablets (4 aluminium blister cards, each with 7 tablets, per carton).

Who distributes Itovebi

Itovebi is distributed by:

Roche Products Pty Limited

ABN 70 000 132 865

Level 8, 30 - 34 Hickson Road

Sydney NSW 2000

AUSTRALIA

Medical enquiries: 1800 233 950 or via www.medinfo.roche.com/australia

Please check with your pharmacist for the latest Consumer Medicine Information.

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