

## Approved Patient Information Leaflet for BINIT 25, 100 and 150

### PATIENT INFORMATION LEAFLET

#### SCHEDULING STATUS

S4

**BINIT 25** film-coated tablets

**BINIT 100** film-coated tablets

**BINIT 150** film-coated tablets

**Erlotinib**

**Contains sugar**

**Each BINIT 25 film-coated tablet contains 13,2 mg lactose monohydrate.**

**Each BINIT 100 film-coated tablet contains 52,7 mg lactose monohydrate.**

**Each BINIT 150 film-coated tablet contains 79,02 mg lactose monohydrate.**

#### **Read all of this leaflet carefully before you start taking BINIT**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BINIT has been prescribed for you personally and you should not share BINIT with other people. It may harm them, even if their symptoms are the same as yours.

#### **What is in this leaflet**

1. What BINIT is and what it is used for

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2. What you need to know before you take BINIT
3. How to take BINIT
4. Possible side effects
5. How to store BINIT
6. Contents of the pack and other information

## **1. What BINIT is and what it is used for**

BINIT contains the active ingredient erlotinib. BINIT is a medicine used to treat cancer by preventing the activity of a protein called epidermal growth factor receptor (EGFR). This protein is known to be involved in the growth and spread of cancer cells.

BINIT is indicated for adults. BINIT can be prescribed for you if you have non-small cell lung cancer or adenocarcinoma of your lung at an advanced stage. It can be prescribed as initial therapy of your disease if your cancer cells have specific EFGR mutations. It can also be prescribed if your disease remains largely unchanged after initial chemotherapy, or if previous chemotherapy has not helped to stop your disease.

BINIT can also be prescribed to you in combination with another treatment called gemcitabine if you have cancer of the pancreas at a metastatic stage.

## **2. What you need to know before you take BINIT**

### **Do not take BINIT**

If you are hypersensitive (allergic) to erlotinib or to any of the other ingredients of BINIT listed in section 6 of this leaflet.

### **Warnings and precautions**

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Take special care with BINIT:

- If you are taking other medicines that may increase or decrease the amount of BINIT in your blood or influence its effect. See 'Other medicines and BINIT'.
- If you use contact lenses and/or have a history of eye problems, such as severe dry eyes, inflammation or ulcers in your eye.

You should tell your doctor if you have:

- Sudden difficulty in breathing associated with cough or fever. Your doctor may need to treat you with other medicines and interrupt your BINIT treatment with BINIT.
- Diarrhoea. Your doctor may need to treat you with anti-diarrhoeal medicines.
- Severe, bloody or persistent diarrhoea, nausea, loss of appetite or vomiting. You should immediately tell your doctor, as he/she may need to interrupt or stop your treatment with BINIT and may need to treat you in the hospital.
- Severe pain in the stomach area or a history of diverticular disease or peptic ulceration.
- Severe blistering or peeling of the skin. Your doctor may need to interrupt or stop your treatment with BINIT.
- Acute or worsening eye problems, such as redness and pain in the eye, increased watering of your eye, blurred vision or sensitivity to light. Your doctor may need to interrupt or stop your treatment with BINIT.

You should tell your doctor if you are taking statin medicine and experience unexplained muscle pain, tenderness, weakness or cramps while taking BINIT. Your doctor may need to interrupt your treatment with BINIT. See 'Other medicines and BINIT'.

Treatment with BINIT is not recommended if you have severe liver disease or severe kidney disease.

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Your doctor will treat you with caution if you have a disorder like Gilbert's syndrome, which can affect your liver and enzymes in your body, causing jaundice (yellowing of the skin and whites of the eyes).

You are advised to stop smoking if you are treated with BINIT, as smoking considerably decreases the amount of BINIT available in your blood.

You are advised to wear protective clothing and/or use sunscreen when you are exposed to the sun during your treatment with BINIT.

### ***Children and adolescents***

BINIT has not been studied in patients under the age of 18 years. The treatment with BINIT is not recommended in children and adolescents.

### **Other medicines and BINIT**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist before you take BINIT if you are taking other medicines that may increase or decrease the amount of BINIT in your blood or influence its effect, such as:

- Ciprofloxacin, erythromycin or clarithromycin (used to treat certain bacterial infections).
- Fluvoxamine (used to treat depression).
- Ketoconazole, itraconazole or voriconazole (used to treat fungal infections).
- Protease inhibitors (used to treat human immunodeficiency virus (HIV) infection).
- Rifampicin (used to treat tuberculosis (TB)).

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- Phenytoin or carbamazepine (used to treat seizures (fits)).
- Barbiturates (used to treat insomnia or anxiety).
- St John's Wort (herbal medicine).
- Omeprazole or ranitidine (used to treat acid reflux).

In some cases, these medicines may reduce the efficacy or increase the side effects of BINIT and your doctor may need to adjust your treatment.

Tell your doctor or pharmacist before you take BINIT if you are taking:

- Anticoagulants, such as warfarin (used to prevent blood clots). BINIT may increase your risk for bleeding and your doctor may need to regularly monitor you with blood tests.
- Statins (a group of medicine used to lower the cholesterol (fat) in your blood). BINIT may increase the risk of statin related muscle problems, which on rare occasions can lead to serious muscle breakdown (rhabdomyolysis) resulting in kidney damage.
- Ciclosporin (used to treat psoriasis, rheumatoid arthritis or during organ transplants).
- Verapamil (used to treat high blood pressure or heart problems).
- Capecitabine (used to treat cancer).

### **BINIT with food, drink and alcohol**

Do not take BINIT with food. See section 3 "How to take BINIT".

### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking BINIT.

Avoid pregnancy while being treated with BINIT. If you can become pregnant, use adequate

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contraception during treatment, and for at least 2 weeks after taking the last tablet. If you become pregnant while on treatment with BINIT, immediately inform your doctor who will decide if treatment should be continued. Do not breastfeed your baby while taking BINIT.

### **Driving and using machines**

BINIT is not likely to affect your ability to drive and use machines. However, do not drive a vehicle or operate machinery until you know how BINIT affects you.

### **BINIT contains lactose monohydrate**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking BINIT.

## **3. How to take BINIT**

Do not share medicines prescribed for you with any other person.

Always take or BINIT exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

### ***Non-small cell lung cancer and bronchial adenocarcinoma***

The usual dose is one 150 mg BINIT tablet each day.

### ***Pancreatic cancer***

The usual dose is one 100 mg BINIT tablet each day. BINIT is given in combination with gemcitabine.

Your doctor will tell you how long your treatment with BINIT will last. Do not stop treatment early.

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If you have the impression that the effect of BINIT is too strong or too weak, tell your doctor or pharmacist.

Do not take BINIT with a meal. Take your BINIT tablet at least 1 hour before you eat or at least 2 hours after you have eaten. Swallow your tablet with a glass of plain water.

Your doctor may adjust your dose in 50 mg steps. For different dosage regimens, BINIT is available in strengths of 25 mg, 100 and 150 mg.

### **If you take more BINIT than you should**

In the event of overdose, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. You may have increased side effects and your doctor may interrupt your treatment.

### **If you forget to take BINIT**

If you forget to take a dose, contact your doctor or pharmacist as soon as possible. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking BINIT**

It is important to keep taking BINIT every day, as long as your doctor prescribes it for you. If you have any further questions on the use of BINIT, ask your doctor or pharmacist.

## **4. Possible side effects**

BINIT can have side effects.

Not all side effects reported for BINIT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BINIT, please consult your health care provider for advice.

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***If any of the following happens, stop taking BINIT and tell your doctor immediately or go to the casualty department at your nearest hospital:***

- Swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to BINIT. You may need urgent medical attention or hospitalisation.

***Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:***

*Frequent side effects:*

- Severe diarrhoea and vomiting (being sick). See also 'Warnings and precautions'.
- Redness, pain or excessive watering of the eyes, blurred vision, sensitivity to light.
- Gastrointestinal bleeding, causing black stool, stomach cramps, pale skin and vomiting blood.
- Renal insufficiency, causing urinating less than usual, feeling tired, shortness of breath, weakness and an irregular heartbeat.

*Less frequent side effects:*

- Interstitial lung disease, causing difficulty in breathing associated with a cough or fever.
- Liver failure, causing pain in your upper right stomach area, nausea (feeling sick), vomiting (being sick), yellowing of your skin and whites of your eyes.
- Red and painful blistering and peeling of your skin.
- Gastrointestinal perforation, causing severe pain in your stomach area that worsens when moving.

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- Nephritis (causing pain or a burning sensation when you urinate, pain in your pelvis, a frequent need to urinate or cloudy urine).

***Tell your doctor if you notice any of the following:***

*Frequent side effects:*

- Infection.
- Nose bleeds.
- Changes in blood test results when your doctor tests your liver function.
- Rash, itching, dry skin, cracked skin, acne or small, raised, acne-like bumps on your face, scalp, chest and upper back.
- Hair loss.
- Redness, tenderness and blistering of the skin around your nails, changes in your nails.
- Loss of appetite or decreased weight.
- Difficulty breathing or coughing.
- Nausea (feeling sick), pain in your stomach area, indigestion, flatulence or inflammation of your mouth or lips.
- Neuropathy (altered skin sensation or numbness in the extremities).
- Headaches.
- Depression.
- Excessive tiredness, fever or chills (a sudden feeling of cold with shivering and a rise in temperature).

*Less frequent side effects:*

- Red, tingling, burning or tender rash with tightness of the skin and thick blisters on the palms of your hands or soles of your feet.
- Changes in eyelashes (such as in-growing eyelashes, excessive growth and thickening)

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or eyebrows.

- Excess body and facial hair growth.
- Brittle and loose nails, hyperpigmentation (causing dark spots or patches on your skin).
- Protein in your urine.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of BINIT.

### **5. How to store BINIT**

- Store at or below 25 °C.
- Keep the blister strip(s) in the outside carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton or container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

### **6. Contents of the pack and other information**

#### **What BINIT contains**

The active substance in BINIT is erlotinib.

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BINIT 25: Each film-coated tablet contains 25 mg erlotinib (as hydrochloride).

BINIT 100: Each film-coated tablet contains 100 mg erlotinib (as hydrochloride).

BINIT 150: Each film-coated tablet contains 150 mg erlotinib (as hydrochloride).

The other ingredients are colloidal anhydrous silica (E551), hypromellose (E464), lactose monohydrate, magnesium stearate (E572), microcrystalline cellulose (E460), Opadry® white (containing hypromellose (E464), macrogol (E1521), talc (E553b) and titanium dioxide (E171)), polyvinylpyrrolidone (E1202) and sodium lauryl sulphate (E487).

### **What BINIT looks like and contents of the pack**

BINIT 25: White to off-white, round, film-coated tablets, debossed with '913' on one side and plain on the other side.

BINIT 100: White to off-white, round, film-coated tablets, debossed with '914' on one side and plain on the other side.

BINIT 150: White to off-white, round, film-coated tablets, debossed with '915' on one side and plain on other side.

BINIT is packed in silver OPA/Aluminium/PVC and aluminium blister strips, packed in a cardboard carton.

Pack size: 30 tablets.

### **Holder of certificate of registration**

Zydus Healthcare SA (Pty) Ltd

Southdowns Office Park

Building B, Ground Floor

22 Karee Street

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Centurion, Pretoria

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