PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

Boehringer Ingelheim

GIOTRIF® 20 mg film-coated tablets
GIOTRIF® 30 mg film-coated tablets
GIOTRIF® 40 mg film-coated tablets

afatinib

Contains sugar

Each GIOTRIF 20 mg film-coated tablet contains 118 mg lactose (as monohydrate)
Each GIOTRIF 30 mg film-coated tablet contains 176 mg lactose (as monohydrate)
Each GIOTRIF 40 mg film-coated tablet contains 235 mg lactose (as monohydrate)

Read all of this leaflet carefully before you start taking GIOTRIF

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

What is in this leaflet

1. What GIOTRIF is and what it is used for

GIOTRIF is a medicine which contains the active substance afatinib. It works by blocking the activity of a group of proteins called the ErbB family of proteins. By blocking the activity of these proteins GIOTRIF can inhibit growth and spread of cancer cells.

GIOTRIF is used to treat adult patients with specific types of cancer of the lung: adenocarcinoma and squamous cell cancer.

2. What you need to know before you take GIOTRIF

Do not take GIOTRIF

- if you are hypersensitive (allergic) to afatinib or any of the other ingredients of GIOTRIF (listed in section 6)
- if you have severe liver disease
- if you are pregnant, planning to become pregnant or are breastfeeding your infant
- if you have an eye condition/disease/disorder with severe impairment of vision/eye sight.

Warnings and precautions

Take special care and talk to your doctor or pharmacist before taking GIOTRIF:

- if you are female, have a low body weight of less than 50 kg or have kidney problems. If any of these apply to you, your doctor may monitor you more closely as the side effects may be more pronounced.
- if you have a history of lung inflammation (interstitial lung disease).
- if you have liver problems. Your doctor may do some liver tests. Treatment with GIOTRIF is not recommended if you have a severe liver disease.
- if you have a history of eye problems such as severe dry eyes, inflammation of the transparent layer at the front of the eye (cornea) or ulcers involving the outer part of the eye, or if you use contact lenses.
- if you have a history of heart problems. Your doctor may want to monitor you more closely.

Inform your doctor immediately while taking GIOTRIF:

- if you develop diarrhoea. Treatment at the first signs of diarrhoea is important.
- if you develop skin rash. Early treatment of skin rash is important.
- if you develop new or sudden worsening of shortness of breath, possibly with a cough or fever. These could be symptoms of an inflammation of the lungs (interstitial lung disease) and can be life-threatening.
- if you have severe pain in your stomach or intestines, fever, chills, sickness, vomiting, or abdominal rigidity or bloating, as these could be symptoms of a tear in the wall of your stomach or intestines ("gastrointestinal perforation"). Also, tell your doctor if you had gastrointestinal ulcers or diverticular disease in the past, or are concomitantly treated with anti-inflammatory drugs (NSAIDs) (used to treat pain and swelling) or steroids (used for inflammation and allergies), as this may increase this risk.
- if you develop acute or worsening redness and pain in the eye, increased eye watering, blurred vision and/or sensitivity to light. You may need urgent treatment.

See also section 4 "Possible side effects".

Children and adolescents

GIOTRIF has not been studied in children or adolescents. Do not give this medicine to children or adolescents under the age of 18 years.

Other medicines and GIOTRIF

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

If taken before GIOTRIF, the following medicines may increase the blood levels of GIOTRIF and therefore the risk of side effects. They should therefore be taken as far apart in time as possible from GIOTRIF. This means preferably 6 hours (for medicines taken twice daily) or 12 hours (for medicines taken once daily) apart from GIOTRIF:

- Ritonavir, ketoconazole (except in shampoo), itraconazole, erythromycin, nelfinavir, saquinavir - used to treat different kinds of infections.
- Verapamil, quinidine, amiodarone - used to treat heart conditions.
- Ciclosporin A, tacrolimus - medicines that affect your immune system.

The following medicines may reduce the effectiveness of GIOTRIF:
- Carbamazepine, phenytoin, phenobarbitone - used to treat seizures.
- St. John's wort *(Hypericum perforatum)*, a herbal medicine to treat depression.
- Rifampicin, an antibiotic used to treat tuberculosis.

Ask your doctor if you are unsure of when to take these medicines.

GIOTRIF may increase the blood levels of other medicines including but not limited to:
- Sulfasalazine, used to treat inflammation/infection.
- Rosuvastatin, used for lowering cholesterol.

Tell your doctor before taking these medicines together with GIOTRIF.

GIOTRIF with food
See section 3 "How to take GIOTRIF".

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, consult your doctor, pharmacist or other healthcare provider for advice before taking GIOTRIF.

Pregnancy
You should not become pregnant while taking GIOTRIF. You should use adequate birth control methods during treatment and for at least 1 month after taking the last dose of GIOTRIF. Harm to your unborn baby cannot be excluded.

If you become pregnant while taking GIOTRIF, you should immediately inform your doctor.

If you plan to become pregnant after taking the last dose of GIOTRIF, you should ask your doctor for advice as your body may take a month to fully eliminate GIOTRIF.

Breastfeeding
Do not breastfeed while taking GIOTRIF as harm to your baby cannot be excluded.

Driving and using machines
You should not drive or use machines until you know how GIOTRIF may affect your eye sight (e.g. redness and/or irritation of the eye, dry eye, tearing, light-sensitivity) or your ability to concentrate and react.

GIOTRIF contains lactose
GIOTRIF contains a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking GIOTRIF.

3. How to take GIOTRIF

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

Always take GIOTRIF exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

The usual dose is 40 mg each day.
Your doctor may adjust (increase or decrease) your dose depending on how well you tolerate GIOTRIF.
Your doctor will tell you how long your treatment with GIOTRIF will last. Do not stop treatment early because your cancer may grow again.
If you have the impression that the effect of GIOTRIF is too strong or too weak, tell your doctor or pharmacist.

When to take GIOTRIF

- It is important to take GIOTRIF without food
- Take GIOTRIF at least 1 hour before eating, or
- If you have already eaten, wait at least 3 hours before taking GIOTRIF.
- Take GIOTRIF once daily at about the same time each day. This makes it easier to remember to take GIOTRIF.
- Do not break, chew or crush the tablet.
- Swallow the tablet whole with a glass of still water.

GIOTRIF is to be taken by mouth. If you have difficulties swallowing the tablet, dissolve it in a glass of still water. No other liquids should be used. Drop the tablet into the water without crushing it, and occasionally stir for up to 15 min until the tablet is broken up into very small particles. Drink the liquid straight away. Then fill the glass again with water and drink it to make sure all medicine is taken.

If you are not able to swallow and have a gastric tube your doctor might suggest that GIOTRIF is given to you via the tube.

If you take more GIOTRIF than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
You may experience increased side effects and your doctor may interrupt your treatment and provide supportive care.

If you forget to take GIOTRIF

- If your next scheduled dose is more than 8 hours away, take the missed dose as soon as you remember.
- If your next scheduled dose is due within 8 hours, skip the missed dose and take your next dose at the usual time. Then carry on taking your tablets at regular times as usual.

Do not take a double dose (two tablets instead of one at the same time) to make up for a missed dose.

If you stop taking GIOTRIF
Do not stop taking GIOTRIF without first consulting your doctor. It is important to take GIOTRIF every day, as long as your doctor prescribes it for you. If you do not take GIOTRIF as prescribed by your doctor your cancer may grow again.

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

4. Possible side effects
GIOTRIF can have side effects.
Not all side effects reported for GIOTRIF are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GIOTRIF, please consult your healthcare provider for advice.

Contact your doctor as soon as possible if you suffer from any of the serious side effects listed below. In some cases your doctor may need to interrupt treatment and reduce your dose or stop treatment:

- **Diarrhoea** (frequent).
  Diarrhoea lasting more than 2 days or more severe diarrhoea may lead to fluid loss, low blood potassium and worsening of kidney function. Diarrhoea can be treated. At the first signs of diarrhoea drink plenty of fluids. Contact your doctor immediately and start appropriate antidiarrhoeal treatment as soon as possible. You should have antidiarrhoeal medicine available prior to taking GIOTRIF.

- **Skin rash** (frequent).
  It is important to treat the rash early. Tell your doctor if a rash starts. If treatment for rash is not working and the rash is getting more severe (for example, you have peeling or blistering of the skin) you should notify your doctor immediately, since your doctor may decide to stop your treatment with GIOTRIF. Rash may occur or worsen in areas exposed to sun. Sun protection with protective clothing and sunscreen is recommended.

- **Inflammation of the lungs** (less frequent) called “interstitial lung disease”.
  Tell your doctor immediately if you develop new or sudden worsening of shortness of breath, possibly with a cough or fever.

- **Eye irritation or inflammation**
  Eye irritation or inflammation may occur (conjunctivitis/keratoconjunctivitis occurs frequently and keratitis less frequently). Tell your doctor if you have sudden or worsening of eye symptoms such as pain or redness or dry eye.

If you experience any of the symptoms above, contact your doctor as soon as possible.

The following other side effects have also been reported:

Frequent side effects:

- Mouth sores and inflammation
- Nail infection
- Decreased appetite
- Bleeding from the nose
- Nausea
- Vomiting
- Itching
- Dry skin
- Pain, redness, swelling or peeling of the skin of your hands and feet
- Increased levels of the liver enzymes (aspartate aminotransferase and alanine aminotransferase) in blood tests
- Inflammation of the lining of the bladder with burning sensations during urination and frequent, urgent need to urinate (cystitis)
- Abnormal taste sensations (dysgeusia)
- Stomach pain, indigestion, heartburn
- Lip inflammation
- Decreased weight
- Runny nose
- Muscle spasms
- Fever
- Nail problems
- Kidney problems

Less frequent side effects:

- Inflammation of the pancreas (pancreatitis)
- Severe blistering or peeling of skin (suggestive of Stevens-Johnson syndrome and toxic epidermal necrolysis)
- Liver injury
- Occurrence of a tear in the wall of your stomach or intestines (gastrointestinal perforation)
- Abnormal growth of your eyelash (including misdirected growth that may lead to damage to the eye surface)

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. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of GIOTRIF.

Suspected adverse reactions can also be reported directly to the holder of the certificate of registration using the email address pv_local_south_africa@boehringer-ingelheim.com.

5. How to store GIOTRIF

Store at or below 30 °C.
Store in the original package in order to protect from moisture and light.
In order to protect from moisture, do not store in the bathroom.
Store all medicines out of reach of children.

Do not use after the expiry date stated on the carton, the pouch and the blister.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What GIOTRIF contains

The active substance is afatinib.
Each film-coated tablet contains 20 mg, 30 mg or 40 mg of afatinib (as dimaleate).

The other ingredients are lactose monohydrate, microcrystalline cellulose (E460), colloidal anhydrous silica (E551), crospovidone type A, magnesium stearate (E470b), hypromellose (E464), macrogol 400, titanium dioxide (E171), talc (E553b), polysorbate 80 (E433).
GIOTRIF 30 mg and 40 mg film-coated tablets also contain indigo carmine aluminium hydroxide (E132).

What GIOTRIF looks like and contents of the pack

GIOTRIF 20 mg: White to yellowish, round, biconvex and bevel-edged film-coated tablets debossed with the code “T20” on one side and the Boehringer Ingelheim company logo on the other.
GIOTRIF 30 mg: Dark blue, round, biconvex and bevel-edged film-coated tablets debossed with the code “T30” on one side and the Boehringer Ingelheim company logo on the other.
GIOTRIF 40 mg: Light blue, round, biconvex and bevel-edged film-coated tablet debossed with the code “T40” on one side and the Boehringer Ingelheim company logo on the other.

GIOTRIF film-coated tablets are packed in blister strips, consisting of a PVC/PVDC forming sheet and a printed aluminium lidding foil.
Each blister strip of 7 tablets is pouched in a laminated aluminium foil pouch with a dessicant sachet; 4 blister strips are packed per printed cardboard carton, in packs of 28 tablets.

Holder of Certificate of Registration

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