PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**

ERCYTA 100 film-coated tablets

ERCYTA 150 film-coated tablets

Erlotinib

Contains sugar (lactose monohydrate)

Read all of this leaflet carefully before you start taking ERCYTA

- 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.
- ERCYTA 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 ERCYTA is and what it is used for

2. What you need to know before you take ERCYTA

3. How to take ERCYTA

4. Possible side effects

5. How to store ERCYTA

6. Contents of the pack and other information

1. What ERCYTA is and what it is used for

ERCYTA 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.

ERCYTA is indicated for adults; it can be prescribed to you if you have non-small cell lung cancer at an advanced stage, when a previous cancer treatment has failed.

ERCYTA can be prescribed to you if you have adenocarcinoma of your lung. It can be prescribed as initial treatment if your cancer cells have specific EGFR mutations.

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

2. What you need to know before you take ERCYTA

Do not take ERCYTA

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

Warnings and precautions

Take special care

- if you are taking other medicines that may increase or decrease the amount of erlotinib in your blood or influence its effect (for example antifungals like ketoconazole, protease inhibitors, erythromycin, clarithromycin, phenytoin, carbamazepine, barbiturates, rifampicin, ciprofloxacin, omeprazole, ranitidine or St. John's Wort) talk to your doctor (see also "Other medicines and ERCYTA"). These medicines may reduce the efficacy or increase the side effects of ERCYTA and your doctor may need to adjust your treatment. Your doctor might avoid treating you with these medicines while you are receiving ERCYTA;

- if you take anticoagulants (medicine which helps to prevent thrombosis or blood clotting, e.g. warfarin). See also “Other medicines and ERCYTA”. Talk to your doctor, he/she will need to regularly monitor you with blood tests;
- if you are taking statins (medicines to lower your blood cholesterol), ERCYTA may increase the risk of statin related muscle problems, which can lead to serious muscle breakdown (rhabdomyolysis) resulting in kidney damage, talk to your doctor.

  See also “Other medicines and ERCYTA”;
- if you wear contact lenses and/or have a history of eye problems such as severe dry eyes, inflammation of the front part of the eye (cornea) or ulcers involving the front part of the eye, tell your doctor.

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 ERCYTA treatment;
- immediately if you develop persistent diarrhoea with nausea, loss of appetite, or vomiting, because your doctor may need to interrupt your ERCYTA treatment and may need to treat you in hospital. Persistent and severe diarrhoea may lead to low blood potassium and kidney failure, particularly if you receive other cancer treatments at the same time;
- if you develop severe pain in the abdomen with nausea, vomiting and blood in the vomit. Your doctor may need to interrupt or stop your treatment;
- if you develop acute or worsening redness and pain in the eye, increased eye watering, blurred vision and/or sensitivity to light, please tell your doctor or nurse immediately as you may need urgent treatment (see “Possible side effects” below);
- if you develop severe blistering or peeling of the skin. Your doctor may need to interrupt or stop your treatment;
- if you experience unexplained muscle pain, tenderness, weakness or cramps. Your doctor may need to interrupt or stop your treatment.

  See section 4, “Possible side effects”.

Liver or kidney disease

It is not known whether ERCYTA has a different effect if your liver or kidneys are not functioning normally. The treatment with ERCYTA is not recommended if you have a severe liver disease or severe kidney disease.

Glucuronidation disorder like Gilbert's syndrome

Your doctor will treat you with caution if you have a glucuronidation disorder like Gilbert's syndrome.

Smoking

You should tell your doctor if you smoke. You should stop smoking if you are treated with ERCYTA, as smoking could decrease the amount of your medicine in the blood.

Children and adolescents

ERCYTA should not be given to children under the age of 18 years. ERCYTA is unlikely to be safe in children and adolescents.

Other medicines and ERCYTA

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

Tell your doctor if you are taking:

- warfarin (an anticoagulant or any other medicine which helps to prevent thrombosis or blood clotting). ERCYTA may increase your tendency to bleed;
- antacids or medicines for stomach ulcers, such as proton pump inhibitors (such as omeprazole) or H_2-receptor antagonists (such as cimetidine, ranitidine) as they may affect the absorption of ERCYTA and how it works;
- if you are taking statins (medicines to lower your blood cholesterol), ERCYTA may increase the risk of statin related muscle problems, which can lead to serious muscle breakdown (rhabdomyolysis) resulting in kidney damage;
- ciprofloxacin, erythromycin, clarithromycin (antibiotics);

- antifungal medicines like ketoconazole (used to treat fungal infections);
- protease inhibitors (used for HIV/AIDS) such as ritonavir, saquinavir;
- phenytoin, carbamazepine (medicines for epilepsy);
- barbiturates (for sedation);
- St. John's Wort (sometimes used for depression);
- rifampicin (medicine for tuberculosis (TB));
- ciclosporin (may be used for rheumatoid arthritis or psoriasis);
- verapamil (medicine used to treat blood pressure);
- tobacco smoking (see "Warnings and precautions").

Certain cancer medicines (such as capecitabine) may affect how ERCYTA works. Your doctor will discuss your treatment with you.

ERCYTA with food and drink

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

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 healthcare provider for advice before taking ERCYTA.

Women who are pregnant should not receive ERCYTA. Avoid pregnancy while being treated with ERCYTA.

If you could become pregnant, use adequate contraception during treatment, and for at least 2 weeks after taking the last tablet. If you become pregnant while you are being treated with ERCYTA, inform your doctor immediately.

Do not breastfeed if you are being treated with ERCYTA and for at least 2 weeks after the last dose.

Driving and using machines

Do not drive, handle tools or operate machinery if you do not feel well.

ERCYTA contains a sugar called lactose monohydrate

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

3. How to take ERCYTA

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

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

The usual starting dose for non-small cell lung cancer and bronchial adenocarcinoma is one ERCYTA 150 mg tablet daily.

The usual starting dose for pancreatic cancer is one ERCYTA 100 mg tablet daily, taken in combination with gemcitabine.

Do not take ERCYTA with a meal. Take ERCYTA at least one hour before a meal, or two hours after you have eaten. Swallow the tablet with a plain glass of water.

Your doctor will tell you what dose to take and for how long your treatment will last.

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

If you take more ERCYTA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ERCYTA

If you miss one or more doses of ERCYTA, contact your doctor or pharmacist as soon as possible.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking ERCYTA

It is important to keep taking ERCYTA every day, as long as your doctor prescribes it for you.

4. Possible side effects

ERCYTA can have side effects.

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

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

- rash or itching with severe blistering or peeling of skin (suggestive of Stevens-Johnson syndrome);
- yellowing of the skin and eyes, pain in abdomen, nausea, vomiting and confusion. These may be signs of liver failure and your doctor may interrupt your treatment;
- severe or persistent diarrhoea;
- abdominal pain or blood in your stools. You may have internal bleeding;
- eye pain with ulcers on the surface of the eye or perforation (sudden drop in visual acuity and ocular pain with excess tear formation);
- severe irritation of the lungs (interstitial lung disease) which may have a fatal outcome in some cases. If you have sudden difficulty in breathing, if you cough or have a fever contact your doctor immediately. Your doctor may decide to permanently stop your treatment with ERCYTA;

- kidney failure. Some signs may be weakness, shortness of breath, confusion and abnormal heart rhythm.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- infections (affecting, for example, your lungs, blood, tissues)
- loss of appetite, decreased weight
- depression
- headache
- altered skin sensation or numbness in the extremities
- eye infections
- bleeding from the nose, coughing
- diarrhoea (which can lead to low blood potassium; see “Warnings and precautions”)
- nausea, mouth irritation, stomach pain, indigestion and flatulence
- abnormal liver test results
- inflammatory reactions of the skin around fingernails and toenails
- infection of hair follicles, acne, cracked skin (skin fissures)
- itching, dry skin and loss of hair
- rash, which may occur or worsen in sun exposed areas. If you are exposed to sun, protective clothing, and/or use of sunscreen may be advisable
- reduced kidney function (determined by blood tests)
- tiredness, fever, rigors.

Less frequent side effects

- eyebrow changes
- eyelash changes (abnormal growth, in-growing eyelashes, thickening of eyelashes)

- excess body and facial hair of a male distribution pattern
- brittle and loose nails
- hyperpigmentation (patches of darker coloured skin)
- flushed or painful hand palms or foot soles (palmar plantar erythrodysaesthesia syndrome)
- inflammation of the kidneys with protein in 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, pharmacist or nurse. You can also report side effects to SAHPRA on the SAHPRA website: www.sahpra.org.za. By reporting side effects, you can help provide more information on the safety of ERCYTA.

5. How to store ERCYTA

Store all medicines out of reach of children.

Store at or below 25 °C in the original packaging (keep blisters in the carton until required for use and keep the bottle tightly closed).

Do not store in a bathroom. Do not use after the expiry date stated on the carton.

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 ERCYTA contains

- The active substance of ERCYTA is erlotinib. Each film-coated tablet contains 100 mg or 150 mg of erlotinib (as erlotinib hydrochloride) depending on the strength.
- The other ingredients are lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate, sodium starch glycolate and Opadry white (consisting of

titanium dioxide, hydroxypropyl cellulose, hydroxypropyl methylcellulose and polyethylene glycol).

What ERCYTA looks like and contents of the pack

ERCYTA 100: White to yellowish, round, biconvex, bevel-edged, coated tablets debossed with 'ERL' on one side and "100" on the other side.

ERCYTA 150: White to yellowish, round, biconvex, bevel-edged, coated tablets debossed with 'ERL' on one side and "150" on the other side.

ERCYTA is supplied in packs of 30 or 100 tablets, packed in rigid, transparent PVC film and aluminium push-through blister foil, or white round HDPE bottles with a white round polypropylene cap with fine ribs at the lateral side, in a cardboard carton.

Not all pack sizes are necessarily marketed at any one time.

Holder of the Certificate of Registration

Viatris South Africa (Pty) Ltd

4 Brewery Street, Isando

Gauteng

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Access to the corresponding Professional Information

TBC