PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

ERLOCIP 25, 100, 150, Film - Coated Tablets

Erlotinib hydrochloride

Contains sugar: lactose monohydrate

Read all of this leaflet carefully before you start taking ERLOCIP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ERLOCIP 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 ERLOCIP is and what it is used for
2. What you need to know before you take ERLOCIP
3. How to take ERLOCIP
4. Possible side effects
5. How to store ERLOCIP
6. Contents of the pack and other information

1. What ERLOCIP is and what it is used for

ERLOCIP is a medicine used to treat cancer by preventing the activity of a protein called epidermal growth factor receptor. This protein is known to be involved in the growth and spread of cancer cells.

ERLOCIP is indicated for adults.

ERLOCIP can be prescribed to you if you have non-small cell lung cancer with EGFR activating mutation at an advanced stage. It can be prescribed either if your disease remains largely unchanged after initial chemotherapy, or if previous chemotherapy has not helped to stop your disease.

ERLOCIP can be prescribed to you if you have adenocarcinoma of your lung.

It can be prescribed as initial therapy if your cancer cells have specific EGFR mutations.

ERLOCIP can also be prescribed to you in combination with another treatment called gemcitabine if you have cancer of the pancreas at a metastatic stage (stage where the cancer has spread from the place where it started to another part of the body).

2. What you need to know before you take ERLOCIP

Do not take ERLOCIP:

- If you are hypersensitive (allergic) to Erlotinib hydrochloride or any of the other ingredients of ERLOCIP listed in **section 6.**

Warnings and precautions

Take special care with ERLOCIP:

- If you develop lung disease or associated symptoms including shortness of breath, pneumonia, bronchiolitis, coughing, fever or lung infection.
- If you suffer from other airway obstruction or respiratory conditions such as shortness of breath

- Prior or concomitant chemotherapy or radiotherapy.
- If you suffer from severe dehydration in the form of diarrhoea, vomiting, substantial weight loss, muscle cramping, weakness or tiredness.
- If you develop or suffer from kidney problems including that of potassium deficiency. Factors that aggravate this include advancing age and the use of concomitant medicines.
- If you develop any form of liver failure. Aggravating factors include pre-existing liver diseases as well as contraindicated toxic medicine.
- If you are lactose intolerant.
- 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 health professional immediately as you may need urgent treatment (see **section 4**).
- If you have severe pain in the abdomen, severe blistering or peeling of skin. Your doctor may need to interrupt or stop your treatment.
- If you have liver disorders
- If you are a smoker, you are advised to stop smoking if you are treated with ERLOCIP as smoking considerably decreases the amount of ERLOCIP available in your blood**.**

Children and adolescents

Do not give this medicine to children under 18. If ERLOCIP is accidentally ingested by a child, go to the hospital immediately and take the package leaflet with you to show to the emergency doctor.

Other medicines and ERLOCIP

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

The following medicines or substances may increase blood levels and increase risk of adverse events associated with ERLOCIP**,** so please inform your doctor if you are taking the following:

- Ketoconazole, itraconazole or voriconazole for the treatment of fungal infections.
- Antibiotics such as erythromycin and ciprofloxacin that are used in the treatment of bacterial infections.
- Fluvoxamine used in the treatment of depression.
- Midazolam used in the treatment of sleeplessness.

The following medicines may lower blood levels and as a result may reduce the effect of ERLOCIP; so please inform your doctor if you are taking:

- Antibiotics such as rifampicin used in the treatment of tuberculosis.
- Anti-epileptic medicines such as phenytoin or carbamazepine which are also used in the treatment of fits and seizures.
- St. John's Wort, a herbal medicine used in the treatment for depression.
- Barbiturates used for the promotion of calmness or inducing sleep

ERLOCIP may alter both the blood levels and the effect of the following medicines; so please inform your doctor if you are currently taking:

- Warfarin for the treatment and prevention of blood clots
- Statins used to treat high cholesterol
- Ciclosporin for the treatment of auto-immune diseases and the prevention of organ rejection.
- Verapamil for the treatment of high blood pressure.
- Omeprazole and antacids used in the treatment for acid reflux and indigestion

Carboplatin, paclitaxel or capecitabine used in the treatment of cancer.

ERLOCIP with food, drink and alcohol

ERLOCIP should be taken at least one hour before or two hours after eating food.

Pregnancy, breastfeeding and fertility

Do not use ERLOCIP if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking ERLOCIP.

Women of childbearing age should avoid pregnancy whilst on ERLOCIP treatment. Contraceptive methods should be implemented during treatment and two weeks after ERLOCIP treatment is completed.

Driving and using machines

ERLOCIP may cause the inflammation of the eye and hence may impair vision. Caution should be observed before and during driving and use of machinery.

ERLOCIP contains sugar, lactose monohydrate.

Do not take ERLOCIP if you have rare hereditary conditions of lactose or galactose intolerance.

3. How to take ERLOCIP:

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

Always take ERLOCIP exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The recommended dose is one 150 mg tablet taken at least one hour before or two hours after ingestion of food. Your doctor may decide to adjust your dose accordingly.

Your doctor will tell you how long your treatment with ERLOCIP will last.

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

If you take more ERLOCIP than you should:

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

In the event of an overdosage, you may experience the following side effects:

- Rash
- Diarrhoea

If you forget to take a dose of ERLOCIP:

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

If you stop taking ERLOCIP

Do not stop taking ERLOCIP unless your doctor tells you to do so. If you have further questions on the use of ERLOCIP, ask your doctor or pharmacist.

4. Possible side effects

ERLOCIP can have side effects.

Not all side effects reported for ERLOCIP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while ERLOCIP, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.

- severe blistering or peeling of skin (suggestive of Stevens-Johnson syndrome).
- difficulty in breathing.

These are all serious side effects. 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:

- Severe dehydration: vomiting and diarrhoea
- Shortness of breath
- Infections such as cold sores or blisters in your mouth, coughs, pink eye, inflammation of the eye (painful or sensitive eyes) and nail disease.
- Eye irritation due to conjunctivitis / keratoconjunctivitis and keratitis.
- If you have severe pain in your abdomen (gastrointestinal perforations) and if you had peptic ulcers or diverticular disease in the past, as this may increase this risk.
- Liver failure. If your blood tests indicate severe changes in your liver function, your doctor may need to interrupt your treatment.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- Fatigue, Fever, rigors (a chill, usually with shivering, as at the onset of high fever)
- Rash
- rash which may occur or worsen in sun exposed areas. If you are exposed to sun, protective clothing, and/or use of sunscreen (e.g. mineral containing) may be advisable.
- diarrhoea
- Itchy

- Dry skin, cracked Skin
- Cutaneous eruptions resembling acne
- keratitis (inflammation of the cornea)
- loss of appetite, decreased weight
- Infection of one or more hair follicles (Folliculitis)
- Alopecia (hair loss)
- Bleeding of the nose
- Anorexia (abnormal weight loss and loss of willingness to eat)
- Nausea
- Acne
- Reduced kidney function
- Stomach pain, indigestion, flatulence
- tiredness, fever, rigors (a chill, usually with shivering, as at the onset of high fever).
- Cough
- Infection
- headache, altered skin sensation or numbness in the extremities
- Depression
- abnormal blood tests for the liver function
- bleeding from the stomach or the intestines
- bleeding from the nose can occur

Less frequent side effects:

- Brittle or loose nails
- Eyebrow or eyelash changes

- Hand-foot syndrome causing redness, swelling, and pain on the palms of the hands and/or the soles of the feet.
- Severe blistering or peeling of skin (suggestive of Stevens-Johnson syndrome)
- Darkened patches or spots on the skin.
- Facial hair growth in women.
- excess body and facial hair of a male distribution pattern, eyelash and eyebrow changes, brittle and loose nails, hyperpigmentation (patches of skin become darker in colour).
- uveitis, which is inflammation of the uvea of the eye.
- ulceration or perforation of the cornea.

Reporting of side effects

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist. If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of ERLOCIP

5. How to store ERLOCIP

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Store in the original package.
- Protect from moisture.
- Do not remove blisters from carton until required for use.

- Do not use after the expiry date stated on the label carton
- Return all unused medicines to your pharmacist. Do not dispose of unused medicines in drains or sewage systems (e.g. toilets).

6. Contents of the pack and other information

What ERLOCIP contains

ERLOCIP 25:

Each film coated tablet contains Erlotinib hydrochloride equivalent to Erlotinib 25 mg

Contains sugar: lactose monohydrate 17,333 mg.

ERLOCIP 100:

Each film coated tablet contains Erlotinib hydrochloride equivalent to Erlotinib 100 mg

Contains sugar: lactose monohydrate 69,333 mg

ERLOCIP 150:

Each film coated tablet contains Erlotinib hydrochloride equivalent to Erlotinib 150 mg

Contains sugar: lactose monohydrate 104,000 mg

Inactive ingredients:

Lactose monohydrate, magnesium stearate, microcrystalline cellulose, Opadry Complete Film Coating System 20B58900 White, sodium lauryl sulphate and sodium starch glycolate.

The film coat is made up of HPMC 2910 / hypromellose, hydroxypropyl cellulose macrogol and titanium dioxide.

What ERLOCIP looks like and contents of the pack

What ERLOCIP looks like:

ERLOCIP 25: White, round, biconvex film coated tablet debossed with "C1" on one side and plain on the other.

ERLOCIP 100: White, round, biconvex film coated tablet debossed with "C2" on one side and plain on the other.

ERLOCIP 150: White, round, biconvex film coated tablet debossed with "C3" on one side and plain on the other.

Contents of the pack:

ERLOCIP 25 mg, 100 mg & 150 mg are packed in a clear PVC film/ Plain aluminium blister foil having NC coating with universal heat lacquer packaged in a carton containing 1 blister pack of 10 tablets each or 3 blister packs of 10 tablets each.

Holder of Certificate of Registration

Cipla Medpro (Pty) Ltd

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7441

Customer Care: 080 222 6662

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