TARLONIB

(Erlotinib Tablets 25, 100, 150 mg)

What is in this leaflet

This leaflet answers some common questions about **TARLONIB**

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking **TARLONIB** against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What TARLONIB is used for

TARLONIB is used to treat the cancer by preventing the activity of a protein called epidermal growth factor receptor (EGFR).

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

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

How TARLONIB works

TARLONIB contains the active substance erlotinib. **TARLONIB** is used to treat the 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.

Ask your doctor if you have any questions about why TARLONIB has been prescribed for you.

This product is available as 25 mg, 100 mg and 150 mg strengths.

Before you use TARLONIB

When you must not use it

Do not take TARLONIB:

If you have an allergy to erlotinib or any ingredient of **TARLONIB** listed at the end of this leaflet (see Product Description)

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- if you have sudden difficulty in breathing associated with cough or fever because your doctor may need to treat you with other medicines and interrupt your **TARLONIB** treatment;
- if you have diarrhoea because your doctor may need to treat you with anti-diarrhoeal (for example loperamide);
- if you have severe or persistent diarrhoea, nausea, loss of appetite, or vomiting because your doctor may need to interrupt your **TARLONIB** treatment and may need to treat you in the hospital;
- 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 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 use 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.
- ***Liver or kidney disease:*** Treatment with **TARLONIB** is not recommended if you have a severe liver or kidney disease.
- ***Smoking:*** You are advised to stop smoking if you are treated with **TARLONIB** as smoking could decrease the amount of your medicine in the blood.
- ***Glucuronidation disorder like Gilbert's syndrome:*** Your doctor must treat you with caution if you have a glucuronidation disorder like Gilbert's syndrome.

Pregnancy and Lactation

Do not take TARLONIB if you are pregnant or breast-feeding unless your doctor says so.

Tell your doctor if you are pregnant, planning to become pregnant or are breast-feeding currently.

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

If you have not told your doctor about any of the above, tell this before you start taking TARLONIB.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a

prescription from your pharmacy, supermarket or health food shop.

Some medicines and **TARLONIB** may interfere with each other. These include:

- Erythromycin, ciprofloxacin, clarithromycin, rifampicin (used to treat infection)
- Fluvoxamine (used to treat depression)
- Ketoconazole, itraconazole, voriconazole (used to treat fungal infection)
- Phenytoin, carbamazepine, barbiturates (used to treat seizures, fits or convulsions)
- St. John's Wort (*Hypericum perforatum*, herbal remedy used to treat depression and anxiety)
- Warfarin (used to thin the blood)
- Statins (class of medicines used to treat diabetes)
- Ciclosporin (used to suppress the immune system)
- Verapamil (used to treat high blood pressure)
- Omeprazole (used to reduce the gastric acid production)
- Ranitidine (used to treat stomach ulcers, indigestion or heartburn,)
- Carboplatin, paclitaxel, capecitabine, bortezomib (used for cancer)
- Antacids

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking **TARLONIB**

How to use TARLONIB

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack ask your doctor or pharmacist for help.

How much to use

Non-small cell lung cancer

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

Metastatic pancreatic cancer

The usual dose is one tablet of 100 mg each day. **TARLONIB** is given in combination with gemcitabine treatment.

Your doctor may adjust your dose in 50 mg steps, when necessary.

Children

The treatment with **TARLONIB** is not recommended for children and adolescents.

How to use it

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

Swallow **TARLONIB** whole with a glass of water. **Do not crush or chew the tablets.**

When to use it

The tablet should be taken at least one hour before or two hours after the ingestion of food.

Try to take your daily dose at about the same time each day. Keeping a regular time for taking **TARLONIB** will help to remind you to take it.

How long to use it

Keep taking **TARLONIB** for as long as your doctor recommends.

If you are taking this medicine for a long time, tell your doctor about any new symptoms or any other exceptional circumstances.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally. Do not take a double dose to make up for the dose you missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

You may have increased side effects and your doctor may interrupt your treatment.

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much TARLONIB. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using TARLONIB

Keep all of your doctor's appointments so that your progress can be checked.

Things you must do

Take TARLONIB exactly as your doctor has prescribed.

Continue taking **TARLONIB** every day as directed by your doctor, even if you have no symptoms.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking TARLONIB.

If your symptoms return or your condition gets worse while taking **TARLONIB**, tell your doctor immediately.

If you need to have any medical tests while you are taking TARLONIB, tell your doctor. It may affect the results of some tests.

Things you must not do

Do not take TARLONIB to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine because you are feeling better, unless advised by your doctor.

Things to be careful of

TARLONIB will not likely to affect the ability to drive or use any tools or machines. Make sure you know how you react to **TARLONIB** before you drive a car or operate any machinery.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking TARLONIB

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Serious side effects

If any of the following happens, stop taking TARLONIB and tell your doctor immediately or go to the casualty/ emergency department at your nearest hospital immediately.

- Severe skin rashes which may include blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals (Stevens Johnson Syndrome)
- Detachment of the top layer of skin from the lower layers of the skin all over the body, leaving large areas that look scalded. The loss of skin causes fluids and salts to ooze from the raw, damaged areas which can easily become infected (toxic epidermal necrolysis)
- If you develop new or sudden worsening of shortness of breath, possibly with a cough or fever (interstitial lung disease)
- Serious lung infection (symptoms includes, fever, chills, shortness of breath, cough, phlegm and occasionally blood)
- Persistent and severe diarrhoea and vomiting (may lead to low blood potassium and impairment of your kidney function), particularly if you receive other chemotherapy treatments at the same time.
- Liver disease (hepatitis) and liver failure (Hepatic failure)

Other side effects

Tell your doctor if you notice any of the following:

- infection
- loss of appetite
- eye irritation or inflammation may occur
- shortness of breath, cough
- loose stools, feeling sick (nausea), vomiting, sore mouth, stomach pain
- rash, itching, dry skin
- tiredness
- weight decreased
- feelings of deep sadness and unworthiness
- numbness
- headache
- indigestion
- wind (flatulence)
- hair loss
- fever, rigors
- changes in liver function tests
- nose bleeds
- bleeding from the stomach or the intestines
- infection of a nail bed
- infection of hair follicles
- inflammatory condition of the skin (redness, itching, and oozing liquid-filled cysts which become scaly, crusted, or hardened (dermatitis acneiform)
- cracked skin
- kidney problems

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of TARLONIB

Storage

Store below 30ºC

Keep out of the reach and sight of children.

Disposal

Return any unused or expired medicine to your doctor, pharmacist or health care professional for safe disposal.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What TARLONIB looks like

TARLONIB 25 are white to off white round biconvex film coated tablets debossed with "RL" on one side and "11" on other side.

TARLONIB 100 are White to off white round biconvex film coated tablets debossed with "RL" on one side and "12" on other side.

TARLONIB 150 are White to off white round biconvex film coated tablets debossed with "RL" on one side and "13" on other side.

Ingredients

Active ingredient:

TARLONIB 25
Each film-coated tablet contains
Erlotinib (as erlotinib hydrochloride)….. 25 mg

TARLONIB 100
Each film-coated tablet contains
Erlotinib (as erlotinib hydrochloride)….. 100 mg

TARLONIB 150
Each film-coated tablet contains
Erlotinib (as erlotinib hydrochloride)….. 150 mg

Inactive ingredients: Lactose Monohydrate, Microcrystalline cellulose, Sodium starch glycolate, Sodium lauryl sulphate, Magnesium stearate, Microcrystalline cellulose, Opadry.

MAL NO. MALXXXXXXXXAZ

Manufacturer

Sun Pharmaceutical Industries Limited (SPIL),

Halol-Baroda Highway,

Halol-389 350, Gujarat, India

Product Registration Holder

RANBAXY (MALAYSIA) Sdn. Bhd.

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