AFATIN (Afatinib Film Coated Tablets)

Afatinib 20mg, 30mg and 40mg (as dimaleate)

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What AFATIN is used for

AFATIN is used on its own to treat adult patients with a specific type of cancer of the lung (non-small cell lung cancer) that is identified by:

i) a change (mutation) in the gene for EGFR: AFATIN can be prescribed to you as your first treatment or if prior chemotherapy treatment has been insufficient.
ii) for patients carrying specific cell type (squamous cell) if prior chemotherapy treatment has been insufficient.

How AFATIN works

AFATIN is a medicine which contains the active substance afatinib. It works by blocking the activity of a group of proteins called the ErbB family (including EGFR [epidermal growth factor receptor or ErbB1], HER2 [ErbB2], ErbB3 and ErbB4). These proteins are involved in the growth and spread of cancer cells and can be affected by changes (mutations) in the genes that produce them. By blocking the activity of these proteins this medicine can inhibit growth and spread of cancer cells.

Before you use AFATIN

-When you must not use it

If you are allergic to afatinib or any of the other ingredients of this medicine.

Children and adolescents

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You should avoid becoming pregnant while taking this medicine. If you could become pregnant, you should use adequate birth control methods during treatment and for at least 1 month after taking the last dose of this medicine. This is because there may be a risk that an unborn baby is harmed.

If you become pregnant while receiving this medicine, you should immediately inform your doctor. Your doctor will decide with you whether treatment should be continued or not.

If you plan to become pregnant after taking the last dose of this medicine, you should ask your doctor for advice as your body may not have fully eliminated this medicine.

Breast-feeding

Do not breast-feed while taking this medicine as a risk to the breast-fed child cannot be excluded.

-Before you start to use it

Talk to your doctor or pharmacist before taking this medicine:

- 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. Treatment with this medicine is not recommended if you have a severe kidney disease.
- 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 this medicine 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 this medicine:

- 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 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 the Side effects section.

-Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including herbal medicines and medicinesobtained without a prescription.

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

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

The following medicines may reduce the effectiveness of AFATIN:

- Carbamazepine, phenytoin, phenobarbital - 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.
AFATIN 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 AFATIN.

How to use AFATIN

-How much to use

Dosage: The recommended dose is 40 mg each day.

Your doctor may adjust (increase or decrease) your dose depending on how well you tolerate this medicine.

-When to use it

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

AFATIN 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 the medicine is taken.

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

-How long to use it

Continue taking AFATIN for as long as your doctor recommends.

-If you forget to use it

- 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 use too much (overdose)

Contact your doctor or pharmacist immediately. You may experience increased side effects and your doctor may interrupt your treatment and provide supportive care.

While you are using it

- Things you must do

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

-Things you must not do

Do not stop taking this medicine without first consulting your doctor. It is important to take this medicine every day, as long as your doctor prescribes it for you. If you do not take this medicine as prescribed by your doctor your cancer may grow again.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

-Things to be careful of

Driving and using machines

If you experience treatment-related symptoms affecting your eyesight (e.g., redness and/or irritation of the eye, dry eye, tearing, light-sensitivity)
or your ability to concentrate and react, it is recommended that you do not drive or use machines until the side effect disappears.

AFATIN contains lactose

This medicine 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 this medicine.

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Side effects
Like all medicines, AFATIN can cause side effects, although not everybody gets them.
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** (very common, may affect more than 1 in 10 people). Diarrhoea lasting more than 2 days- or more severe diarrhoea may lead to fluid loss (common, may affect up to 1 in 10 people), low blood potassium (common) and worsening kidney function (common). 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 AFATIN.

- **Skin rash** (very common). 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 AFATIN. Rash may occur or worsen in areas exposed to sun. Sun protection with protective clothing and sunscreen is recommended.

- **Inflammation of the lungs** (uncommon, may affect up to 1 in 100 people) 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 / kerato conjunctivitis occurs commonly and keratitis uncommonly). Tell your doctor if you have sudden or worsening 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.

Very common side effects (may affect more than 1 in 10 people):
- Mouth sores and inflammation
- Nail infection
- Decreased appetite
- Bleeding from the nose
- Nausea
- Vomiting
- Itching
- Dry skin

Common side effects (may affect up to 1 in 10 people):
- 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 (dysgeusia) taste sensations
- Stomach pain, indigestion, heartburn
- Lip inflammation
- Decreases weight
- Runny nose
- Muscle spasms
- Fever
- Nail problems

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of AFATIN
-Storage
Do not store above 30°C. Store in original package in order to protect from moisture and light.
Keep out of the reach and sight of children.

-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 it looks like
AFATIN 20:
White to off white, round biconvex, bevel-edged, film coated tablets debossed with 'A2' on one side and 'H' on other side and free from physical defects. Diameter: Approximately 7.90 mm

AFATIN 30:
White to off white, round biconvex, bevel edge film coated tablets debossed with 'A3' on one side and 'H' on other side and free from physical defects. Diameter: Approximately 8.90 mm

AFATIN 40:
White to off white, round biconvex, bevel-edged film coated tablets debossed with 'A4' on one side and 'H' on the other side and free from physical defects. Diameter: Approximately 9.90 mm

-Ingredients
- Active ingredient: Afatinib
- Inactive ingredients:

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Tablet core: Lactose monohydrate, microcrystalline cellulose, crospovidone, colloidal silicon dioxide, magnesium stearate.
Film-coating: Hypromellose (E464), Titanium dioxide (E171), Talc (E553b), Macrogol (E1521), Polysorbate 80 (E433).

MAL number(s):
AFATIN 20: MALXXXXXXXXAZ
AFATIN 30: MALXXXXXXXXAZ
AFATIN 40: MAL24036011AZ

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