Package leaflet: Information for the user

Gefitinib Accord 250 mg Film-coated Tablets
gefitinib

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Gefitinib Accord is and what it is used for

Gefitinib Accord contains the active substance gefitinib which blocks a protein called 'epidermal growth factor receptor' (EGFR). This protein is involved in the growth and spread of cancer cells.

Gefitinib Accord is used to treat adults with non-small cell lung cancer. This cancer is a disease in which malignant (cancer) cells form in the tissues of the lung.

2. What you need to know before you take Gefitinib Accord

Do not take Gefitinib Accord
- if you are allergic to gefitinib or any of the other ingredients of this medicine (listed in section 6).
- if you are breast-feeding.

Warnings and precautions
Talk to your doctor or pharmacist or nurse before taking Gefitinib Accord
- if you have ever had any other lung problems. Some lung problems may get worse during treatment with Gefitinib Accord
- if you have ever had problems with your liver.

Children and adolescents
Gefitinib Accord is not indicated in children and adolescents under 18 years.

Other medicines and Gefitinib Accord
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- Phenytoin or carbamazepine (for epilepsy).
- Rifampicin (for tuberculosis).
- Itraconazole (for fungal infections).
- Barbiturates (a type of medicine used for sleeping problems).

- Herbal remedies containing St John's wort (Hypericum perforatum, used for depression and anxiety).
- Proton-pump inhibitors, H2-antagonists and antacids (for ulcers, indigestion, heartburn and to reduce acids in the stomach).

These medicines may affect the way Gefitinib Accord works.

- Warfarin (a so-called oral anticoagulant, to prevent blood clots). If you are taking a medicine containing this active substance, your doctor may need to do blood tests more often.

If any of the above applies to you, or if you are not sure, check with your doctor or pharmacist before taking Gefitinib Accord.

Pregnancy, breast-feeding and fertility
Talk to your doctor before taking this medicine if you are pregnant, may become pregnant or are breast-feeding.
It is recommended that you avoid becoming pregnant during treatment with Gefitinib Accord because Gefitinib Accord could harm your baby.
Do not take Gefitinib Accord if you are breast-feeding for the safety of your baby.

Driving and using machines
If you feel weak whilst taking this medicine, take care driving or using tools or machines.

Gefitinib Accord contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Gefitinib Accord

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

- The recommended dose is one 250 mg tablet per day.
- Take the tablet at about the same time each day.
- You can take the tablet with or without food.
- Do not take antacids (to reduce the acid level of your stomach) 2 hours before or 1 hour after taking Gefitinib Accord.

If you have trouble swallowing the tablet, dissolve it in half a glass of still (non-fizzy) water. Do not use any other liquids. Do not crush the tablet. Swirl the water until the tablet has dissolved. This may take up to 20 minutes. Drink the liquid straight away. To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it.

If you take more Gefitinib Accord than you should
If you have taken more tablets than you should, talk to a doctor or pharmacist straight away.

If you forget to take Gefitinib Accord
What to do if you forget to take a tablet depends on how long it is until your next dose.

- If it is 12 hours or more until your next dose: take the missed tablet as soon as you remember. Then take the next dose as usual.
- If it is less than 12 hours until your next dose: skip the missed tablet. Then take the next tablet at the usual time.

Do not take a double dose (two tablets at the same time) to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you notice any of the following side effects - you may need urgent medical treatment:

- Allergic reaction (common), particularly if symptoms include swollen face, lips, tongue or throat, difficulty to swallow, hives, nettle rash and difficulty breathing.
- Serious breathlessness, or sudden worsening breathlessness, possibly with a cough or fever. This may mean that you have an inflammation of the lungs called 'interstitial lung disease'. This may affect about 1 in 100 patients taking Gefitinib Accord and can be life-threatening.
- Severe skin reactions (rare) affecting large areas of your body. The signs may include redness, pain, ulcers, blisters, and shedding of the skin. The lips, nose, eyes and genitals may also be affected.
- Dehydration (common) caused by long term or severe diarrhoea, vomiting (being sick), nausea (feeling sick) or loss of appetite.
- Eye problems (uncommon), such as pain, redness, watery eyes, light sensitivity, changes in vision or ingrowing eyelashes. This may mean that you have an ulcer on the surface of the eye (cornea).

Tell your doctor as soon as possible if you notice any of the following side effects:

Very common: may affect more than 1 in 10 people
- Diarrhoea
- Vomiting
- Nausea
- Skin reactions such as an acne-like rash, which is sometimes itchy with dry and/or cracked skin
- Loss of appetite
- Weakness
- Red or sore mouth

Increase of a liver enzyme known as alanine aminotransferase in a blood test; if too high, your doctor may tell you to stop taking Gefitinib Accord

Common: may affect up to 1 in 10 people
- Dry mouth
- Dry, red or itchy eyes
- Red and sore eyelids
- Nail problems
- Hair loss
- Fever
- Bleeding (such as nose bleed or blood in your urine)
- Protein in your urine (shown in a urine test)
- Increase of bilirubin and the other liver enzyme known as aspartate aminotransferase in a blood test; if too high, your doctor may tell you to stop taking Gefitinib Accord
- Increase of creatinine levels in a blood test (related to kidney function)
- Cystitis (burning sensations during urination and frequent, urgent need to urinate)

Uncommon: may affect up to 1 in 100 people
- Inflammation of the pancreas. The signs include very severe pain in the upper part of the stomach area and severe nausea and vomiting.
- Inflammation of the liver. Symptoms may include a general feeling of being unwell, with or without possible jaundice (yellowing of the skin and eyes). This side effect is uncommon; however, some patients have died from this.
- Gastrointestinal perforation

Rare: may affect up to 1 in 1000 people
- Inflammation of the blood vessels in the skin. This may give the appearance of bruising or patches of non-blanching rash on the skin.

- Haemorrhagic cystitis (burning sensations during urination and frequent, urgent need to urinate with blood in the urine).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6767836; Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Gefitinib Accord

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.
After dispersion in water, the preparation should be used within 90 minutes.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Gefitinib Accord contains
The active substance is gefitinib. Each tablet contains 250 mg of gefitinib.
The other ingredients are:
Tablet core: Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, povidone, sodium laurilsulfate, magnesium stearate in the core of the tablet.
Film-coating: Poly(vinyl alcohol), macrogol, talc, titanium dioxide (E171), yellow iron oxide (E172) and red iron oxide (E172).

What Gefitinib Accord looks like and contents of the pack
Gefitinib Accord are brown, film-coated, round, biconvex tablets, debossed with “LP100” on one side and plain on the other side. The diameter of table is approximately 11.13mm.

Pack size of 30 x 1 tablets in PVC/PVDC-Al perforated unit dose blister packed in PET/Al pouch packs.

Marketing Authorisation Holder
Accord Healthcare Ireland Limited
Euro House
Euro Business Park
Little Island
Cork
T45 K857
Ireland

Manufacturer
Pharmadox Healthcare Limited

KW20A Kordin Industrial Park
Paola
PLA 3000
Malta

This medicinal product is authorised in the Member States of the EEA under the following names:

Country	Invented Name
DE	Gefitinib Accord 250 mg Filmtabletten
AT	Gefitinib Accord 250 mg Filmtabletten
BE	Gefitinib Accord 250 mg Filmtabletten/comprimés pelliculés/filmomhulde tabletten
CZ	Gefitinib Accord
DK	Gefitinib Accord
FI	Gefitinib Accord 250 mg tabletti, kalvopäällysteinen
IE	Gefitinib Accord 250 mg film-coated tablets
IT	Gefitinib Accord
PL	Gefitinib Accord
PT	Gefitinib Accord
RO	Gefitinib Accord 250 mg comprimate filmate
SE	Gefitinib Accord
UK	Gefitinib Accord 250 mg film-coated tablets
ES	Gefitinib Accord 250 mg comprimidos recubiertos con película
FR	Gefitinib Accord 250 mg comprimé pelliculé

This leaflet was last revised in October 2019