

*Your doctor is the best resource for medical advice and information. The health information contained herein is provided for educational / awareness purposes only and is not intended to replace discussions with a medical practitioner and/or medical advice or be construed as a promotional information.*

# **Package Leaflet: Information for the user**

## **DACOPLICE 15 mg film-coated tablets**

## **DACOPLICE 30 mg film-coated tablets**

## **DACOPLICE 45 mg film-coated tablets**

### **Dacomitinib**

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**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- If you have any further questions, ask your doctor.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Dacoplice (Dacomitinib) is and what it is used for
2. What you need to know before you take Dacoplice (Dacomitinib)
3. How to take Dacoplice (Dacomitinib)
4. Possible side effects
5. How to store Dacoplice (Dacomitinib)
6. Contents of the pack and other information

#### **1. What Dacoplice (Dacomitinib) is and what it is used for**

Dacoplice (Dacomitinib) contains the active substance dacomitinib, which belongs to a group of medicines called protein tyrosine kinase inhibitors which are used to treat cancer.

Dacoplice (Dacomitinib) is used as a first line treatment for patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations. If a test has shown that your cancer has certain changes (mutations) in a gene called 'EGFR' (epidermal growth factor receptor) and has spread to your other lung or other organs, your cancer is likely to respond to treatment with Dacoplice (Dacomitinib).

Dacoplice (Dacomitinib) can be used as your first treatment once your lung cancer has spread to your other lung or other organs.

## **2. What you need to know before you take Dacoplice (Dacomitinib)**

### **Do not take Dacoplice (Dacomitinib)**

#### **Warnings and precautions**

#### **Talk to your doctor before taking Dacoplice (Dacomitinib):**

- if you ever had any other lung problems. Some lung problems may get worse during treatment with Dacoplice (Dacomitinib), as Dacoplice (Dacomitinib) may cause inflammation of the lungs during treatment. Symptoms may be similar to those from lung cancer. Tell your doctor right away if you have any new or worsening symptoms including weakness, difficulty in breathing, cough and raise temperature .
- If you are being treated with any of the medicines listed in section *Other medicines and Dacoplice (Dacomitinib)*.

Tell your doctor immediately while taking this medicine:

- if you develop diarrhoea. Immediate treatment of diarrhoea is important.
- if you develop skin rash. Early treatment of skin rash is important.

#### **Children and adolescents**

Dacoplice (Dacomitinib) has not been studied in children or adolescents and it must not be given to patients under the age of 18 years.

#### **Other medicines and Dacoplice (Dacomitinib)**

Tell your doctor if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription and even those not prescribed.

The following medicines may reduce how well Dacoplice (Dacomitinib) works:

- Proton Pump Inhibitor like rabeprazole

You should not take these medicines during your treatment with Dacoplice (Dacomitinib). As an alternative, you can take a locally-acting antacids or an H2-receptor antagonist. Medicines known as CYP2D6 Substrates like dextromethorphan should be avoided while taking Dacoplice (Dacomitinib). If you take H2-receptor antagonist take the dose of Dacoplice (Dacomitinib) at least 6 hours before or 10 hours after taking H2-receptor antagonist .

#### **Dacoplice (Dacomitinib) with food and drink**

Dacoplice (Dacomitinib) tablets may be taken with or without food.

## **Pregnancy and breast-feeding**

You should not use Dacoplice (Dacomitinib) if you are pregnant.

### Pregnancy

You should not become pregnant during treatment with Dacoplice (Dacomitinib) because this medicine could harm the baby. If there is any possibility that you may become pregnant you must use effective contraception during treatment, and for at least 17 days after the final dose. If you become pregnant while taking this medicine, you should immediately talk to your doctor.

### Breast-feeding

Do not breast-feed while taking this medicine and at least 17 days after the last dose because it is not known if it can harm your baby.

## **Driving and using machines**

There is no data available of effects on ability to drive and use machines while taking Dacoplice (Dacomitinib).

## **3. How to take Dacoplice (Dacomitinib)**

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

- The recommended dose is 45 mg taken by mouth each day.
- Take the tablet at about the same time each day.
- Swallow the tablet whole with a glass of water.
- You can take the tablet with or without meals.

Your doctor may decrease the dose of your medicine depending on how well you tolerate it.

## **If you take more Dacoplice (Dacomitinib) than you should**

If you have taken too much Dacoplice (Dacomitinib), see a doctor or go to a hospital immediately.

## **If you forget to take Dacoplice (Dacomitinib)**

If you miss a dose or vomit, take your next dose as scheduled. Do not take a double dose to make up for the forgotten tablets.

## **If you stop taking Dacoplice (Dacomitinib)**

Do not stop taking Dacoplice (Dacomitinib) unless your doctor tells you to.

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

#### 4. Possible side effects

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

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

- Inflammation of the lungs (common, may affect up to 1 in 100 patients)  
Difficulty in breathing, shortness of breath, possibly with a cough or fever. This may mean that you have an inflammation of the lungs called interstitial lung disease and can be fatal.
- Diarrhoea (very common, may affect more than 1 in 10 patient)  
Diarrhoea can be fatal. Contact your doctor immediately at first sign of diarrhoea. You may require intravenous hydration and/or anti-diarrhoeal medication (e.g., loperamide) for treatment of diarrhoea.,
- Skin rash (very common)  
Tell your doctor immediately, if a rash starts or the rash is getting worse (for example, you have peeling or cracking of the skin). Your doctor may advise to use moisturizer before starting the Dacoplice and treat rash. Your doctor may also decide to withhold your treatment with Dacoplice (Dacomitinib). Rash may occur or worsen in areas exposed to sun. Sun protection with protective clothing and sunscreen is recommended.

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

*Very common (may affect more than 1 in 10 patient):*

- Diarrhoea
- Stomatitis
- Nausea
- Constipation
- Mouth ulceration
- Rash (dermatitis acneiform, rash, and rash maculo-papular)
- Paronychia (nail infection, nail toxicity, onychoclasia, onycholysis, onychomadesis, paronychia)
- Dry skin
- Alopecia (Hair loss)
- Pruritus
- Palmar-plantar erythrodysesthesia syndrome
- Dermatitis
- Decreased appetite
- Decreased weight
- Cough (epistaxis, nasal inflammation, nasal mucosal disorder, nasal mucosal ulcer)
- Rhinitis)
- Nasal mucosal disorder
- Dyspnea
- Upper respiratory tract infection
- Chest pain
- Conjunctivitis
- Pain in extremity
- Musculoskeletal pain
- Asthenia (Weakness)
- Insomnia (Difficulty sleeping)

*Common (may affect up to 1 in 10 patient):*

- Fatigue
- skin fissures
- hypertrichosis
- skin exfoliation/exfoliative skin reactions
- vomiting
- dysgeusia
- interstitial lung disease/ pneumonitis (Inflammation of the lungs which can cause weakness, breathlessness, cough and raise temperature)
- keratitis

- dehydration (Reduction of water in the body)

Laboratory Abnormalities (>20% patients), like:

- Anemia (Reduction in red blood cells which can make the skin pale and cause weakness or breathlessness)
- Lymphopenia
- Hypoalbuminemia
- Increased ALT, Increased AST, (Blood tests which show changes in the way the liver is working)
- Hyperglycemia (High glucose (blood sugar) level)
- Hypocalcemia
- Hypokalemia (Low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm)
- Hyponatremia (Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits or coma)
- Increased creatinine
- Increased alkaline phosphatase
- Hypomagnesemia
- Hyperbilirubinemia

## **5. How to store Dacoplice (Dacomitinib)**

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 bottle or carton and blister after EXPIRY. The expiry date refers to the last day of that month.

Store below 30°C.

This medicine may pose a risk for the environment. Do not throw away any medicines via wastewater or household waste. Ask your doctor 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 Dacoplice (Dacomitinib) contains**

- The active substance is dacomitinib (as dacomitinib monohydrate). Dacoplice (Dacomitinib) tablets come in different strengths.  
Dacoplice 15 mg tablet: Each film-coated tablet contains 15 mg dacomitinib  
Dacoplice 30 mg tablet: Each film-coated tablet contains 30 mg dacomitinib  
Dacoplice 45 mg tablet: Each film-coated tablet contains 45 mg dacomitinib
- The other ingredients are:
  - Microcrystalline Cellulose
  - Lactose Monohydrate

- Sodium Starch Glycolate
- Magnesium Stearate
- Opadry® II Blue 85F30716 film coating contains;
- Polyvinyl Alcohol, Talc, Titanium Dioxide, Macrogol/PEG 3350, FD&C Blue #2/IndigoCarmine Aluminium Lake.

### **What Dacoplice (Dacomitinib) looks like and contents of the pack**

- Dacoplice (Dacomitinib) 15 mg film-coated tablets are supplied as blue film-coated, round biconvex tablets, debossed with “Pfizer” on one side and “DCB15” on the other side.
- Dacoplice (Dacomitinib) 30 mg film-coated tablets are supplied as blue film-coated, round biconvex tablet, debossed with “Pfizer” on one side and “DCB30” on the other side.
- Dacoplice (Dacomitinib) 45 mg film-coated tablets are supplied as blue film-coated, round biconvex tablet, debossed with “Pfizer” on one side and “DCB45” on the other side.

It is available as 30 tablets in high-density polyethylene (HDPE) bottles containing 1 g desiccant with polypropylene (PP) closure with heat induction seal liner.

OR

10 tablets per blister pack of aluminium foil with aluminium foil liding; 3 blisters strips per carton.

All strengths/pack sizes mentioned in this document might not be available in the market.

### **Imported and marketed by**

Pfizer Products India Private Limited,  
The Capital- B Wing, 1802, 18<sup>th</sup> Floor,  
Plot No. C-70, G Block, Bandra Kurla Complex,  
Bandra (East), Mumbai 400 051,  
India

### **Manufacturer**

M/s. Pfizer Manufacturing Deutschland GmbH Betriebsstätte Freiburg Mooswaldallee 1,  
Freiburg - 79090 (Germany)

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