PACKAGE LEAFLET

Package leaflet: Information for the patient

Ivacaftor Teva 150 mg Film-coated Tablets
ivacaftor

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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Ivacaftor Teva is and what it is used for

Ivacaftor Teva contains the active substance ivacaftor. Ivacaftor acts at the level of the cystic fibrosis transmembrane conductance regulator (CFTR), a protein that forms a channel at the cell surface that allows the movement of particles such as chloride in and out of the cell. Due to mutations in the *CFTR* gene (see below), chloride movement is reduced in those with cystic fibrosis (CF). Ivacaftor helps certain abnormal CFTR proteins open more often to improve chloride movement in and out of the cell.

Ivacaftor Teva tablets are indicated:
- As monotherapy for patients aged 6 years and older and weighing 25 kg or more with cystic fibrosis (CF) who have an *R117H CFTR* mutation or one of the following gating mutations in the *CFTR* gene: *G551D*, *G1244E*, *G1349D*, *G178R*, *G551S*, *S1251N*, *S1255P*, *S549N* or *S549R*.

2. What you need to know before you take Ivacaftor Teva

Do not take Ivacaftor Teva
- if you are allergic to ivacaftor or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Ivacaftor Teva

- Talk to your doctor if you have liver problems or have previously had them. Your doctor may need to adjust your dose.
- Increased liver enzymes in the blood have been seen in some people receiving Ivacaftor Teva. Tell your doctor right away if you have any of these symptoms, which may be a sign of liver problems:
  - Pain or discomfort in the upper right stomach (abdominal) area
  - Yellowing of the skin or the white part of the eyes
  - Loss of appetite
  - Nausea or vomiting
  - Dark urine

- Your doctor will do some blood tests to check your liver before and during treatment, particularly during the first year and especially if your blood tests showed high liver enzymes in the past.

- Depression (including suicidal thoughts and behaviours) has been reported in patients while taking Ivacaftor Teva, mainly in a combination regimen with tezacaftor/ivacaftor or ivacaftor/tezacaftor/elexacaftor, usually starting within the first three months of treatment. Talk to a doctor straightaway if you (or someone taking this medicine) experience any of the following symptoms: sad or altered mood, anxiety, feelings of emotional discomfort or thoughts of harming or killing yourself, which may be signs of depression.

- Talk to your doctor if you have kidney problems or have previously had them.

- If you have two Class I mutations (mutations known not to make CFTR protein), you should not take Ivacaftor Teva, as you are not expected to respond to this medicine.

- Ivacaftor Teva is not recommended if you have undergone an organ transplant.

- Talk to your doctor if you are using hormonal contraception – for example, women using the contraceptive pill. This may mean you are more likely to get a rash while taking Ivacaftor Teva in combination with ivacaftor/tezacaftor/elexacaftor.

- Abnormality of the eye lens (cataract) without any effect on vision has been noted in some children and adolescents treated with Ivacaftor Teva (alone or in combination with tezacaftor/ivacaftor or ivacaftor/tezacaftor/elexacaftor). Your doctor may perform some eye examinations prior to and during treatment.

- Ivacaftor Teva should only be used if you have one of the mutations in the *CFTR* gene indicated in section 1 (What Ivacaftor Teva is and what it is used for).

Children and adolescents

Do not give this medicine to children under 1 month of age as it is not known if ivacaftor is safe and effective in these children.

Do not give this medicine in combination with tezacaftor/ivacaftor to children under 6 years of age or in combination with ivacaftor/tezacaftor/elexacaftor to children under 2 years of age as it is not known if they are safe and effective for them.

Other medicines and Ivacaftor Teva

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. Some medicines can affect how Ivacaftor Teva works or make side effects more likely. In particular, tell your doctor if you are taking any of the medicines listed below. Your doctor may decide to adjust your dose or that you need extra check-ups.

- **Antifungal medicines** (used for the treatment of fungal infections). These include fluconazole, itraconazole, ketoconazole, posaconazole, and voriconazole.
- **Antibiotic medicines** (used for the treatment of bacterial infections). These include clarithromycin, erythromycin, rifabutin, rifampicin, and telithromycin.
- **Epilepsy medicines** (used for the treatment of epileptic seizures or fits). These include carbamazepine, phenobarbital, and phenytoin.
- **Herbal medicines.** These include St. John's wort (*Hypericum perforatum*).
- **Immunosuppressants** (used after an organ transplantation). These include ciclosporin, everolimus, sirolimus, and tacrolimus.
- **Cardiac glycosides** (used for the treatment of some heart conditions). These include digoxin.
- **Anticoagulant medicines** (used to prevent blood clots). These include warfarin.

- **Medicines for diabetes.** These include glimepiride and glipizide.
- **Medicines for lowering blood pressure.** These include verapamil.

Ivacaftor Teva with food and drink

Avoid food or drink containing grapefruit during treatment as these may increase the side effects of Ivacaftor Teva by increasing the amount of ivacaftor in your body.

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 for advice before taking this medicine. It may be better to avoid using Ivacaftor Teva during pregnancy, if possible, and your doctor will help you decide what is best for you and your child.

Ivacaftor passes into breast milk. If you plan to breast-feed, ask your doctor for advice before taking Ivacaftor Teva. Your doctor will decide whether to recommend that you stop breast-feeding or for you to stop ivacaftor therapy. Your doctor will take into account the benefit of breast-feeding for the child and the benefit of therapy for you.

Driving and using machines

Ivacaftor Teva can make you dizzy. If you feel dizzy, do not drive, cycle or use machines.

Ivacaftor Tevacontains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Ivacaftor Teva contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

3. How to take Ivacaftor Teva

Always take this medicine exactly as your doctor has told you to. Check with your doctor if you are not sure.
Your doctor will determine which medicine and dose is right for you. Ivacaftor Teva dosing recommendations are provided in Table 1.

Table 1: Dosing recommendations

Age/weight	**Morning dose**	**Evening dose**
Ivacaftor Teva as monotherapy		
6 years and older, ≥ 25 kg	One Ivacaftor 150 mg tablet	One Ivacaftor 150 mg tablet

Take the morning and evening doses approximately 12 hours apart with food that contains fat.

You must keep using all other medicines you use, unless your doctor tells you to stop using any.

If you have liver problems, either moderate or severe, your doctor may need to reduce the dose of your tablets, because your liver will not clear the medicine as fast as in people who have normal liver function.

This medicine is for oral use.

Swallow the tablet whole. Do not break, chew or dissolve the tablets. Take Ivacaftor Teva tablets with food that contains fat.

Meals or snacks that contain fat include those prepared with butter or oils or those containing eggs. Other fat-containing foods are:

- Cheese, whole milk, whole-milk dairy products, yogurt, chocolate
- Meats, oily fish
- Avocados, hummus, soy-based products (tofu)
- Nuts, fat-containing nutritional bars or drinks

If you take more Ivacaftor Teva than you should

You may experience side effects, including those mentioned in section 4 below. If so, contact your doctor or pharmacist to ask for advice. If possible, have your medicine and this leaflet with you.

If you forget to take Ivacaftor Teva

Take the missed dose if less than 6 hours have passed since the time you missed the dose. Otherwise, wait until your next scheduled dose as you normally would. Do not take a double dose to make up for a forgotten dose.

If you stop taking Ivacaftor Teva

Take Ivacaftor Teva for as long as your doctor recommends. Do not stop unless your doctor advises you to. 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.

Serious side effects

Stomach (abdominal) ache and increased liver enzymes in the blood.

Possible signs of liver problems

Increased liver enzymes in the blood are common in patients with CF and have also been reported in patients taking Ivacaftor Teva alone or in combination with tezacaftor/ivacaftor or ivacaftor/tezacaftor/elexacaftor.

In patients taking Ivacaftor Teva in combination with ivacaftor/tezacaftor/elexacaftor, liver damage and worsening of liver function in people with severe liver disease has been reported. The worsening of liver function can be serious and may require transplantation.

These may be signs of liver problems:

- Pain or discomfort in the upper right area of the stomach (abdominal) area
- Yellowing of the skin or white part of the eyes
- Loss of appetite
- Nausea or vomiting
- Dark urine

Depression
Signs of this include sad or altered mood, anxiety, feelings of emotional discomfort.

Tell your doctor straight away if you have any of these symptoms.

Very common side effects (may affect more than 1 in 10 people)
- Upper respiratory tract infection (the common cold), including sore throat and nasal congestion
- Headache
- Dizziness
- Diarrhoea
- Stomach or abdominal pain
- Changes in the type of bacteria in mucus
- Increased liver enzymes (signs of stress on the liver)
- Rash

Common side effects (may affect up to 1 in 10 people)
- Runny nose
- Ear pain, ear discomfort
- Ringing in the ears
- Redness inside the ear
- Inner ear disorder (feeling dizzy or spinning)
- Sinus problems (sinus congestion)
- Redness in the throat
- Breast mass
- Feeling sick (nausea)
- Flu
- Low blood sugar (hypoglycaemia)
- Abnormal breathing (shortness of breath or difficulty breathing)
- Wind (flatulence)
- Spots (acne)
- Itchy skin
- Increased creatine phosphokinase (sign of muscle breakdown) seen in blood tests

Uncommon side effects (may affect up to 1 in 100 people)
- Ear congestion
- Breast inflammation
- Enlargement of the breast in males
- Nipple changes or pain
- Wheezing
- Increased blood pressure

Not known (frequency cannot be estimated from the available data)
- Damage to the liver (liver injury)
- Raised bilirubin measurement (liver blood test)

Additional side effects in children and adolescents
Side effects seen in children and adolescents are similar to those observed in adults. However, increased liver enzymes in the blood are more frequently seen in young children.

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 Website: www.hpra.ie By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ivacaftor Teva

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 blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Ivacaftor Teva contains

The active substance is ivacaftor.
Each film-coated tablet contains 150 mg of ivacaftor.

The other ingredients are:
- Tablet core: cellulose microcrystalline (E460(i)), lactose monohydrate, povidone, poloxamer, croscarmellose sodium (E468), sodium laurilsulfate, silica colloidal anhydrous (E551), and magnesium stearate.
- Tablet film coating: poly(vinyl alcohol) part hydrolysed (E1203), calcium carbonate (E170), macrogol (E1521), talc (E553b) and indigo carmine aluminum lake (E132).

What Ivacaftor Teva looks like and contents of the pack

Ivacaftor Teva 150 mg film-coated tablets are blue, oval shaped, 16.7 mm × 8.5 mm, and debossed with “TV” on one side debossed with “L15” on the other.

Ivacaftor Teva is available in blisters containing 28 or 56 film-coated tablets, or perforated unit dose blisters containing 28 x 1 or 56 x 1 film coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

TEVA GmbH
Graf-Arco-Str. 3
89079 Ulm
Germany

Manufacturer(s)

Actavis International Ltd; 4, Sqaq tal-Gidi off Valletta Road, Luqa LQA 6000, Malta

Balkanpharma Dupnitsa AD, Samokovsko Shosse 3, 2600 Dupnitsa, Bulgaria

Merckle GmbH, Graf-Arco-Str. 3, 89079 Ulm, Germany

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria	Ivacaftor ratiopharm 150 mg Filmtabletten
Belgium	Ivacaftor Teva 150 mg filmomhulde tabletten / comprimés pelliculés / Filmtabletten
Czech Republic	Ivakaftor Teva
Germany	Ivacaftor-ratiopharm 150 mg Filmtabletten
Denmark	Ivacaftor Teva
Estonia	Ivacaftor Teva
Spain	Ivacaftor Teva 150 mg comprimidos recubiertos con película EFG

Croatia	Ivakaftor Teva 150 mg filmom obložene tablete
Hungary	Ivacaftor Teva 150 mg filmtabletta
Ireland	Ivacaftor Teva 150 mg Film-coated Tablets
Lithuania	Ivacaftor Teva 150 mg plėvele dengtos tabletės
Latvia	Ivacaftor Teva 150 mg apvalkotās tabletes
Luxembourg	Ivacaftor Teva 150 mg comprimés pelliculés
Netherlands	Ivacaftor Teva 150 mg filmomhulde tabletten
Poland	Ivacaftorum Teva
Portugal	Ivacaftor Teva
Romania	Ivacaftor Teva 150 mg comprimate filmate
Sweden	Ivacaftor Teva
Slovakia	Ivakaftor Teva 150 mg

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