Package leaflet: Information for the user

Ivacaftor Aurobindo 150 mg, filmomhulde tabletten
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 <Invented name> is and what it is used for
2. What you need to know before you take <Invented name>
3. How to take <Invented name>
4. Possible side effects
5. How to store <Invented name>
6. Contents of the pack and other information

1. What <Invented name> is and what it is used for

<Invented name> 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.

<Invented name> 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*.

- In combination with tezacaftor/ivacaftor tablets for patients aged 6 years and older with CF who have two *F508del* mutations in the *CFTR* gene (homozygous for the *F508del* mutation) or who have an *F508del* mutation and certain other second mutations that result in reduced amount and/or function of the CFTR protein (heterozygous for the *F508del* mutation with a residual function (RF) mutation). If you have been prescribed < Invented name > to be taken with tezacaftor/ivacaftor, read the package leaflet of the latter. It contains important information about how to take these two medicines.

- In combination with ivacaftor/tezacaftor/elexacaftor tablets for patients aged 6 years and over who have CF, with at least one mutation in the CFTR gene that is responsive to < Invented name > in combination with ivacaftor/tezacaftor/elexacaftor. If you have been prescribed < Invented name > to be taken with ivacaftor/tezacaftor/elexacaftor, read the package leaflet of the latter. It contains important information about how to take these two medicines.

2. What you need to know before you take <Invented name>

Do not take <Invented name>
- 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 <Invented name>.

- 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 (alone or in combination with ivacaftor/tezacaftor or ivacaftor/tezacaftor/elexacaftor). 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, 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 <Invented name>, as you are not expected to respond to this medicine.
- <Invented name> 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 <Invented name> 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 <Invented name> (alone or in combination with tezacaftor/ivacaftor or ivacaftor/tezacaftor/elexacaftor). Your doctor may perform some eye examinations prior to and during treatment.
- <Invented name> should only be used if you have one of the mutations in the *CFTR* gene indicated in section 1 (What <Invented name> is and what it is used for).

Children and adolescents
Do not give this medicine to children under 6 years of age.
For children below the age of 6, another product containing ivacaftor is available.

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 <Invented name>
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Some medicines can affect how <Invented name> works or make side effects more likely. 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.

<Invented name> with food and drink
Avoid food or drink containing grapefruit during treatment as these may increase the side effects of <Invented name> 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 <Invented name> 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 <Invented name>. 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
<Invented name> can make you dizzy. If you feel dizzy, do not drive, cycle or use machines.

<Invented name> contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

<Invented name> contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take <Invented name>

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

Your doctor will determine which medicine and dose is right for you.
<Invented name> dosing recommendations are provided in Table 1.

Table 1: Dosing recommendations

Age/weight	Morning dose	Evening dose
<Invented name> as monotherapy		
6 years and older, ≥ 25 kg	One <Invented name> 150 mg tablet	One <Invented name> 150 mg tablet
<Invented name> in combination with tezacaftor/ivacaftor		
6 years to less than 12 years, < 30 kg	One tezacaftor 50 mg/ivacaftor 75 mg tablet	One ivacaftor 75 mg tablet*
6 years to less than 12 years, ≥ 30 kg	One tezacaftor 100 mg/ivacaftor 150 mg tablet	One <Product name> 150 mg tablet
12 years and older	One tezacaftor 100 mg/ivacaftor 150 mg tablet	One <Product name> 150 mg tablet
<Invented name> in combination with ivacaftor/tezacaftor/elexacaftor		
6 years to less than 12 years, < 30 kg	Two ivacaftor 37.5 mg/tezacaftor 25 mg/elexacaftor 50 mg tablets	One ivacaftor 75 mg tablet*
6 years to less than 12 years, ≥ 30 kg	Two ivacaftor 75 mg/tezacaftor 50 mg/elexacaftor 100 mg tablets	One <Product name> 150 mg tablet
12 years and older	Two ivacaftor 75 mg/tezacaftor 50 mg/elexacaftor 100 mg tablets	One <Product name> 150 mg tablet

* <Invented name> is only available as 150 mg tablets. Thus, it is not possible to administer <Invented name> to paediatric patients that require less than a full 150 mg dose. Other ivacaftor products, offering such an option, should be used in these cases.

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 <Invented name> 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 <Invented name> 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 <Invented name>
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 <Invented name>
Take <Invented name> 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 <Invented name> alone or in combination with tezacaftor/ivacaftor or ivacaftor/tezacaftor/elexacaftor.

In patients taking <Invented name> 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 the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

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, blister or bottle 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 <Invented name> contains
- The active substance is ivacaftor.

Each film-coated tablet contains 150 mg of ivacaftor.

- The other ingredients are:
  Tablet Core: Cellulose, microcrystalline, lactose monohydrate, croscarmellose sodium, sodium laurilsulfate, silica, colloidal anhydrous, magnesium stearate, hypromellose acetate succinate.

  Tablet Coating: Polyvinyl alcohol-part. hydrolyzed, macrogol 3350 (E1521), titanium dioxide (E171), talc (E553b), iron oxide red (E172), iron oxide yellow (E172), iron oxide black (E172).

What <Invented name> looks like and contents of the pack
<Invented name> 150 mg film-coated tablets are brown, capsule shaped, biconvex, film-coated tablets debossed with “I" on one side and "150" on other side.

<Invented name> is available in blister, perforated unit dose blister packs or HDPE bottle containing molecular sieve desiccant. Do not swallow the desiccant.

Pack sizes:
Blister packs: 28, 56and 60 film-coated tablets.

Unit dose blister packs: 28x1, 56x1 and 98x1 film-coated tablets

HDPE bottle: 60 film-coated tablets.

Not all pack sizes may be marketed.

Marketing authorization holder and Manufacturer
Vergunninghouder
Aurobindo Pharma B.V.
Baarnsche Dijk 1
3741 LN Baarn
Nederland

Fabrikanten
APL Swift Services (Malta) Ltd
HF26, Hal Far Industrial Estate, Hal Far
BBG 3000 Birzebbugia
Malta

Generis Farmacêutica S.A.
Rua Joao De Deus N 19, Venda Nova
2700-487 Amadora
Portugal

Arrow Generiques
26 Avenue Tony Garnier
69007 Lyon
Frankrijk

In het register ingeschreven onder
Ivacaftor Aurobindo 150 mg, filmomhulde tabletten RVG 135043

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

Belgium : Ivacaftor AB 150 mg filmomhulde tabletten/comprimés pelliculés/Filmtabletten
France : IVACAFTOR ARROW 150 mg, comprimé pelliculé

Germany :	Ivacaftor PUREN 150 mg Filmtabletten
Italy :	Ivacaftor Aurobindo
Luxemburg :	Ivacaftor AB 150 mg comprimés pelliculés/Filmtabletten
Netherlands :	Ivacaftor Aurobindo 150 mg, filmomhulde tabletten
Poland :	Ivacaftor Aurovitas
Portugal :	Ivacaftor Generis Phar
Spain :	Ivacaftor Aurovitas 150 mg comprimidos recubiertos con película EFG.

Deze bijsluiter is voor het laatst goedgekeurd in juni 2026.