Package leaflet: Information for the patient

Kaftrio 60 mg/40 mg/80 mg granules in sachet
Kaftrio 75 mg/50 mg/100 mg granules in sachet
ivacaftor/tezacaftor/elexacaftor

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

What is in this leaflet

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

1. What Kaftrio is and what it is used for

Kaftrio contains three active substances: ivacaftor, tezacaftor and elexacaftor. The medicine helps lung cells to work better in some patients with cystic fibrosis (CF). CF is **an inherited condition in which the lungs and the digestive system can become clogged with thick, sticky mucus**.

Kaftrio taken with ivacaftor is for **patients aged 2 to less than 6 years who have CF, with at least one *F508del* mutation** in the *CFTR* (*cystic fibrosis transmembrane conductance regulator*) gene**.** Kaftrio is intended as a long-term treatment.

Kaftrio works on a protein called CFTR. The protein is damaged in some people with CF, if they have a mutation in the *CFTR* gene.

Kaftrio is normally taken with another medicine, ivacaftor. Ivacaftor causes the protein to work better, while tezacaftor and elexacaftor increase the amount of protein at the cell surface.

Kaftrio (taken with ivacaftor) helps your child's breathing by improving his/her lung function. You may also notice that your child does not get ill as often, or that it is easier for your child to gain weight.

2. What you need to know before your child takes Kaftrio

Do not give your child Kaftrio:
- **If your child is allergic** to ivacaftor, tezacaftor, elexacaftor, or any other ingredients of this medicine (listed in section 6).

Talk to your child's doctor and do not give your child this medicine, if this applies to your child.

Warnings and precautions

- **Talk to your child's doctor if your child has liver problems** or has had them previously. Your doctor may need to adjust your child's dose.
- Your doctor will do some **blood tests to check your child's liver** before and during treatment with Kaftrio, especially if your child's blood tests showed high liver enzymes in the past. Liver enzymes in the blood can increase in patients receiving Kaftrio.

Tell your doctor right away if your child has any symptoms of liver problems. These are listed in section 4.

- **Talk to your child's doctor** as soon as possible if your child experiences **low mood or any other changes in mood and behaviour**.
  - Effects on mood and behaviour have been reported in patients while taking Kaftrio, usually starting within the first three months of treatment.
  - Symptoms may include anxiety, low or altered mood, and problems with sleep, concentration or forgetfulness.
  - Some children, while taking Kaftrio, may consistently display behaviours that are different to their usual patterns. This could include being more disruptive or difficult to manage.

- **Talk to your child's doctor if your child has kidney problems,** or your child has previously had them.

- **Talk to your child's doctor** before starting treatment with Kaftrio if your child has received **an organ transplant**.

- **Your child's doctor may do eye examinations** before and during treatment with Kaftrio. Cloudiness of the eye lens (cataract) without any effect on vision has occurred in some children and adolescents receiving this treatment.

Children under 2

Do not give Kaftrio granules to children under the age of 2 years because it is not known if Kaftrio granules are safe and effective in this age group.

Other medicines and Kaftrio

Tell your child's doctor or pharmacist if your child is taking, has recently taken, or might take any other medicines. Some medicines can affect how Kaftrio works or may make side effects more likely. In particular, tell your child's doctor if you take any of the medicines listed below. Your child's doctor may change the dose of one of the medicines if your child takes any of these.

- **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, rifampicin, rifabutin 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, glipizide, glyburide, nateglinide and repaglinide.
- **Medicines for lowering blood cholesterol.** These include pitavastatin and rosuvastatin.
- **Medicines for lowering blood pressure.** These include verapamil.

Kaftrio with food and drink
Avoid giving your child food or drinks containing grapefruit during treatment as these may increase the side effects of Kaftrio by increasing the amount of Kaftrio in your child's body.

Driving and using machines
Kaftrio can make your child dizzy. If your child feels dizzy, it is advised that your child does not ride his/her bike or do anything else that needs his/her full attention.

Kaftrio granules contains lactose and sodium
If you have been told by your child's doctor that your child has an intolerance to some sugars, contact your child's doctor before your child takes this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium-free".

3. How to take Kaftrio

Always give your child this medicine exactly as your child's doctor or pharmacist has told you. Check with your child's doctor or pharmacist if you are not sure.

Your child's doctor will determine the correct dose for your child. Your child must keep using all other medicines, unless your child's doctor tells him/her to stop using any.

Kaftrio is usually taken with ivacaftor.

Recommended dose for patients aged 2 to less than 6 years

Age	Weight	Morning dose	Evening dose
2 to less than 6 years	<14 kg	One sachet of ivacaftor 60 mg/tezacaftor 40 mg/elexacaftor 80 mg granules	One sachet of ivacaftor 59.5 mg granules
	≥14 kg	One sachet of ivacaftor 75 mg/tezacaftor 50 mg/elexacaftor 100 mg granules	One sachet of ivacaftor 75 mg granules

Give your child the morning and evening doses about 12 hours apart.

The granules are for oral use.

To prepare Kaftrio granules:
- Hold the sachet with the cut line on top.
- Shake the sachet gently to settle the Kaftrio granules.
- Tear or cut sachet open along cut line.
- Carefully pour all the Kaftrio granules in the sachet into 1 teaspoon (5 mL) of soft food or liquid in a small container (like an empty bowl). Look inside the sachet to make sure there are no granules left inside.
    - The food or liquid should be at or below room temperature.

    - Examples of soft foods or liquids include pureed fruits, flavoured yogurt or pudding, and milk or juice.
- Mix the Kaftrio granules with food or liquid.

After mixing, give Kaftrio within 1 hour. Make sure all the medicine is taken.

Give both Kaftrio and ivacaftor doses 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

Avoid giving your child food and drink containing grapefruit while your child is taking Kaftrio. See *Kaftrio with food and drink* in section 2 for more details.

If your child has liver problems, either moderate or severe, your child's doctor may reduce the dose of your child's medicine or decide to stop treatment with Kaftrio. See also *Warnings and precautions* in section 2.

If your child takes more Kaftrio than he/she should
Contact your child's doctor or pharmacist for advice. If possible, take your child's medicine and this leaflet with you. Your child may get side effects, including those mentioned in section 4 below.

If you forget to give your child Kaftrio
If you forget to give your child a dose, work out how long it is since the missed dose.

- **If less than 6 hours** have passed since your child missed a dose, either morning or evening, give the forgotten dose as soon as possible. Then go back to your usual schedule.
- **If more than 6 hours** have passed:
    - **If your child missed a morning dose** of Kaftrio, give it as soon as you remember. Do not give the evening dose of ivacaftor. Give the next morning dose at the usual time.
    - **If your child missed an evening** dose of ivacaftor, do not give the missed dose. Wait for the next day and take the morning dose of Kaftrio as usual.

Do not give a double dose to make up for any missed doses.

If you stop giving your child Kaftrio
Give Kaftrio to your child for as long as your child's doctor recommends. Do not stop unless your child's doctor advises you to.

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

4. Possible side effects

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

Serious side effects:

Possible signs of liver problems
Liver damage and worsening of liver function in people with or without liver disease. The worsening of liver function can be serious and may require transplantation.

Increased liver enzymes in the blood are very common in patients treated with Kaftrio. 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 the white part of the eyes
- Loss of appetite
- Nausea or vomiting
- Dark urine

Tell your child's doctor straight away if he/she have any of these symptoms.

Very common side effects (may affect more than 1 in 10 people)
- Rash (more common in women than in men)

Tell your child's doctor straight away if you notice a rash.

Other side effects:
Very common (may affect more than 1 in 10 people)
- Headache
- Dizziness
- Upper respiratory tract infection (common cold)
- Oropharyngeal pain (sore throat)
- Nasal congestion
- Stomach or abdominal pain
- Diarrhoea
- Increased liver enzymes (signs of stress on the liver)
- Changes in the type of bacteria in mucus
- Increased creatine phosphokinase (sign of muscle breakdown) seen in blood tests

Common (may affect up to 1 in 10 people)
- Flu
- Abnormal breathing (Shortness of breath or difficulty breathing)
- Low blood sugar (hypoglycaemia)
- Runny nose
- Sinus problems (sinus congestion)
- Redness or soreness in the throat
- Ear problems: ear pain or discomfort, ringing in the ears, inflamed eardrum
- Spinning sensation (inner ear disorder)
- Wind (flatulence)
- Spots (acne)
- Itchy skin
- Breast mass
- Feeling nauseous

Uncommon (may affect up to 1 in 100 people)
- Breast and nipple problems: inflammation, pain
- Enlargement of the breast in men
- Increases in blood pressure
- Wheezing
- Blocked ears (ear congestion)

Not known (frequency cannot be estimated from the available data)
- Damage to the liver (liver injury)
- Raised bilirubin measurement (liver blood test)
- Low mood. Signs of this can include changes in behaviour in children

Additional side effects in adolescents
Side effects in adolescents are similar to those observed in adults.

Reporting of side effects
If your child gets any side effects, talk to your child's doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the:

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Kaftrio

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 outer carton and on the 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 child's pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Kaftrio contains
- The active substances are ivacaftor, tezacaftor and elexacaftor.

Kaftrio 60 mg/40 mg/80 mg granules
Each sachet contains 60 mg of ivacaftor, 40 mg of tezacaftor and 80 mg elexacaftor.

Kaftrio 75 mg/50 mg/100 mg granules
Each sachet contains 75 mg of ivacaftor, 50 mg of tezacaftor and 100 mg elexacaftor.

- The other ingredients are: colloidal silicon dioxide, croscarmellose sodium, hypromellose, hypromellose acetate succinate, lactose monohydrate, magnesium stearate, mannitol, sodium lauryl sulfate, and sucralose.

See the end of section 2 for important information about the contents of Kaftrio.

What Kaftrio looks like and contents of the pack
Kaftrio 60 mg/40 mg/80 mg granules are white to off-white, granules in a sealed sachet.

Kaftrio 75 mg/50 mg/100 mg granules are white to off-white, granules in a sealed sachet.

Kaftrio is available in pack size of 28 sachets (4 weekly wallets, each with 7 sachets).

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This leaflet was last revised in June 2026

Other sources of information
Detailed information on this medicine is available on the website of Medicines and Healthcare products Regulatory Agency: http://www.mhra.gov.uk.