Package leaflet: Information for the patient

Lyfnua® 45 mg film-coated tablets
gefapixant

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

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2. What you need to know before you take Lyfnua
3. How to take Lyfnua
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1. What Lyfnua is and what it is used for

Lyfnua contains the active substance gefapixant.

Lyfnua is a medicine used in adults for chronic cough (cough that lasts longer than 8 weeks) and:
- the cough does not go away even after using other medicines or
- the reason for the cough is unknown.

The active substance in Lyfnua, gefapixant, blocks the action of nerves that trigger abnormal coughing.

2. What you need to know before you take Lyfnua

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

Warnings and precautions
Talk to your doctor or pharmacist before and while taking Lyfnua if you:
- are **allergic** to medicines containing sulphonamide
- have **sleep apnoea** – where your breathing stops and starts while you sleep
- develop **an acute infection of the lung / lower respiratory system (e.g., pneumonia or bronchitis)**
- experience **change in how things taste, loss of taste,** or **being less able to taste**, that continues even after you stop taking Lyfnua.

Children and adolescents
Do not give this medicine to children and adolescents below the age of 18 years. This is because it has not been studied in this age group.

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

Pregnancy and breast-feeding
It is not known if Lyfnua can harm your unborn baby. Therefore, it is better to avoid use of Lyfnua if you are pregnant.

If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Animal studies have shown that Lyfnua may pass into breast milk. A risk for your baby cannot be excluded. You and your doctor should decide together if you will take Lyfnua or breast-feed.

Driving and using machines
You may feel dizzy after taking Lyfnua. If this happens, do not drive or use tools or machines until you no longer feel dizzy.

Lyfnua contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. How to take Lyfnua

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

How much to take
The recommended dose of Lyfnua is:
- one 45 mg tablet twice every day.

Adults with kidney problems
Your doctor may change how much and how often you take Lyfnua if:
- you have severe kidney failure and are not on dialysis.

How to take
Swallow the tablet whole. Do not break, crush, or chew the tablet.
You can take the tablet with or without food.

If you take more Lyfnua than you should
If you take too much Lyfnua, talk to a doctor or pharmacist straight away.

If you forget to take Lyfnua
If you miss a dose, skip that dose and take the next dose at the scheduled time.
Do not take a double dose 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.

The possible side effects are:

Very common (may affect more than 1 in 10 people)
- change in how things taste (such as a: metallic, bitter, or salty taste)
- being less able to taste
- loss of taste

Common (may affect up to 1 in 10 people)
- feeling sick (nausea)
- things tasting different than before
- cough (worsening, increase)
- dry mouth
- upper respiratory tract infection (an infection in the upper part of the airways including the nose and throat)
- diarrhoea
- pain in your mouth or throat
- feeling less hungry than usual
- feeling dizzy
- upper abdominal (belly) pain
- indigestion
- unusual feeling in mouth (e.g., tingling or prickling sensation)
- loss of feeling in the mouth
- increased saliva production
- insomnia (difficulty in sleeping)
- headache

Uncommon (may affect up to 1 in 100 people)
- bladder, urinary or kidney stones

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 Yellow Card Scheme at 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 Lyfnua

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

This medicine does not require any special storage conditions.

Do not use this medicine if you notice that the packaging is damaged or shows signs of tampering.

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 Lyfnua contains
The active substance is gefapixant. Each film-coated tablet contains 45 mg gefapixant (as citrate). The other ingredients are silica (colloidal anhydrous) (E551), crospovidone (E1202), hypromellose (E464), magnesium stearate (E470b), mannitol (E421), microcrystalline cellulose (E460), sodium stearyl fumarate. The tablets are film-coated with a coating material containing the following ingredients: hypromellose (E464), titanium dioxide (E171), triacetin (E1518) and red ferric oxide (E172). The tablets are polished with carnauba wax (E903).

What Lyfnua looks like and contents of the pack
Lyfnua is a pink, round and convex tablet, debossed with 777 on one side and plain on the other side.

Lyfnua is available in opaque white PVC/PE/PVdC blisters with push through aluminium lidding foil.

Lyfnua is available in packs containing 28, 56 and 98 film-coated tablets in non-perforated blisters (14 tablets per card), multipacks containing 196 (2 packs of 98) film coated tables in non-perforated blisters.

Not all pack sizes may be marketed.

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