

Package leaflet: Information for the patient

Kynmobi 10 mg sublingual film
Kynmobi 15 mg sublingual film
Kynmobi 20 mg sublingual film
Kynmobi 25 mg sublingual film
Kynmobi 30 mg sublingual film
apomorphine hydrochloride

Kynmobi 10 mg sublingual film
Kynmobi 15 mg sublingual film
Kynmobi 20 mg sublingual film
Kynmobi 25 mg sublingual film
Kynmobi 30 mg sublingual film
Treatment Initiation Pack
apomorphine hydrochloride

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

What is in this leaflet

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

1. What Kynmobi is and what it is used for

Kynmobi is a medicine to place under the tongue (sublingual film) that contains the active substance apomorphine hydrochloride. It is for use, as needed, with other Parkinson's medicines taken orally (by your mouth) to reduce the amount of time spent in an "OFF", a period during the day when your Parkinson's symptoms are noticeably worse. Parkinson's disease is a progressive disease of the nervous system that causes shaking and affects your movement.

2. What you need to know before you use Kynmobi

Do not take Kynmobi

- if you are allergic to apomorphine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you are taking certain medicines to treat nausea called 5HT3 antagonists including ondansetron, granisetron, dolasetron, palonosetron and alosetron.
- if you have a psychotic disorder, a medical term that describes many mental diseases that cause abnormal thinking and perceptions; people with psychoses lose touch with reality
- if you have dementia
- if you have canker sores (also called Aphthous ulcers), small, shallow, lesions that develop on the soft tissues in the mouth and that can make eating and talking uncomfortable.

- if you have liver problems
- if you have breathing difficulties

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Kynmobi.

- if you have lung problems
- if you have heart problems
- if you have liver problems
- if you frequently have nausea (feel sick) or vomiting
- if you have low blood pressure or feel faint or dizzy when you stand. Rise slowly after sitting or lying down after taking Kynmobi
- if you are taking any medicines to treat high blood pressure
- if you or someone in your family are known to have an abnormality of electrocardiogram (ECG) called “long QT syndrome”.
- if you suffer from a mental illness with symptoms such as hallucinations, delusions, disordered thoughts, loss of contact with reality

Mouth (oral) irritation is a very common side effect of Kynmobi. You should tell your doctor if you develop any of the following signs or symptoms.

- redness
- mouth sores (ulceration)
- dryness of the mouth, lips, or tongue
- swelling
- mouth pain or pain with swallowing

These signs and symptoms may go away if Kynmobi treatment is stopped.

Talk to your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm you or others. These behaviours are called «impulse control disorders» and can include: addictive gambling, excessive eating or spending, an abnormally high sex drive or an increased preoccupation with sexual thoughts or feelings. Behaviours such as these have been reported in patients using other medicines for Parkinson’s disease. Your doctor may need to review your treatments.

Some patients may develop addiction-like symptoms leading to craving for large doses of Kynmobi and other medicines used to treat Parkinson’s disease.

Kynmobi can cause neuroleptic malignant syndrome (a nervous system disorder usually caused by antipsychotic medicines). This is a disorder that causes you to have a high fever, confusion, changes in breathing and heartbeat, and stiffness in your muscles.

When reducing your dose of Kynmobi or stopping treatment, you may have withdrawal symptoms such as: lack of interest, anxiety, depression, fatigue, sweating, panic attacks, insomnia, irritability and pain.

This medicine can cause penile erection. If they develop into prolonged painful erections, please contact your doctor.

Children and adolescents

Kynmobi should not be used in children and adolescents under 18 years of age

Other medicines and Kynmobi

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

Tell your doctor pharmacist, or nurse if you are taking:

- domperidone, a medicine to prevent nausea,
- medicines to lower your blood pressure or to treat your heart condition like nitroglycerin under your tongue (sublingual). Your blood pressure may decrease and cause dizziness. You should lie down before and after taking sublingual nitroglycerin.
- Medicines such as clozapine to treat mental disorders.
- certain medicines that have an effect on heart rate
- medicines that can affect the levels of electrolytes (salts) in your body
- other medications for Parkinson's disease.

Kynmobi with alcohol

You should not drink alcohol while taking this medicine.

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, pharmacist or nurse for advice before taking this medicine.

Kynmobi is not recommended if you are pregnant. You should use effective contraception if you might become pregnant.

It is not known if Kynmobi passes into breast milk in humans. Talk to your doctor who will advise, if you should either stop breast-feeding or discontinue Kynmobi taking into account the benefit of your therapy and of breast feeding for your child.

Driving and using machines

Kynmobi can make you feel light-headed, dizzy, or sleepy. Do not drive or operate machinery if you experienced any of these side effects.

Kynmobi contains metabisulphite

Kynmobi contains metabisulphite which may rarely cause severe hypersensitivity reactions and bronchospasm with symptoms such as rash or itchy skin, difficulty breathing, puffiness of the eyelids, face or lips, swelling or redness of the tongue. If you experience these side effects, immediately go to the nearest hospital.

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

3. How to take Kynmobi

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

Dose when you start treatment:

A treatment initiation pack containing 2 sublingual films of each strength is available. This package is usually needed for your doctor to find the right dose for you.

Your doctor, pharmacist or nurse will decide how much Kynmobi to take and how often. Not all sublingual films from the treatment initiation pack may be needed (for example, if 20 mg is the right dose for you, the 25 mg and 30 mg films will not be needed).

Maintenance dose:

The recommended dose of Kynmobi will depend on your needs and is defined by your doctor. You should not take more than one film of Kynmobi for an "OFF" episode. You may take Kynmobi up to 5 times per day, but no sooner than 2 hours between doses.

Do not use more than 5 films per day. The maximum dose of Kynmobi per day is 150 mg.

This medicine should be placed under your tongue and must be taken whole. Do not cut, chew, or swallow it. See '**Step-by-step instructions**' in this leaflet for full information.

If you take more Kynmobi than you should

If you take more Kynmobi than you should, tell your doctor, pharmacist or nurse, or go to a hospital immediately. Take the medicine package and this leaflet with you. This will help the doctor identify what you have taken.

If you stop taking Kynmobi

Do not stop taking Kynmobi unless your doctor tells you to as your symptoms may get worse.

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

4. Possible side effects

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

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

Very common: may affect more than 1 in 10 people

- Feeling sleepy
- Yawning
- Feeling sick
- Pain, redness, sores or a change in sensation in your mouth, lip or tongue

Common: may affect up to 1 in 10 people

- Hearing, seeing, feeling, smelling, or tasting things that are not there
- Abnormal, uncontrollable, involuntary movements
- Shortness of breath
- Oral thrush (Candida - a yeast infection of the mouth)
- Feeling dizzy
- Headache
- Fainting
- Blurred vision
- A fall in blood pressure on standing up which may cause dizziness, light-headedness or fainting
- Low blood pressure
- Sudden feeling of warmth
- High blood pressure
- Runny nose
- Vomiting
- Swelling or dryness of your mouth, lips, tongue or gums
- Gagging without vomiting
- Excessive sweating
- Cold sweat
- Feeling low in energy or tired
- Not feeling right
- Feeling cold
- Chills
- Fall
- Skin rash

Uncommon: may affect up to 1 in 100 people

- Psychotic disorder: a medical term that describes many mental diseases that cause abnormal thinking and perceptions; people with psychoses lose touch with reality
- Heart arrest
- Irregular or slow heart rate
- Allergic reaction. Signs may include rash, hives, itching, flushing, drop in blood pressure, throat tightness

- Uncontrollable urges leading to craving for large doses of Kynmobi and other medicines used to treat Parkinson's disease.
- Recurring, unwanted thoughts, ideas or sensations that make you feel driven to do something repetitively
- Red, swollen patches in the corners of your mouth
- Decreased appetite
- Anxiety
- Feeling confused
- Drooling
- Sudden onset of sleep
- Excessive tearing/watering eye
- Rapid reddening of your neck, upper chest, or face
- Pallor
- Constipation
- Indigestion
- Burping
- Difficulty or discomfort in swallowing
- Changes in the colour of your teeth or teeth cavities
- Spontaneous penile erection
- Feeling drunk
- Vitamin B6 increased
- Agitation
- Swelling in your legs and arms
- Positive coombs' test
- haemolytic anaemia, an abnormal breakdown of red blood cells in the blood vessels or elsewhere in the body.
- Reduction in blood platelets which increases risk of bleeding or bruising;

Rare: may affect up to 1 in 1,000 people

- eosinophilia, an abnormally high amount of white blood cells in the blood or in body tissues.

Unknown (frequency cannot be estimated from available data) side effects are:

- Unable to resist the impulse to perform an action that is harmful, which may include excessive gambling, repetitive meaningless actions, increased sex interest, uncontrolled shopping or spending too much
- Aggression

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 Kynmobi

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

Do not store above 25 °C. Store in the sachet in order to protect from light and moisture.

Keep Kynmobi in the sachet until you are ready to take it.

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 Kynmobi contains

- The active substance is apomorphine hydrochloride
- The other ingredients are: disodium edetate (E385), FD&C Blue #1 (E133), Glycerol (E422), glyceryl monostearate (E471), hydroxyethyl cellulose 250 G and 250 L (E1525), hydroxypropyl cellulose (E463), maltodextrin, levomenthol, Pyridoxine hydrochloride (for pH-adjustment), sodium hydroxide (E524) (for pH-adjustment), sodium metabisulfite (E223) (see section 2), sucralose (E955), white ink (Shellac (E904), Dehydrated alcohol (E1510), Isopropyl alcohol, Butyl alcohol, Propylene glycol (E1520), Strong ammonia solution (E527), Purified water, Potassium hydroxide (E525), titanium dioxide (E171))

What Kynmobi looks like and contents of the pack

Kynmobi sublingual film is a blue to green rectangular film with a white printed number identifying the strength (e.g., “10” is 10 mg).

Kynmobi is available in the following pack sizes:

Treatment initiation pack containing 10 sublingual films with 2 sublingual films of 10 mg, 15 mg, 20 mg, 25 mg, 30 mg each.

Pack containing 15 or 30 sublingual films.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Bial, Portela & C.^a S.A.
À Av. Da Siderurgia Nacional
4745-457 S. Mamede do Coronado
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Tel: +351229886100
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Manufacturer
Labtec GmbH
Heykenaukamp 10
21147 Hamburg
Germany

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

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Step-by-step instructions

Taking Kynmobi

Step 1 Your doctor has told you to take Kynmobi 10 mg, 15 mg, 20 mg, 25 mg, or 30 mg. Complete **Steps 2 through 7** to take Kynmobi.

Step 2 **Drink water.** Before taking each Kynmobi, drink water to moisten your mouth. This helps the film dissolve more easily (see **Figure A**).



Figure A

Step 3 **Open the Kynmobi sachet.**
Hold the wing tabs on the sachet between your thumb and pointer finger of each hand. Make sure to place your fingers directly on the raised dots on each wing tab. Gently pull the wing tabs apart to open the pouch (see **Figure B**).

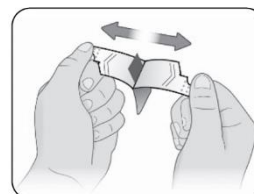


Figure B

Step 4 **Take Kynmobi out of the sachet.**
Hold Kynmobi between your fingers by the outside edges and remove the entire Kynmobi from the sachet (see **Figure C**).
Kynmobi must be taken whole.
Throw away Kynmobi if it is broken or missing pieces. Use a new Kynmobi for your dose.

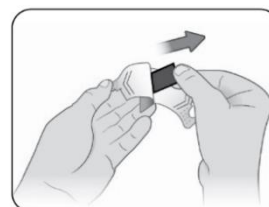


Figure C

Step 5 **Place entire Kynmobi under your tongue.**
Place Kynmobi as far back under your tongue as you can (see **Figure D**).
Close your mouth.

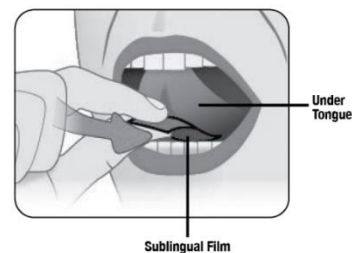


Figure D

Step 6

Keep Kynmobi in place until it has completely dissolved (see **Figure E**).

- **Do not** chew or swallow Kynmobi.
- **Do not** swallow your saliva or talk while Kynmobi is dissolving because this can affect how well the medicine in Kynmobi is absorbed.



Figure E

Step 7

Open your mouth to check if Kynmobi has completely dissolved.

It can take **about 3 minutes** for Kynmobi to dissolve. After Kynmobi completely dissolves, you may swallow.