Package leaflet: Information for the user

Propranolol Hydrochloride 40 mg Film-coated Tablets
propranolol, hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet, as 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 Propranolol Azure is and what it is used for

Propranolol Azure belongs to a group of medicines called beta-blockers, which act on different levels in the body, including the heart.

Propranolol Azure is indicated for:
- Treatment of high blood pressure (hypertension).
- Treatment of chest pain (angina).
- Treatment of certain heart disorders (obstructive hypertrophic cardiomyopathy).
- Control of irregular heartbeats (arrhythmias).
- Protection of the heart after myocardial infarction.
- Migraine (headache) prevention.
- Treatment of tremors.
- Treatment of anxiety symptoms.
- Treatment of certain thyroid disorders (thyrotoxicosis).
- Treatment of pheochromocytoma (high blood pressure due to a tumour usually near the kidney) administered together with another treatment: an alpha-adrenergic blocking agent.
- Prevention of bleeding in the esophagus caused by high blood pressure in the liver.

2. What you need to know before you take Propranolol Azure

Do not take Propranolol Azure
- If you are allergic (hypersensitive) to propranolol or to any of the other ingredients of this medicine (listed in section 6).
- If you suffer from asthma, wheezing or any other breathing difficulties.
- If you have or have ever had heart problems, including heart failure or heart block, or if you have ever had a very slow or irregular heart rate, low blood pressure (hypotension) or poor blood circulation.
- If you suffer from a tight, painful feeling in the chest in periods of rest (Prinzmetal's angina).
- If you suffer from untreated pheochromocytoma (high blood pressure due a tumour near the kidney).
- If you are on strict fasting diet.

- If you have had a shock caused by heart problems or heart rhythm-related illness (sick sinus syndrome).
- If you are prone to low blood sugar level.
- If you are pregnant, or think you may be pregnant, or are breastfeeding.

Warnings and precautions

Talk to your doctor or pharmacist, or nurse before taking this medicine.

- If you are allergic to any substance.
- If you have liver, kidney, thyroid, circulation or heart problems.
- If you have a feeling of shortness of breath or swollen ankles (heart failure).
- If you have a history of allergic reactions to certain substances, this medicinal product may increase these reactions. Higher doses of adrenaline may also be required than those normally used to treat allergic reactions.
- If you are taking a medicine called clonidine for high blood pressure (hypertension) or to prevent migraines (headache), do not stop taking clonidine or propranolol without first consulting your doctor (see "Other medicines and Propranolol Azure").
- Propranolol may mask the signs of certain thyroid disorders (thyrotoxicosis).
- The use of propranolol in patients with high blood pressure in the liver may worsen liver function.
- If you are diabetic, propranolol may alter your response to insulin or other anti-diabetic treatments. Propanolol may cause low blood sugar levels even in patients who are not diabetic.
- If you suffer from muscle weakness (myasthenia gravis).
- If you have conditions like chronic obstructive pulmonary disease and bronchospasm because the use of propranolol can aggravate these conditions.
- If you are admitted to hospital, tell the healthcare staff, especially the anesthesiologist in case of surgery, that you are taking propranolol.

Other medicines and Propranolol Azure

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

Propanolol should not be used in combination with calcium channel blockers with negative inotropic effects (e.g. verapamil, diltiazem), as it can lead to an exaggeration of these effects. This may result in severe hypotension and bradycardia.

Other medicines which can cause problems when taken together with your medicine:

- Nifedipine, nisoldipine, nicardipine, isradipine, lacidipine (used to treat hypertension or angina)
- Lidocaine (local anesthetic)
- Disopyramide, quinidine, amiodarone, propafenone and glycosides (to treat heart problems)
- Adrenaline (a heart stimulant)
- Ibuprofen and indometacin (for pain and inflammation)
- Ergotamine, dihydroergotamine or rizatriptan (for migraine)
- Chlorpromazine and thioridazine (for certain psychiatric disorders)
- Cimetidine (for stomach problems)
- Rifampicin (for the treatment of tuberculosis)
- Theophylline (for asthma)
- Warfarin (to thin the blood) and hydralazine (for hypertension)
- Fingolimod (for treating multiple sclerosis)
- Fluvoxamine and barbiturates (to treat anxiety and insomnia)
- MAO inhibitors (to treat depression).

If you are taking clonidine (for hypertension or migraine) and Propranolol together, you must not stop taking clonidine unless your doctor tells you to do so. If it becomes necessary for you to stop taking clonidine, your doctor will give you careful instructions on how to do it.

Interference with laboratory tests:
If you are going to undergo a laboratory test (including blood and urine tests), tell the doctor that you are taking this medicine, as it may alter the results (bilirubin in blood or catecholamines).
High levels of certain antibodies (ANA) have been observed in clinical analyses on very rare occasions.

Propranolol Azure with food, drink and alcohol
Alcohol consumption may influence the effect of the tablets.

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

Pregnancy:
The use of this medicine is not recommended during pregnancy, unless your doctor considers it essential.

Breastfeeding:
Breastfeeding is not recommended when taking this medicine.

Driving and using machines
Propanolol is unlikely to affect your ability to drive or to operate machinery. However, some people may occasionally feel dizzy or tired when taking Propranolol Azure. If this happens to you, ask your doctor for advice.

Propranolol Azure contains lactose
If your doctor has told you that you are intolerant to certain sugars, ask your doctor for advice before taking this medicine.

Propranolol Azure contains orange yellow S (E-110) and Allura red AC (E-129)
This medicine may cause allergic reactions because it contains orange yellow S (E-110) and allura red AC (E-129).

Use in athletes:
This medicine contains propranolol, which can cause a positive result in doping control tests.

3. How to take Propranolol Azure

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

Remember to take your medicine.

Your doctor will tell you how long to take propranolol for. Do not stop the treatment before your doctor tells you to. Do not take more doses than your doctor has told you.

It is better to take the tablet every day at the same time. Swallow the tablet whole with a glass of water.

Tell your doctor or pharmacist if you feel that the action of this medicine is too strong or too weak.

Use in adults
The following table shows the usual dose intervals per day for an adult according to their disease. The dose is often divided into several smaller doses throughout the day:

Treatment of high blood pressure (hypertension)	160 mg to 640 mg	4 to 16 tablets
Treatment of chest pain (angina)	80 mg to 480 mg	2 to 12 tablets
Treatment of some heart disorders (obstructive hypertrophic cardiomyopathy)	30 mg to 160 mg	*
Control of irregular heartbeats (arrhythmias)	30 mg to 240 mg	*
Protection of the heart after myocardial infarction	160 mg	4 tablets
Migraine prevention	80 mg to 240 mg	2 to 16 tablets
Treatment of tremors	40 mg to 160 mg	1 to 4 tablets
Treatments for anxiety symptoms	30 mg to 160 mg	*
Treatment of certain thyroid disorders (thyrotoxicosis)	30 mg to 160 mg	*
Treatment of pheochromocytoma	30 mg to 160 mg	*
Prevention of bleeding in the esophagus caused by high blood pressure in the liver	80 mg to 320 mg	2 to 8 tablets

*The use of other propranolol presentations is considered appropriate for adjusting the dose.

Use in children
In certain circumstances, propranolol may be used to treat children with arrhythmias (irregular heartbeat). The doctor will adjust the dose according to the child's age or weight.

Use in elderly patients
Your doctor will adjust the dose according to the evolution of your disease.

Use in patients with liver or kidney disease
If you have liver or kidney disease, your doctor will adjust the dose, usually starting treatment with the lowest dose in the dosing interval.

If you take more Propranolol Azure than you should
In case of overdose or accidental ingestion, immediately consult your doctor or pharmacist, indicating the medication and the amount ingested.

It is recommended that you take the pack and package insert of this medicine to the healthcare personnel.

If you forget to take Propranolol Azure

If you forget a dose, wait for the following dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Propranolol Azure
Do not stop taking the tablets, even if you feel well, unless told to do so by your doctor, in which case, stop taking them gradually.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them. The following side effects may happen with this medicine.

Common *(may affect up to 1 in 10 people)*
- cold fingers and toes
- the heart beating more slowly
- numbness and spasms in the fingers followed by warmth and pain (Raynaud's phenomenon)
- sleep disturbance/nightmares
- breathlessness
- fatigue.

Uncommon *(affecting up to 1 in every 100 people)*
- diarrhoea
- nausea
- vomiting.

Rare *(affecting up to 1 in every 1,000 people)*
- worsening of breathing difficulties, sometimes with fatal outcome, if you have or have had asthma or asthmatic complaints.
- heart failure, worsening of heart problems
- swelling of the skin which may occur in the face, tongue, larynx, abdomen, or arms and legs (angioedema).
- worsening of blood circulation, pain, weakness and cramps in the legs if you already
- mood changes
- confusion
- psychosis or hallucinations (disturbances of the mind)
- dizziness, particularly on standing up
- tingling sensation in hands
- disturbances of vision
- hair loss
- skin rash, worsening of psoriasis or psoriasis-type skin reactions
- dry eyes
- ease of bruising (may alter the number and types of your blood cells such as reduce the number of platelets (thrombocytopenia))
- purple spots on the skin (purpura).

Very rare *(affecting up to 1 in every 10,000 people)*
- muscle weakness (myasthenia gravis)
- low levels of blood sugar may occur in diabetic and non diabetic patients including the newborn, toddlers and children, elderly patients, patients on artificial kidneys (haemodialysis) or patients on medication for diabetes. It may also occur in patients who are fasting or have been fasting recently or who have a long-term liver disease.

- excessive sweating.

Not known *(frequency cannot be estimated from the available data)*
- headache or seizure linked to low levels of sugar in the blood.
- inability in a man to achieve an erection (impotence)
- decrease in renal blood flow
- joint pain(arthralgia)
- constipation
- dry mouth
- shortness of breath or breathlessness (dyspnoea)
- conjunctivitis (inflammation of the eya also called 'pink eye')
- depression
- severe and dangerous lowered white blood cell count (agranulocytosis)
- worsening of angina pectoris (chest pains).

Reporting side effects
If you get any type of side effect, 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: 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 Propranolol Azure

Keep this medicine out of the sight and reach of children.

Do not store above 30ºC.

Do not use this medicine after the expiration date which is stated on the container after "EXP". The expiration date refers to the last day of that month.

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 additional information

What Propranolol Azure contains
- The active ingredient is propranolol hydrochloride. Each tablet contains 40 mg of propranolol hydrochloride.
- The other ingredients are carmellose calcium, gelatin, lactose, and magnesium stearate in the tablet core, and Opadry II Pink 85F240137 (containing partially hydrolyzed polyvinyl alcohol (E-1203), titanium dioxide (E-171), macrogol (E-1521), talc (E-553b), carmine (E-120), sunset yellow FCF (E-110) and allura Red AC (E-129)) in the coating.

What Propranolol Azure looks like and contents of the pack
Pink, round film-coated tablets scored on one side. The tablet can be split into equal doses.

Each pack contains 50 film-coated tablets, packed in PVC/PVDC/Aluminum blister packs.

Marketing Authorisation Holder
Azure Pharmaceuticals Ltd, 12 Hamilton Drive, The Rock Road, Blackrock, Co. Louth, A91 T997, Ireland.

Manufacturer
Kern Pharma, S.L., Venus, 72 – Pol. Ind. Colón II, 08228 Terrassa – Barcelona, Spain

This medicine is authorised in the Member States of the EEA under the following names:
Spain: Propranolol Kern Pharma 40 mg comprimidos recubiertos con película EFG
Ireland: Propranolol Azure 40 mg Film-coated Tablets

This leaflet was last revised in August 2023