

LEAFLET: INFORMATION FOR THE USER

Propranolol HCl Accord 10 mg, film-coated tablets
Propranolol HCl Accord 40 mg, film-coated tablets Propranolol HCl Accord 80 mg, film-coated tablets
propranolol hydrochloride

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

Do you have any questions? Contact your doctor, pharmacist, or nurse.

Do not pass this medicine on to others, as it is prescribed only for you. It may harm others, even if their symptoms are the same as yours.

Do you experience a lot of side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor, pharmacist, or nurse.

Contents of this leaflet

1. What is this medicine used for?
2. When should you not use this medicine or be extra careful?
3. How do you use this medicine?
4. Possible side effects
5. How do you store this medicine?
6. Contents of the packaging and other information

1. What is this medicine used for?

Propranolol HCl Accord contains propranolol hydrochloride, which belongs to a group of medicines called beta-blockers. It works on the heart and circulation, but also on other parts of the body. Propranolol HCl Accord can be used for:

hypertension (high blood pressure)

angina (chest pain)

certain heart rhythm disorders (arrhythmias)

protection of the heart after a heart attack

migraine

essential tremor (involuntary and rhythmic shaking)

certain thyroid conditions (thyrotoxicosis and hyperthyroidism, caused by an overactive thyroid)

hypertrophic cardiomyopathy (thickened heart muscle)

pheochromocytoma (high blood pressure due to a tumor in the adrenal glands)

bleeding in the esophagus due to high blood pressure in the liver

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

You are allergic to any of the substances in this medicine. You can find these substances in section 6

If you have heart failure (insufficient pumping power of the heart) that is untreated or not controlled

If you have had a shock (disturbed blood circulation characterized by a strong drop in blood pressure, paleness, restlessness, weak rapid heartbeat, clammy skin, and reduced consciousness) caused by heart problems

If you have severe heart defects (second- or third-degree heart block: certain conduction disorders in the heart leading to arrhythmias), a condition that can be treated with a pacemaker

If you suffer from heart conduction problems (problems in the conduction of impulses in the heart) or heart rhythm problems

If you have a very slow or very irregular heartbeat

If you have increased acidity of the blood (metabolic acidosis)

If you are on a strict diet where you must fast a lot (long periods where you are not allowed to eat)

If you suffer from asthma, wheezing, or other breathing difficulties

If you have an untreated pheochromocytoma (high blood pressure due to a tumor in the adrenal glands)

If you suffer from severe circulation problems (which can cause your fingers and toes to tingle or become pale or blue)

If you have a tight, painful feeling in the chest during periods of rest (Prinzmetal angina)

If you have very low blood pressure

If you think any of these points apply to you or if you are unsure about anything, talk to your doctor before using this medicine.

When should you be extra careful with this medicine?

Talk to your doctor or pharmacist before using this medicine if you:

experience allergic reactions to, for example, insect bites

have diabetes, because this medicine can change your normal response (an increased heart rate) to low blood sugar levels. This medicine can cause low blood sugar levels even in patients without diabetes

have thyrotoxicosis. This medicine can mask the symptoms of thyrotoxicosis.

have kidney or liver problems (including liver cirrhosis). In that case, consult your doctor, as you may need to undergo certain checks during treatment

have heart problems

suffer from muscle weakness (myasthenia gravis)

have conditions such as COPD (chronic obstructive pulmonary disease: long-term lung disease with persistent narrowing of the airways making breathing more difficult) and bronchospasm (tightness due to cramping of the airway muscles) because using this medicine can worsen these conditions

are using certain medicines called calcium channel blockers with negative inotropic effects (this medicine can make the heart contract less effectively), such as verapamil and diltiazem (see the section 'Are you taking any other medicines?')

If you or someone in your family has (or has had) psoriasis.

If you need to undergo surgery, tell the anesthetist that you are using Propranolol.

If you wear contact lenses, Propranolol reduces tear production, making them feel less comfortable.

If you smoke, the effectiveness of Propranolol may be reduced.

Are you using any other medicines?

Are you using any other medicines besides Propranolol HCl Accord, have you done so recently, or is there a possibility that you will use other medicines in the near future? If so, tell your doctor or pharmacist. Propranolol HCl Accord can affect the action of some medicines, and some medicines can affect the action of Propranolol HCl Accord.

Propranolol HCl Accord should not be used in combination with calcium channel blockers with negative inotropic effects (e.g., verapamil, diltiazem), as it can enhance that effect (negative inotropic: the heart can contract less effectively). This can result in severely lowered blood pressure and slowed heart rate.

Other medicines that can cause problems when used simultaneously with Propranolol HCl Accord include:

nifedipine, nisoldipine, nicardipine, isradipine, lacidipine (used for the treatment of high blood pressure or angina)
lidocaine (a local anesthetic)
disopyramide, quinidine, amiodarone, propafenone, and glycosides (for the treatment of heart problems)
adrenaline (a medicine that stimulates the heart)
ibuprofen and indomethacin (for the treatment of pain and inflammation)
ergotamine, dihydroergotamine, or rizatriptan (for migraine)
chlorpromazine and thioridazine (for certain mental disorders)
cimetidine (for stomach problems)
rifampicin (for the treatment of tuberculosis: an infectious disease where nodules (tubercles) are formed and all organs except the muscular system can be affected)
theophylline (for asthma)
warfarin (to thin the blood) and hydralazine (for the treatment of high blood pressure)
fingolimod (for the treatment of multiple sclerosis; a condition of the central nervous system where inflammation and scarring occur in the protective layer around the nerve pathways, causing some nerves to work less effectively or not at all)
fluvoxamine and barbiturates (for the treatment of anxiety and insomnia)
MAO inhibitors (for the treatment of depression).

If you are using clonidine (for the treatment of high blood pressure or migraine) and Propranolol HCl Accord at the same time, you should not stop using clonidine unless your doctor tells you to do so. If it is necessary to stop using clonidine, your doctor will give you careful instructions on how to do so.

What should you be aware of with alcohol?
Alcohol can affect how this medicine works.

Surgeries

If you need to go to the hospital for surgery, tell the anesthesiologist (the person who manages your anesthesia) or the medical hospital staff that you are using Propranolol HCl Accord.

Driving and using machines

It is unlikely that this medicine will affect your ability to drive or operate machines. However, some people may occasionally feel dizzy or tired when using this medicine. If this is the case for you, ask your doctor for advice.

Pregnancy, breastfeeding, and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Pregnancy:

The use of this medicine is not recommended during pregnancy unless your doctor deems it necessary.

Breastfeeding:

Breastfeeding is not recommended while using this medicine.

Propranolol HCl Accord contains lactose

Propranolol HCl Accord film-coated tablets contain lactose. If your doctor has told you that you are intolerant to certain sugars, contact your doctor before taking this medicine.

3. How to use this medicine?

Always use this medicine exactly as your doctor, pharmacist, or nurse has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Take this medicine with some water before meals. Swallow the tablets whole. Do not chew the tablets.

Do not stop taking the medicine unless your doctor tells you to.

Adults

The following table shows the recommended dosages for adults:

	Recommended dosage	Total daily dosage (maximum dosage)
Hypertension (high blood pressure)	Start with 40 mg two or three times daily. The dosage may be increased weekly by 80 mg/day.	160 mg to 320 mg
Angina (chest pain) and involuntary tremor	Start with 40 mg two or three times daily. The dosage may be increased weekly by 40 mg/day	120 mg to 240 mg
Heart protection after a heart attack	Start with 40 mg four times a day. After a few days, switch to 80 mg	160 mg

	twice a day.	
Migraine	Start with 40 mg two or three times daily. The dosage may be increased weekly by 40 mg/day	80 mg to 160 mg
Arrhythmias (heart rhythm disorders), hyperthyroidism and thyrotoxicosis (certain thyroid conditions) and hypertrophic cardiomyopathy (thickening of the heart muscle)	10 to 40 mg three to four times daily	120 mg to 160 mg
Pheochromocytoma	Before surgery: 60 mg per day Treatment if surgery is not possible: 30 mg per day	30 mg to 60 mg
Liver disease due to high blood pressure	Start with 40 mg twice daily, increase to 80 mg twice daily	160 mg to 320 mg

Children and adolescents up to 18 years:

Propranolol HCl Accord can also be used to treat migraine and heart rhythm disorders (arrhythmias) in children:

- Migraine: the dosage for children under 12 years is 20 mg two to three times daily, the dosage for children 12 years and older is the same as the adult dosage.
- Arrhythmias: the doctor will adjust the dosage according to the child's age or weight.

Elderly

Elderly should start with the lowest dose. The optimal dose is determined per patient by the doctor.

Liver or kidney problems

The optimal dose is determined per patient by the doctor.

Have you taken too much of this medicine?

If you have accidentally taken more than the prescribed dose, contact the nearest emergency department or your doctor or pharmacist immediately. An overdose can cause an extremely slow heartbeat, too low blood pressure, heart failure, and breathing difficulties with symptoms such as fatigue, hallucinations (perceptions (seeing, hearing, smelling, feeling) of things that are not there), small involuntary tremors, confusion, nausea, vomiting, body spasms, fainting or coma, and low blood sugar. Always take the remaining tablets, the box, and the label with you so the medicine can be easily recognized (identified).

Have you forgotten to take this medicine?

If you have forgotten to take a dose, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop using this medicine

Do not stop using this medicine without first consulting your doctor. In some cases, you need to taper off this medicine slowly.

Do you have any other questions about the use of this medicine? Then contact your doctor, pharmacist, or nurse.

4. Possible side effects

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

Common (may affect up to 1 in 10 patients):

- cold fingers and toes
- slow heart rate, drop in blood pressure upon standing, fainting, palpitations, arrhythmias, worsening of heart failure
- numbness and muscle spasms in the fingers, followed by warmth and pain (Raynaud's syndrome)
- disturbed sleep/nightmares, especially at the start of treatment; dizziness, confusion
- fatigue and/or exhaustion (often temporary)
- allergic skin reactions: redness, itching, rash, hair loss

Uncommon (may affect up to 1 in 100 patients):

- nausea, vomiting, and diarrhea or constipation
- muscle weakness

Rare (may affect up to 1 in 1000 patients):

- attacks of airway constriction, breathing problems worsen, sometimes with fatal outcome, if you have or have had asthma or asthmatic complaints
- heart failure, heart problems worsen
- swelling of the skin in the face, tongue, throat, abdomen, or arms and legs (angioedema)
- dizziness, especially when standing up
- circulation works less well in the limbs, if you already have poor circulation
- mood swings
- confusion
- psychosis (serious mental illness where control over one's own thinking, behavior, and actions is disturbed; contact with reality is also disturbed) or hallucinations (perceptions (seeing, hearing, smelling, feeling) of things that are not there), if you stop using this medicine too quickly
- paresthesia (an abnormal sensation, usually tingling or prickling in ['sleeping' body parts])
- visual disturbances
- dry eyes
- your medicine can change the number and types of your blood cells, such as a reduction in the number of platelets in your blood (thrombocytopenia), which can cause you to bruise and bleed more easily.
- purple spots on the skin (purpura), large patches of hair loss, psoriasis-like skin reactions (even years later), worsening of psoriasis
- dry mouth

Very rarely (may occur in up to 1 in 10,000 patients):

- deficiency or very severe reduction of white blood cells
- temporary increase in certain types of white blood cells (transient eosinophilia)
- worsening of a certain pathological muscle weakness (myasthenia gravis), headache, depressive moods
- a low blood sugar level (blood glucose level) can occur in patients with or without diabetes, including older patients, patients on dialysis (removal of waste products from the blood by filtration), or patients using diabetes medications. It can also occur in patients who are fasting (not eating) or who have recently fasted, or in patients with a long-term liver condition.
- worsening of diabetes, change in certain blood fat levels (decrease in HDL cholesterol, increase in triglycerides)
- sweating more than usual
- conjunctivitis
- muscle pain, muscle cramps
- with long-term treatment: joint and cartilage disorders
- deterioration of kidney function in patients with severely impaired renal function
- libido and erectile dysfunction
- increase in certain blood values (GOT, GPT, ANA)

Not known (frequency cannot be determined from the available data):

- shortness of breath or breathlessness (dyspnea)
- depression

You should only stop this medication after consulting your doctor and you must stop gradually (partly due to the side effects mentioned above).

Additional side effects in children and adolescents up to 18 years

Very rare (may occur in up to 1 in 10,000 patients):

- a low amount of sugar in the blood (blood sugar level) in newborns, infants, and children

Not known (frequency cannot be determined from the available data):

- Seizures in newborns, infants, and children due to a low amount of sugar in the blood

Reporting side effects

If you experience side effects, contact your doctor, pharmacist, or nurse. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb. Website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

Keep out of the sight and reach of children.

There are no special storage conditions for this medicine.

Do not use this medicine after the expiry date. It can be found on the label after EXP. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

The active substance in this medicine is propranolol hydrochloride. Each film-coated tablet contains 10 mg / 40 mg / 80 mg propranolol hydrochloride.

The other substances in this medicine are:

corn starch
lactose monohydrate
microcrystalline cellulose (E460)
magnesium stearate

Composition of the film coating: hypromellose (E464) microcrystalline cellulose (E460) acetylated monoglycerides and diglycerides titanium dioxide (E171)

What do Propranolol HCl Accord film-coated tablets look like and what is in a package?

10 mg: White to off-white, round, biconvex (rounded on both sides) film-coated tablets with the imprint 'A' on one side and a score line on the other side.

40 mg: White to off-white, round, biconvex (rounded on both sides) film-coated tablets with the imprint 'AL' on one side and a score line on the other side.

80 mg: White to off-white, round, biconvex (rounded on both sides) film-coated tablets with the imprint 'AM' on one side and a score line on the other side.

The score line is only to facilitate breaking to make swallowing easier and not for dividing into equal doses.

PVC-PVdC/Alu blister packaging in packages of 25, 28, 30, 50, 56, 60, 100 and 250 film-coated tablets.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Accord Healthcare B.V.,
Winthontlaan 200,
3526 KV Utrecht,
Netherlands

Manufacturer

Accord Healthcare Polska Sp.z o.o.,
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Accord Healthcare B.V.,
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3526 KV Utrecht,
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Accord Healthcare Single Member S.A.
64th Km National Road Athens,
Lamia, 32009, Greece

Registration number:
10 mg: RVG 55387
40 mg: RVG 55388
80 mg: RVG 55880

This medicine is registered in EEA member states under the following names:

NL	Propranolol HCl Accord 10mg/40mg/80mg, film-coated tablets
BG	Propranolol Accord 40mg/80mg film-coated tablets
CY	Propranolol Accord 10mg/40mg film-coated tablets
EE	Propranolol Accord 40mg õhukese polümeerikattega tabletid
ES	Propranolol Accord 10mg/40mg film-coated tablets.
FI	Propranolol Accord 10mg/40mg/80mg film-coated tablets
FR	Propranolol Accord 40mg scored film-coated tablet
MT	Propranolol 10mg/40 mg/80 mg film-coated tablets
PT	Propranolol Accord
SE	Propranolol Accord 10mg/40mg film-coated tablets
UK	Propranolol 10mg/40mg/80mg film-coated tablets

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