• worsening of your blood circulation, if you already suffer from poor circulation

- worsening of breathing difficulties, if you have or have had asthma
- hair loss, skin rash, including worsening of psoriasis, purple spots on the skin (purpura)

Very rare (may affect up to 1 in 10,000 people)

severe muscle weakness (myasthenia gravis)
there may be changes to some of the cells or other parts of your blood. It is possible that your doctor may occasionally take blood samples to check whether propranolol has had any effect on your blood.

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

• 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.

Seizure linked to low levels of sugar in the blood.

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 the Yellow Card Scheme at: <u>www.mhra.gov.uk/yellowcard</u> 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.

How to store Propranolol tablets

Keep Propranolol tablets out of the sight and reach of children.

Do not store the tablets above 25°C. Do not take the tablets after the expiry date which is stated on the carton. The expiry date is also stated on the back of the strip after 'Exp'. 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. Continued top of next column 50995392 BBBA9693

Contents of the pack and other information What Propranolol tablets contain

• the active substance (the ingredient that makes the tablets work) is propranolol hydrochloride. Each tablet contains either 10mg, 40mg, 80mg or 160mg of the active substance.

• the other ingredients are lactose, magnesium stearate, maize starch, stearic acid, hypromellose (E464).

• the coating contains polysorbate, carmoisine (E122), titanium dioxide (E171), iron oxide red (E172), hypromellose (E464).

What Propranolol tablets look like and contents of the pack

Propranolol tablets 10mg are pink, circular, biconvex film-coated tablets impressed "C" on one face and the identifying letters "P" and "A" on either side of a central division line on the reverse. Propranolol tablets 40mg and 80mg are pink filmcoated tablets.

Propranolol tablets 160mg are pink, circular, biconvex film-coated tablets impressed "C" on one face and the identifying letters "P" and "D" on either side of a central division line on the reverse. Pack sizes are 28 and 56 tablets. Not all pack sizes may be available.

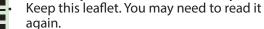
Marketing Authorisation Holder and Manufacturer

Accord, Barnstaple, EX32 8NS, UK

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accord

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.



- 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

- What Propranolol tablets are and what they are used for
- 2 What you need to know before you take Propranolol tablets
- B How to take Propranolol tablets
- 4 Possible side effects
- How to store Propranolol tablets
- Contents of the pack and other information

What Propranolol tablets are and what they are used for

Propranolol is one of a group of medicines called beta-blockers. It has effects on the heart and circulation and also on other parts of the body. Propranolol can be used for many conditions including:

- hypertension (high blood pressure)
- angina pectoris (chest pain)
- some arrhythmias (disorders of heart rhythm)
- protection of the heart after a myocardial infarction (heart attack)

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Propranolol 10mg, 40mg, 80mg and 160mg tablets

Package leaflet: Information for the patient

- prevention of migraine
 - essential tremor, anxiety
 - certain thyroid conditions (such as thyrotoxicosis, which is caused by an overactive thyroid gland)
 - hypertrophic cardiomyopathy (thickened heart muscle)
 - phaeochromocytoma (high blood pressure due to a tumour usually near the kidney)
 - bleeding in the oesophagus or stomach caused by high blood pressure in the liver.

2 What you need to know before you take Propranolol tablets

Do not take Propranolol tablets and **tell your doctor** if you:

- are **allergic** to Propranolol or any of the other ingredients of this medicine (listed in section 6)
- have untreated/uncontrolled heart failure or are in shock caused by heart problems
- suffer with heart conduction or rhythm problems (second or third-degree heart block or sick sinus syndrome)
- have a slow heart rate
- have low blood pressure
- suffer from severe blood circulation problems (which may cause your fingers and toes to tingle or turn pale or blue)
- suffer from diabetes mellitus (low blood sugar levels may be hidden by this medicine) or increased acidity of the blood (metabolic acidosis)
- are on a strict fasting diet
- suffer from a tight, painful feeling in the chest in periods of rest (**Prinzmetal's angina**)
- suffer from **asthma** or any other breathing difficulties
- suffer from **untreated phaeochromocytoma** (high blood pressure due to a tumour near the kidney).

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Warnings and precautions

Talk to your doctor or pharmacist before taking Propranolol tablets if you:

 have heart failure (please also see "Do not take" section above)

- suffer from blood circulation problems (which may cause your fingers and toes to tingle or turn pale or blue)
- have a heart weakness or first-degree heart block
- have diabetes. Propranolol may change your normal response to low blood sugar, which usually involves an increase in heart rate. Propranolol may cause low blood sugar levels even in patients who are not diabetic (please see section 4 "Possible side effects")
- have kidney or liver problems (including cirrhosis of the liver)
- have thyrotoxicosis. Propranolol may hide the symptoms of thyrotoxicosis.
- have a phaeochromocytoma (a tumour near the kidney) (please also see "Do not take" section above) have a history of allergic reactions.

Other medicines and Propranolol tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Propranolol can interfere with the action of some other medicines and some medicines can have an effect on propranolol tablets. The medicines which can cause some problems when taken together with propranolol tablets are: • insulin (to treat diabetes)

- ergotamine, dihydroergotamine or rizatriptan (for migraine)
- disopyramide, guinidine, amiodarone, propafenone (to treat irregular heartbeat (arrhythmia))
- digitalis glycosides (digoxin) (to treat heart conditions)
- verapamil, diltiazem, nifedipine, nisoldipine, nicardipine, isradipine, lacidipine and dihydropyridine (to treat heart diseases)
- adrenaline (used in anaphylactic shock)
- lidocaine (to treat irregular heartbeat or as a local anaesthetic)
- cimetidine (to treat stomach ulcers)
- hydralazine (to treat high blood pressure)
- clonidine (for hypertension or migraine). If you are taking clonidine 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.

- ibuprofen and indometacin (for pain and inflammation)
- chlorpromazine and thioridazine (for psychiatric illness)
- anaesthetics
- warfarin (to thin the blood)
- rifampicin (to treat infection)
- theophylline (treating asthma)

Propranolol tablets with alcohol

You are advised to avoid alcohol whilst taking this medicine.

Pregnancy, breast-feeding and fertility

Propranolol tablets are not recommended during pregnancy or breast-feeding. 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.

Driving and using machines

Your medicine is unlikely to affect your ability to drive or to operate machinery. However, some people may occasionally feel dizzy or tired when taking propranolol tablets. If this happens to you, ask your doctor for advice.

If you are going to have an anaesthetic or any blood or urine tests, please tell your doctor or dentist that you are taking Propranolol tablets. If you see another doctor or go into hospital, let them know what

Propranolol tablets contain Lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Propranolol tablets contain Carmoisine (E122)

Propranolol tablets contain carmoisine (E122) which may cause allergic reactions.

B How to take Propranolol tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Propranolol tablets should be swallowed with a drink of water, before meals.

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Your doctor will have decided how many propranolol tablets you need to take each day depending on your condition. Follow your doctor's instructions about when and how to take your tablets. Please read the label on the carton. This will also tell you how many tablets to take and when you should take them. Ask your doctor or pharmacist if you are not sure. The following table shows the recommended total daily dosages for an adult:

Hypertension

(high blood pressure) 160 mg to 320 mg Angina (chest pains) 120 mg to 240 mg Arrythmias (disorders of heart rhythm) 30 mg to 160 mg Protection of the heart after a heart attack 160 mg Prevention of migraine 80 mg to 160 mg 80 mg to 160 mg Essential tremor Anxiety 40 mg to 120 mg Certain thyroid conditions (such as thyrotoxicosis) 30 mg to 160 mg Hypertrophic cardiomyopathy (thickened heart muscle) 30 mg to 160 mg Phaeochromocytoma 30 mg to 60 mg Bleeding in the oesophagus caused by high blood pressure in the liver 80 mg to 160 mg

Elderly people may be started on a lower dose.

Children and Adolescents:

Under some circumstances, propranolol tablets can be used to treat children with the following conditions:

irregular heartbeats, phaeochromocytoma, thyrotoxicosis, Fallot's tetralogy, migraine. The dosage will be adjusted by the doctor according to the child's age or weight.

If you take more Propranolol tablets than you should

Propranolol is severely toxic if used in overdose. If you have accidently taken more than the prescribed dose or are experiencing symptoms of overdose, you should urgently seek medical attention. Overdose causes difficulty breathing, low blood pressure, drowsiness, fits, dilated pupils, an excessively slowed heart beat with symptoms such as dizziness, sickness, confusion, hallucinations, body spasms, breathlessness on exertion, fainting or coma. Overdose could result in heart attack.

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If you forget to take Propranolol tablets

If you forget to take a dose, take it as soon as you remember, unless it is nearly time for your next dose. Take your next dose at the usual time. Don't take two doses at the same time. If you are worried, ask your doctor or pharmacist for advice.

If you stop taking Propranolol tablets

Do not stop taking your medicine without talking to your doctor first. In some cases, it may be necessary to stop taking the medicine gradually. 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.

Stop treatment and contact a doctor at once if you have the following symptoms of an:

- intolerance to Propranolol tablets such as slow heart rate and low blood pressure causing dizziness, light-headedness, fainting or blurred vision
- allergic reaction such as itching, difficulty breathing or swelling of the face, lips, throat or tongue

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

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

- disturbed sleep/nightmares
- the heart beating more slowly
- cold fingers and toes, numbress and spasm in the fingers which is followed by warmth and pain (Raynaud's phenomenon)
- fatique

Uncommon (may affect up to 1 in 100 people): feeling or being sick, diarrhoea

Rare (may affect up to1 in 1,000 people):

- bruising more easily (thrombocytopaenia)
- mood changes, confusion, memory loss, psychosis
- or hallucinations (disturbances of the mind) tingling sensation (pins and needles)
- disturbances of vision, dry eyes
- breathlessness and/or swollen ankles, if you also have heart failure
- heart block which may cause an abnormal heart beat, dizziness, tiredness or fainting dizziness, particularly on standing up

Anaesthetics or tests

medicines you are taking.