NORBEAT TABLET

PROPRANOLOL HYDROCHLORIDE TABLET 40 MG

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What Norbeat Tablet is used for

This medicine is used to treat high blood pressure, to control irregular heart rhythms (arrhythmias) and to relieve chest pain caused by angina. It may also be helpful after a heart attack. This medicine is also used to prevent migraine headaches, relieve uncontrollable shaking (tremors), and help certain problems related to the thyroid gland and adrenal gland.

How Norbeat Tablet works

Norbeat is a beta-blocker. Beta-blockers reduce the workload on the heart and help it to beat more regularly.

Before you use Norbeat tablet When you must not take it

Inform your doctor if you have any problem listed below, as the doctor will decide whether you should be started on Norbeat.

- Raynaud's disease- refers to a disorder in which the fingers or toes (digits)
 suddenly experience decreased blood circulation.
- Malignant Hypertension- very high blood pressure that comes on suddenly and quickly.
- Bronchial Asthma- is a lung disease in which the airways that carry air into and out of the lungs become inflamed and narrow.

- Sinus bradycardia- means your heart beats very slowly.
- Certain type of heart block- delay in the normal flow of electrical impulses that cause the heart to beat.
- Congestive heart failure- is a condition in which the body's tissues aren't receiving enough blood and oxygen due to the heart's reduced pumping action.
- Myasthenia gravis- is a chronic condition that causes muscles to tire and weaken easily.
- Hypersensitivity to Propranolol.

Before you start to take it

Inform your doctor if you have an unusual allergic reaction to propranolol, other beta-blockers, medicines, foods, dyes or preservatives. Inform your doctor as well if you are pregnant or trying to get pregnant or you are breast-feeding.

Taking other medicine

Tell your doctor if you are taking or has been taking other medicines, as interaction may happen, as listed below:

- Phenothiazines and other antipsychotic agents.
- Sympathomimetic agent.
- Antimuscarinic agents and medicine with anticholinergic effects.
- Diuretics and cardiovascular medicine.
- Neuromuscular blocking agents.
- Ergot alkaloids.
- Ibuprofen, anti- inflammatory, analgesic, nonsteroidal (NSAID) especially indomethacin.
- Hypoglycemic therapy, Antidiabetic agents, oral or insulin.
- Calcium channel blocking agents, Nifedipine.
- Digitalis glycosides.

How to take Norbeat Tablet How much to take

Propranolol hydrochloride is usually given by mouth. Dosage is largely determined by the response of the patient.

In most conditions, treatment should begin with a small dose, which should be gradually increased.

Initial doses used for hypertension are 40 to 80 mg of Propranolol hydrochloride twice daily increased as required to a usual range of 160 to 320 mg daily; some patients may require up to 640 mg daily. Propranolol is not suitable for the emergency treatment of hypertension; it should not be given intravenously in hypertension.

In chest pain, initial doses of Propranolol hydrochloride 40 mg given 2 or 3 times daily are increased at weekly intervals as required to a usual range of 120 to 240 mg daily. Some patients may require up to 320 mg daily.

Propranolol hydrochloride is administered within 5 to 21 days of heart attack to prevent re-attack in doses of 40 mg given four times daily for 2 or 3 days ,followed by 80 mg twice daily. Another regimen is to give 180 to 240 mg daily in divided doses.

Propranolol may be given orally in doses of 30 to 160 mg daily in divided doses in the long-term management of irregular heart beat; some suggest doses of up to 320 mg daily.

Doses for the temporarily suppression of thyrotoxicosis (excessive amount of thyroid hormones in the bloodstream) and in thyrotoxic crisis (acute, life-threatening state induced by excessive release of thyroid hormones in individual with thyrotoxicosis) are usually 10 to 40 mg three or four times daily.

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In phaeochromocytoma (a rare, catecholamine-secreting tumor that may precipitate life-threatening hypertension), 60 mg daily should be given on 3 preoperative days always in association with alpha blockade.

If the tumor is inoperable, prolonged treatment may be given with a daily dose of 30 mg.

A suggested dose for anxiety is 40 mg daily; this may be increased to 40 mg two or three times daily.

An initial dose of 40 mg two or three times daily is used in migraine prevention; the dose can be increased at weekly intervals up to 160 mg daily. Some patients have been given 240 mg daily.

In hypertrophic subaortic stenosis (enlargement or an obstruction or narrowing at the outlet of the left ventricle just below the aortic valve), the usual dose of propranolol hydrochloride is 10 to 40 mg given three to four times daily.

Essential tremor may be treated with 40 mg given two to three times daily. The dose can be increased at weekly intervals to 160 mg daily although doses up to 320 mg may be necessary.

For children.

Propranolol has been used in the treatment of hypertension in children in initial doses of 1 mg per kg body-weight daily in divided doses by mouth, increased as required to a usual range to 2 to 4 mg per kg daily in divided doses.

For arrhythmias, phaeochromocytoma, and thyrotoxicosis, the suggested dose is 250 to 500 μ g per kg three or four times daily by mouth. Children under 12 years of age may be given 20 mg two or three times daily for the prophylactic management of migraine.

When to take it

Take Norbeat according to doctors' or pharmacists' advice.

How long to take it

Follow doctor's advice.

If you forget to take it

Take the missed dose as soon as possible as you remember it. However if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

If you take too much (overdose)

Get medical help as soon as possible.

While you are using Norbeat Tablet *Things you must do*

Follow doctor's advice.

Things you must not do

Do not stop taking without consulting doctor first.

Do not give your medicine to whom experiencing the same symptoms as you.

Things to be careful of

- Beta blockers may mask the symptoms of hyperthyroidism(means your thyroid makes too much thyroid hormone) and of hypoglycaemia(is a condition characterized by an abnormally low level of blood sugar (glucose)).
- They may unmask myasthenia gravis(a chronic condition that causes muscles to tire and weaken easily).
- Psoriasis (a chronic skin condition that causes skin cells to grow too quickly, resulting in thick, white, silvery or red patches of skin).
- Elderly patients with hypertension may not respond as well to beta blockers as younger patients.

- In patients with significant liver or kidney impairment, care should be taken when starting treatment and selecting the initial dose.
 - The dose may need to be reduced in patients with kidney or liver dysfunction.
- Abrupt withdrawal of beta blockers has sometimes resulted in heart problem.
- Patients undergoing long-term treatment with a beta blocker should have their medication discontinued gradually over a period of 1 to 2 weeks.
- Some authorities have advocated their gradual and temporary withdrawal prior to anesthesia in order to provide better control of the circulatory system.
- Pregnancy The safety of these agents in pregnancy is not fully established.
 Inform your doctor if you are pregnant or planning to get pregnant.
- Breast-feeding It is distributed into breast milk. Please consult your doctor if you plan to breast-feed your baby when you are taking Norbeat.

Side Effects

Like all medicines, Norbeat Tablet can cause side effects, although not everybody gets them.

Among the most serious side effects are heart failure, heart block and bronchospasm.

Visit your doctor or pharmacist immediately if you experience any side effects even if they are not listed here, after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website <u>portal.bpfk.gov.my</u> (Consumers → Reporting).

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Storage and Disposal of Norbeat Tablet

Storage

Store below 25°C.Protect from light & moisture and KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

Disposal

Medicines should not be disposed of via waste water or household waste. These measures will help you to protect the environment.

Products Description

What it looks Like

White, round shaped, uncoated tablet, with standard concave face.

Ingredients:

Active material used is Propranolol Hydrochloride 40 mg and other ingredients used is Purified Talc, Corn Starch,Lactose,Magnesium Stearate,Povidone

MAL No.: MAL19950083A

Manufacturer and Product Registration

Holder

SM PHARMACEUTICALS SDN.BHD(218628-M) Lot 88,Sungai Petani Industrial Estate 08000,Sungai Petani Kedah Darul Aman,Malaysia

Date of Revision: 02.10.2014

Serial Number

BPFK (R4/1)021014/00025