

Apo-Timol

timolol maleate
10mg Tablets USP

What is in this leaflet

Please read this leaflet carefully before you start using Apo-Timol.

This leaflet answers some common questions about Apo-Timol. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Apo-Timol against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Apo-Timol is used for

The name of your medicine is Apo-Timol tablet. It contains the active ingredient timolol maleate.

Timolol is a hydrophilic non-cardioselective beta-adrenergic blocking agent.

Apo-Timol is indicated for patients with

- high blood pressure, including conditions that makes your heart work harder than normal
- the management of irregular heartbeat
- chest pain due to reduced supply of blood to the heart
- treatment of common or classical migraine
- reduced supply of blood to the heart to reduce the risk of cardiac death, including sudden death, and another heart attack in those who have survived the acute phase of a heart attack

Your doctor may have prescribed Apo-Timol for another reason.

Ask your doctor if you have any questions about why Apo-Timol has been prescribed for you.

If you have any concerns, you should discuss this with your doctor.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

Apo-Timol should not be administered to children.

Before you use Apo-Timol

When you must not use it

Do not use Apo-Timol if:

- **You are allergic to Timolol or any of the ingredients listed at the end of this leaflet including lactose and the dyes FD&C Blue No. 1 and FD&C Blue No. 2.**

Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **You have the following health/medical conditions:**
 - Asthma or other obstructive lung disorders or sudden constrictions of the muscles in the walls of the branches in the lungs
 - uncontrolled heart failure
 - cardiogenic shock
 - abnormal heart rhythms
 - the electrical impulse in the heart beat is not sent to all parts of the heart in the correct way
 - slow heart rate

- **The expiry date (EXP.) printed on the pack has passed.**

If you take it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.

- **The packaging is torn or shows signs of tampering or it does not look quite right.**

If you are not sure whether you should start using Apo-Timol, talk to your doctor.

Before you start to use it

Tell your doctor if:

1. You have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:

- Slow heart rate
- heart failure
- hyperthyroidism
- diabetes mellitus
- kidney and liver impairment
- respiratory diseases
- muscle weakness
- obstruction of one or more arteries that supply blood to the brain
- history or tendency to have severe anaphylactic reactions

3. You are currently pregnant or you plan to become pregnant.

Apo-Timol is not recommended during pregnancy unless the potential benefit justifies the potential risk to the mother and foetus.

4. You are currently breast-feeding or you plan to breastfeed.

Timolol is detectable in human milk. Due to the potential of serious adverse reactions in infants, a decision should be made whether to discontinue nursing or to discontinue timolol therapy, taking into account the importance of the medication to the mother.

5. You are planning to have surgery or an anaesthetic.

6. You are currently receiving or are planning to receive dental treatment.

If you have not told your doctor about any of the above, tell them before you start using Apo-Timol.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Apo-Timol.

Some medicines may interfere with Apo-Timol. These include:

- calcium antagonists
- non-steroidal anti-inflammatory medicines (NSAIDs)
- catecholamine-depleting agents
- digitalis

- clonidine
- quinidine

These medicines may be affected by Apo-Timol, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Other medicines not listed above may also interact with timolol.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Apo-Timol.

How to use Apo-Timol

Follow carefully all directions given to you by doctor. Their instructions may be different to the information in this leaflet.

The label should be carefully read.

How much to take

Hypertension (High blood pressure):

Therapy should be initiated with a daily single or divided oral dose of 10mg, increasing to a maximum daily dose of 60mg, subject to the patient's response. Daily dosages above 20mg should be administered on a divided dose schedule.

Angina (Chest pain):

Therapy should begin with a single oral dose of 5mg taken two or three times daily. Increases in dosage may be necessary with the first increase not exceeding 10mg per day in divided doses and subsequent increases should not exceed 15mg per day in divided doses. There should be an interval of at least three days between increases in dosage. The usual dosage range of Apo-Timol tablets is 15 to 45mg daily, with the majority of patients responding to a daily dosage of 35 to 45mg.

Ischaemic Heart Disease (reduced supply of blood to the heart):

Apo-Timol tablets may be administered in a single dose of 10mg taken twice daily for long-term treatment in patients who survived the acute phase of a heart attack.

Atrial Fibrillation (Irregular heart beat):

Therapy may be initiated with a single oral dose of 10mg taken twice daily, increasing to 30mg twice daily, subject to response.

Migraine:

Apo-Timol tablets may be administered in single dose of 10 to 20mg daily for the treatment of common and classic migraine.

Renal insufficiency:

Dosage adjustments may be necessary.

Apo-Timol is not recommended for children.

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

The tablets are to be administered orally and swallowed whole with water.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Timolol treatment should not be abruptly withdrawn from patients with coronary heart disease. Heart attacks, irregular heartbeats or sudden death have been reported in such patients following the abrupt stopping of beta blocker therapy, with or without preceding chest pain. Dosage of timolol should be gradually reduced over about two weeks while maintaining the same frequency of administration and patients should be carefully observed.

Your doctor will advise you when you can stop taking Apo-Timol completely.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

While you are using Apo-Timol

Things you must do

Immediately stop taking Apo-Timol and check with your doctor if a skin rash or other allergic reaction occurs.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Apo-Timol.

Take your medicine exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking this medicine.

Tell your doctor (immediately) if you become pregnant while you are taking it.

Visit your doctor regularly. Your doctor needs to check your progress and see whether you need to keep taking Apo-Timol.

Always discuss with your doctor any problems or difficulties during or after taking Apo-Timol.

Tell your doctor if for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Keep enough Apo-Timol to last weekends and holidays.

Things you must not do

Do not give Apo-Timol to anyone else, even if they have the same condition as you.

Do not take your medicine to treat any other condition unless your doctor tells you to.

Do not stop taking your medicine, or change the dosage without first checking with your doctor.

Do not take any other medicine while you are taking Apo-Timol without first telling your doctor.

Do not take Apo-Timol for a longer time than your doctor has prescribed.

Things to be careful of

Do not drive, operate machinery, or participate in any dangerous activities where alertness is required, until you know how Apo-Timol affects you.

Apo-Timol may cause dizziness and vertigo. Therefore, it may affect alertness or concentration.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Apo-Timol.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you take too much Apo-Timol the most common signs and symptoms to be expected are symptomatic bradycardia, hypotension, bronchospasm and acute cardiac failure.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Apo-Timol.

Apo-Timol helps most people with the medical conditions listed in the beginning of this leaflet, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Most adverse effects reported have been mild and transient.

Tell your doctor or if you have or notice any of the following:

- abnormal physical weakness, lack of energy, chest pain, extremity pain, headache, fatigue, decreased exercise tolerance
- slow hear beat, heart attack, Raynaud's phenomenon (spasms of blood vessels in the extremities especially the fingers), palpitation, irregular heartbeats, temporary loss of consciousness, cold extremities, pain during

exercise, low blood pressure, oedema, pulmonary oedema, heart failure, slow blood flow.

- nervousness, dizziness, vertigo, pins and needles, local weakness, loss of concentration, increased dreaming, hallucinations, nightmares, insomnia, depression, drowsiness and decreased libido.
- indigestion, nausea, vomiting, diarrhoea and enlargement of the liver
- impotence, urination difficulties
- tinnitus, visual disturbances, double vision, drooping upper eyelid, eye irritation and dry eyes
- slight increases in blood urea nitrogen, serum potassium, serum uric acid and triglycerides and slight decreases in haemoglobin, haematocrit and HDL-cholesterol may occur with timolol therapy, but these are not progressive or associated with clinical manifestations

Tell your doctor immediately if you notice any of the following:

These may be serious side effects. You may need medical attention.

- Slow heart rate
- heart failure
- hyperthyroidism
- diabetes mellitus
- kidney and liver impairment
- respiratory difficulties
- muscle weakness
- severe headache
- allergic reactions

If you or someone you know or care for experience any of the following, stop taking Apo-Timol and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using Apo-Timol

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

No special requirements for disposal.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

Product description

What it looks like

APO-TIMOL tablets are round, light blue, flat-faced, bevelled-edged tablets. Scored and engraved T10 on one side, other side plain.

Apo-Timol 10mg tablets are available in bottle of 100 tablets.

Ingredients

Active ingredient:

Each tablet contains 10mg of the active ingredient timolol maleate.

Inactive ingredients:

- Brilliant blue (FD & C Blue No. 1)
- Indigo carmine (FD & C Blue No. 2, Indigotine)
- Croscarmellose sodium
- Magnesium stearate
- Microcrystalline cellulose
- Lactose monohydrate

This medicine contains lactose.

This medicine does not contain glucose.

Sponsor Details

Apo-Timol is supplied in New Zealand by:

Apotex NZ Ltd
32 Hillside Road
Wairau Valley
AUCKLAND 0627

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