New Zealand Consumer Medicine Information

# **Apo-Nadolol**

#### nadolol

40mg and 80mg Tablets

## What is in this leaflet

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

This leaflet answers some common questions about Apo-Nadolol. 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-Nadolol 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-Nadolol is used for

The name of your medicine is Apo-Nadolol tablet. It contains the active ingredient Nadolol. It belongs to a group of medicines called beta-blockers. It works by relaxing blood vessels and slowing heart rate to improve blood flow or lowering your blood pressure.

Apo-Nadolol is used to treat:

- Chest pain (angina)
- High blood pressure (hypertension)
- Irregular heart beat (arrhythmias)
- Migraine headaches
- Overactive thyroid gland

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

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

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

There is no evidence that this medicine is addictive.

Apo-Nadolol should not be administered to children.

## Before you use Apo-Nadolol

#### When you must not use it

Do not use Apo-Nadolol if:

• You are hypersensitive to, or have had an allergic reaction to nadolol or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing, difficulty breathing or tightness in chest; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

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:
  - You have or have had asthma, wheezing or other lung diseases
  - Heart problems
  - You have a very slow heart beat
- 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, shows signs of tampering or it does not look quite right.

If you are not sure whether you should start using Apo-Nadolol, 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:
  - a history of heart problems
  - breathing problems due to long term problems (called bronchitis or emphysema)
  - suffer from hay fever
  - diabetes. Apo-Nadolol may cause low blood sugar in some, even in patients who are not diabetic, such as children, elderly and those who are fasting.

- liver problems
- an overactive thyroid gland
- kidney problems
- a history of severe allergies

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

Do not take this medicine while pregnant until you and your doctor have discussed the risks and benefits involved.

- 4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding. Nadolol can pass into breast milk and may affect your baby. Your doctor will discuss with you the risks and benefits of taking nadolol when breast-feeding.
- 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-Nadolol.

### 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-Nadolol.

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

- Medicines for chest pain (angina) such as verapamil and diltiazem
- General anesthetics
- Medicines that reduce catecholamine in the body such as reserpine
- The medicine used to treat/regulate heart beat digoxin
- Other medicines used to treat/regulate heart beat such as lignocaine, phenytoin, procainamide, disopyramide or quinidine
- Medicines used to raise blood pressure such as adrenaline and noradrenaline
- Anti-diabetic drugs such as insulin or tablets like metformin or gliclazide
- Anti-muscarinic agents (medicines which relax smooth muscle in the body)
- Medicines for depression (monoamine oxidase inhibitors)
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) such as indomethacin
- Medicines used to treat high blood pressure such as phenothiazines or haloperidol
- Medicines used to narrow blood vessels such as ergot alkaloids which are used to treat migraines

These medicines may be affected by Apo-Nadolol, 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 Apo-Nadolol.

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

### How to use Apo-Nadolol

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

The label should be carefully read.

#### How much to take

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

Elderly patients and patients with kidney problems Your doctor may decide to lower your dose of Apo-Nadolol if necessary.

Children

Apo-Nadolol should not be given to children.

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

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

### How to take it

Take this medicine orally. Take with or without food once daily and swallow the tablet(s) with a full glass of 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.

If you stop treatment suddenly your illness may get worse.

When you doctor tells you that you can stop taking Apo-Nadolol, you need to do this gradually. You doctor will help you do this.

### If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine 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 to take your medicine, ask your pharmacist for some hints to help you remember.

### While you are using Apo-Nadolol

### Things you must do

Immediately stop taking Apo-Nadolol 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-Nadolol.

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.

Tell your doctor if you are breastfeeding or are planning to breastfeed 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-Nadolol.

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

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-Nadolol to last weekends and holidays.

#### Things you must not do

Do not give Apo-Nadolol 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-Nadolol without first telling your doctor.

Do not take Apo-Nadolol 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-Nadolol affects you.

Apo- Nadolol is likely to produce minor or moderate adverse effects on the ability to drive or use machinery. Especially when therapy is being initiated, your ability to drive or operate machinery may be impaired. Care should be taken until you know how it affects you.

### 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-Nadolol.

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

Signs and symptoms of overdose

Cardiac disorders: slowing of heart beat, heart failure, breathing difficulties, low blood pressure, low blood sugar level.

# Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Apo-Nadolol or if you have any questions or concerns.

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.

Nadolol is generally well tolerated.

### Tell your doctor immediately if you notice any of the following.

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

- Pain in your chest and feeling weak or dizzy. These could be signs of heart problems
- Slow heart rate
- Feeling dizzy or weak. These could be signs of low blood pressure

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

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

This list includes the most common side effects. Mostly, these are mild and transient:

- Stomach pain, wind (flatulence), constipation, diarrhea, indigestion and loss of appetite
- Changes in behaviour
- Slurred speech
- Cough and blocked nose
- Ringing in the ears
- Headache
- Feeling or being sick
- Breathing difficulties such as asthma
- Dry mouth, eyes or skin
- Weight gain
- Sweating
- Difficulty in getting or maintaining an erection or in ejaculating (impotence)
- Lack of interest in sexual activities (libido)
- Feeling nervous, anxious, shaky or sweaty
- Inflammation, irritation or swelling caused by blood flow to the stomach

- Difficulty sleeping (insomnia)
- Seeing or hearing things that are not there (hallucinations), confusion, blurred vision
- Depression and short term memory loss
- High temperature and sore throat
- A cold or numb feeling in your fingers or toes
- Unusual skin sensation such as numbness, tingling, picking, burning or creeping on the skin
- Hair loss
- Skin rashes or feeling weak due to changes in your blood cell count which show up on blood test results

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-Nadolol

### 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.

## **Product description**

### What it looks like

APO-NADOLOL 40mg tablets are white, round, biconvex tablets, 8.0mm diameter, identified APO over breakline over N40 on one side.

APO-NADOLOL 80mg tablets are white, round, biconvex tablets, 11.2mm diameter, identified APO over breakline over N80 on one side.

APO-NADOLOL 40mg and 80mg tablets are available in blisters of 30 tablets and bottles of 50, 100 or 500 tablets.

\* Not all strengths, pack types and/or pack sizes may be available.

#### Ingredients

#### Active ingredient:

Each tablet contains 40mg or 80mg of nadolol as the active ingredient.

Inactive ingredients:

- Colloidal silicon dioxide
- Croscarmellose sodium
- Lactose
- Magnesium stearate
- Microcrystalline cellulose

This medicine is gluten free.

This medicine contains lactose.

## **Sponsor Details**

Apo-Nadolol is supplied in New Zealand by:

#### Apotex NZ Ltd

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# Date of Preparation

This leaflet was prepared on 26 June 2018.