#### **Consumer Medicine Information**

# What is in this leaflet

This leaflet answers some common questions about TENOLTEN 50. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking TENOLTEN 50 against the benefits they expect it will have for you.

This medicine may also be used in emergency situations where you may be unconscious. In this case, this leaflet may be given to you after the medicine has been used.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine.

You may need to read it again.

# What TENOLTEN 50 is used for

TENOLTEN 50 belongs to a group of medicines called beta-blockers.

It works by affecting the body's response to certain nerve impulses, especially in the heart. As a result, it decreases the heart's need for blood and oxygen and therefore reduces the amount of work the heart has to do. It widens the blood vessels in the body, causing blood pressure to fall. It also helps the heart to beat more regularly.

TENOLTEN 50 is used to:

- lower high blood pressure, which is called hypertension;
- · prevent angina;
- treat irregular heart rhythm or beat called arrhythmias; or
- treat heart attacks, or reduce your risk of heart complications following a heart attack.

TENOLTEN 50 may be either used alone or in combination with other medicines to treat your condition.

TENOLTEN 50 may also be used in emergency situations or during surgery to treat a fast heart beat before, during or after surgery.

#### **Hypertension:**

All people have blood pressure. This pressure helps to push blood all around your body. Your blood pressure changes during the day, depending on how busy you are or how you are feeling.

You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

Regular blood pressure checks are the only way of knowing that you have hypertension. There are usually no symptoms of hypertension and you may feel fine. If hypertension is not treated, serious health problems such as stroke, heart disease and kidney failure may occur.

TENOLTEN 50 helps to lower your blood pressure.

#### Angina

Angina is a discomfort or pain felt in your chest. The pain may also be felt down your arms or neck and sometimes your shoulders and back. This may be caused by not enough oxygen or blood reaching areas of your heart.

Angina pain is often brought on by exercise or stress.

TENOLTEN 50 is used to prevent angina. It is not used to relieve a sudden attack of angina.

#### Irregular heart beat (arrhythmia):

A number of factors such as some heart diseases, an over active thyroid gland or chemical imbalances may cause your heart to have an irregular heart beat or rhythm.

TENOLTEN 50 helps restore your heart's normal rhythm.

# Reducing heart complications after heart attack:

After a heart attack, you may have complications such as an irregular heart beat or an increased chance of having another heart attack.

TENOLTEN 50 helps to prevent these complications from occurring.

# Ask your doctor if you have any questions about why it has been prescribed for you.

Your doctor may have prescribed TENOLTEN 50 for another reason.

TENOLTEN 50 is not recommended for use in children, as there have been no studies of its effects in children.

There is no evidence that TENOLTEN 50 is addictive.

### Before you take it

### When you must not take it

Do not take TENOLTEN 50 if:

- You have or have had asthma (difficulty in breathing, wheezing and coughing), bronchitis or other lung problems in the past
- 2. You have the following conditions:
- a history of allergic problems, including hay fever. Symptoms of an allergy may include: rash, itching, watery eyes or sneezing;
- a very slow heart beat (less than 45-50 beats/minute);
- a severe blood vessel disorder causing poor circulation in the arms and legs;
- · certain other heart conditions;
- phaeochromocytoma (a rare tumour of the adrenal gland) which is not being treated with other medicines; or
- low blood pressure (hypotension) too much acid in your blood (metabolic acidosis).
- 3. You are receiving:
- certain anaesthetics for medical dental procedures; or
- emergency treatment for shock or severely low blood pressure.
- 4. You have an allergy to TENOLTEN 50 or any of the ingredients listed at the end of this leaflet, or to any other beta-blocker medicine.
- You are pregnant, intend to become pregnant, are breast feeding or intend to breast feed.

Your doctor will discuss the possible risks and benefits of using TENOLTEN 50 during pregnancy and breast feeding.

TENOLTEN 50 passes into breast milk and may therefore affect the breast-fed baby.

If you are not sure whether any of these apply to you, check with your doctor.

Do not use TENOLTEN 50 if the package is torn or shows signs of tampering.

Do not use TENOLTEN 50 if the expiry date printed on the pack has passed.

This medicine may not work as well after this date.

# Before you start to take it Tell your doctor if:

- 1. you have any allergies to:
- any other medicine, including eye drops, or other beta-blocker medicines;
- any other substances, such as foods, preservatives or dyes; or
- · insect stings.

TENOLTEN 50 may make allergies worse or make them harder to treat.

- 2. you have or have had a history of any of the following conditions:
- · heart problems;
- diabetes
- an over active thyroid gland called hyperthyroidism;
- · kidney problems; or
- · circulation problems.

# If you have not told your doctor about any of the above, tell them before you take TENOLTEN 50.

### Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

Some medicines and TENOLTEN 50 may interfere with each other.

These include:

- · other beta-blocker medicines;
- medicines used to treat high blood pressure or angina;
- · medicine used to treat heart problems;
- insulin and tablets used to treat diabetes; or
- medicines used to treat arthritis, pain, or inflammation.

If any of these medicines and TENOLTEN 50 are taken together, it may affect how each of them work. You may need to take different amounts of your medicine, or you may need to take different medicines.

Your doctor will advise you on which medicines to be careful with or to avoid while taking TENOLTEN 50.

# How to take it

### How much to take

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

## **Hypertension:**

The usual dose is from 50 mg (1 tablet) up to 200 mg (4 tablets) of TENOLTEN 50 daily. If your dose is 100 mg or less, take it once a day. If you need to take more than 100 mg (2 tablets), take half of your TENOLTEN 50 in

the morning and the other half in the evening.

#### **Angina or Irregular Heart Beat:**

The usual dose is from 50 mg (1 tablet) up to 100 mg (2 tablets) taken as a single dose or half the dose in the morning and half at night.

#### Heart attack:

The usual dose is 50 mg (1 tablet) of TENOLTEN 50 daily.

Certain people e.g. the elderly or those with kidney problems, may require a lower dose.

#### When to take it

It does not matter if you take your medicine before or after food.

Swallow TENOLTEN 50 with a glass of water, during or immediately after a meal.

Take your tablet at the same time everyday. This will help you remember when to take the tablet.

# How long to take it

# Take TENOLTEN 50 every day. Continue taking TENOLTEN 50 until your doctor advises you to stop.

It helps to treat high blood pressure, irregular heart beat, heart attacks and prevent angina but does not cure it.

Do not stop taking TENOLTEN 50 without checking with your doctor.

Your doctor may want you to gradually reduce the amount of TENOLTEN 50 you are taking. This should take place over a period of about 2 weeks before stopping completely. Do not stop suddenly as this may worsen your condition.

#### If you forget to take it

If it is less than six hours from when you missed your dose, take it as soon as you remember, and then go back to taking your tablets at the same time you would normally.

If it is more than six hours since your last dose, skip the dose you missed and take your next dose when you would normally.

# Do not take a double dose of TENOLTEN 50 to make up for the dose that you missed.

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

## If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to Accident & Emergency at your nearest hospital, if you think that you or anyone else may have taken too much TENOLTEN 50. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep these telephone numbers handy.

If you take too much TENOLTEN 50, you may feel faint or dizzy or you may find it difficult to breathe

# While you are taking it

### Things you must do

Attend all of your doctor's appointments so that your progress can be checked.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking TENOLTEN 50.

Tell your doctor immediately if you become pregnant while taking TENOLTEN 50.

Immediately tell your doctor if you have an allergic reaction to any foods, medicines or insect stings.

TENOLTEN 50 can cause allergic reactions to be worse and harder to treat.

If you have diabetes, check your blood sugar level regularly and report any changes to your doctor.

TENOLTEN 50 may affect your diabetes. It may hide the symptoms of low blood sugar levels, such as a fast heart beat. It may also take longer for your blood sugar level to get back to normal even if you follow the usual treatment for diabetes. Your diabetic medicines may have to be changed or the doses adjusted.

If you continue to have angina attacks, or have more of them whilst taking TENOLTEN 50, tell your doctor.

TENOLTEN 50 is used to help prevent angina, so your angina attacks should become less severe and occur less often.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. You may feel light-headed or dizzy after taking TENOLTEN 50. This is because your blood pressure is falling suddenly.

# If this problem gets worse or continues, talk to your doctor.

To help your body get used to the change in blood pressure, you may find the following hints useful:

Stand up slowly when getting up from a chair or bed. This will allow your body get used to the change in position and blood pressure.

If you feel dizzy, sit or lie down until you feel better.

If you feel faint, sit down and put your head between your knees.

Drink lots of water when exercising and during hot weather when taking TENOLTEN 50, especially if you sweat a lot.

If you do not drink enough water while taking TENOLTEN 50, you may feel faint, light-headed or sick. The recommended healthy minimum water intake is 6-8 glasses a day.

If you are having surgery (even at the dentist), tell your doctor or dentist that you are taking

TENOLTEN 50.

TENOLTEN 50 may affect some of the medicines used during surgery.

If you have to have any medical tests while you are taking TENOLTEN 50, tell your doctor. TENOLTEN 50 may affect the results of some tests.

#### Things you must not do

Do not stop taking TENOLTEN 50 without checking with your doctor.

Do not take any new medicines with TENOLTEN 50, unless your doctor has told you to.

Do not give TENOLTEN 50 to anyone else, even if they have the same condition as you.

Do not use TENOLTEN 50 to treat any other complaint unless your doctor tells you to.

### Things to be careful of

Take care driving or operating machinery until you know how TENOLTEN 50 affects you.

TENOLTEN 50 may cause dizziness, fatigue, light-headedness or faintness in some people.

# Be careful not to over exercise when you first start taking TENOLTEN 50.

It helps prevent angina resulting from physical activity and exercise. You may be tempted to exercise too much. Talk to your doctor about how much exercise you can do.

Dress warmly during cold weather, especially if you will be outside for a long time (for example, when playing or watching sport in winter).

TENOLTEN 50, like other beta blocker medicines, may make you more sensitive to cold temperatures, especially if you have circulation problems. Beta-blockers tend to decrease blood circulation in the skin, fingers and toes.

#### Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking TENOLTEN 50, even if you think the problems are not connected with the medicine.

# If you get any side effects, do not stop taking TENOLTEN 50 without first talking to your doctor.

Like other medicines TENOLTEN 50 can cause some side effects. If they occur, most are likely to be minor and last only a short time. However, some may be serious and need medical attention.

# Tell your doctor if you notice any of the following and they worry you:

- stomach upsets such as diarrhoea, constipation, abdominal pain or heartburn (indigestion)
- · dry mouth, change in taste sensation;
- dizziness, headache or buzzing or ringing in the ears;
- slow or irregular heart beat;
- dry eyes, problems with vision;
- · runny or blocked nose;
- difficulty sleeping, nightmares;
- skin reactions (e.g. rash, itching, worsening of psoriasis);
- cold fingers and toes;
- increased hair loss;
- tingling, 'pins and needles' or walking unsteadily; or
- · sexual problems.

For the most part these side effects have been mild.

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

- confusion or disorientation;
- depression or mood changes or a worsening of these;
- unusual thoughts, hallucinations (seeing, feeling or hearing things that are not there):
- light-headedness or fainting which may be due to low blood pressure; or
- yellowing of the skin and/or eyes (iaundice)

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately, or go to accident and emergency at your nearest hospital:

wheezing, chest tightness or difficulty breathing;

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- · unexplained bruising; or
- swelling of the face, lips or throat.

These are very serious side effects and you may need urgent medical attention or hospitalisation. These side effects are rare.

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

Some people may get other side effects while taking TENOLTEN 50.

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

## After taking it

#### Storage

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

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not work as well.

Do not keep TENOLTEN 50 in the bathroom or near a sink.

# Do not leave TENOLTEN 50 in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep this medicine out of reach of children. A locked cupboard which children cannot

reach is a good place to store medicines.

# Disposal

If your doctor tells you to stop using the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

# Product description

### What TENOLTEN 50 looks like

TENOLTEN 50 (50 mg atenolol) is presented in pack size of 30 tablets in blister.

#### **TENOLTEN 50** (AUST R 186397)

White coloured, round, biconvex tablets with 8 mm diameter, with the inscription ATENOLOL 50 on one side and a scoring line on other side.

# Ingredients

### **Active Ingredient:**

Atenolol

Each tablet contains 50 mg Atenolol.

#### Other Ingredients:

- Starch-maize;
- Gelatin;
- Magnesium carbonate-heavy;
- · Magnesium stearate; and
- Sodium lauryl sulfate.

# Sponsor/Marketing Authorisation Holder

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Atenolol 50 mg AUST R 186397

## **TENOLTEN 50**