Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Visken.

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 taking this medicine against the benefits they expect it will provide.

The information in this leaflet was last updated on the date listed on the final page. Some more recent information on the medicine may be available

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Visken is used for

Visken belongs to a group of medicines called beta-blockers.

It works by affecting the body's response to some nerve impulses, especially in the heart. As a result, the heart needs less blood and oxygen and does not have to work as hard. Blood vessels in the rest of the body are also widened, causing blood pressure to decrease.

Visken can be used alone or in combination with other medicines to treat your condition.

Hypertension

Visken is used to treat high blood pressure, also called hypertension. Everyone has blood pressure. This pressure helps to move your blood around your body. Your blood pressure may be different at various times of the day, depending on how busy you are. You have hypertension when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have it is to have your blood pressure checked on a regular basis. You may feel fine and have no symptoms but, if high blood pressure is not treated, it can lead to serious health problems. Visken helps to lower your blood pressure.

Angina

Visken is used to prevent a type of chest pain called angina. Angina is a pain or uncomfortable feeling in the chest, often spreading to the arms or neck and sometimes to the shoulders and back. This may be caused by too little blood and oxygen getting to the heart. Exercise or stress usually brings on the pain of angina but it can also happen while you are resting. Visken helps to prevent angina from happening. It is not used to treat an attack once it starts.

Irregular heart beat (arrhythmia)

Visken is used to treat irregular heart beat (arrhythmia). An irregular heart beat, also known as an arrhythmia, is a disturbance in the normal rhythm or beat of the heart. Arrhythmias may be caused by a number of factors, including some heart diseases, an overactive thyroid gland, and chemical imbalances. Visken helps to restore the normal rhythm of the heart.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Visken is only available with a doctor's prescription. It is not addictive.

There is not enough information to recommend its use in children.

Before you take Visken

When you must not take it

Do not take Visken if you have ever had an allergy to:

- pindolol (the active ingredient in Visken)
- any of the other ingredients of Visken listed at the end of this leaflet
- · any other beta-blocker medicines

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing;
- swelling of the face, lips, tongue or other parts of the body;
- rash, itching or hives on the skin.

Do not take Visken if you have any of the following health problems / medical conditions:

- a history of bronchial asthma, wheezing, difficulty breathing, chronic cough or other severe lung problems
- a history of allergic problems, including hay fever
- irregular or a very slow heart beat, less than 45 to 50 beats per minute
- an alteration in the structure and function of the right ventricle of the heart caused by a primary disorder of respiratory system (called "Cor pulmonale")
- sudden loss of consciousness in the past
- chest pain, mainly occurring when at rest
- severe heart disease or certain other heart conditions
- severe blood flow disturbances of your blood vessels causing paleness or poor circulation in the arms and legs
- too much acid in your blood (metabolic acidosis)

If you are not sure whether any of the above medical conditions apply to you, your doctor can advise you.

Do not take Visken after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to take it

Tell your doctor if you have any of the following health problems / medical conditions:

- diabetes mellitus (sugar diabetes)
- an overactive thyroid gland
- severe kidnev problems
- certain types of angina such as Prinzmetal angina (also known as variant angina)
- milder forms of circulatory disturbances of blood vessels (conditions marked e.g. by paleness, cold hands or feet)
- phaeochromocytoma (a rare tumour of the adrenal gland) which is not being treated already with other medicines
- psoriasis (a skin disease characterised by thickened patches of red skin, often with silvery scales)
- shock or severely low blood pressure

Your doctor may want to take special precautions if you have any of the above conditions.

Tell your doctor if you are pregnant or intend to become pregnant.

Visken may affect your baby, especially if you take it in the last stages of pregnancy. Your doctor can discuss the risks and benefits of taking this medicine during pregnancy.

Tell your doctor if you are breast-feeding or intend to breast-feed.

Very small amounts of the active ingredient in Visken pass into breast milk and could affect your baby.

Tell your doctor if you are allergic to bee or wasp stings or to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies. Beta-blocker medicines can make an allergic reaction worse.

Taking other medicines

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

Other medicines and Visken may interfere with each other. These medicines include:

- other beta-blocker medicines including eye drops
- other medicines used to treat high blood pressure such as calcium channel blockers or calcium antagonists
- clonidine, a medicine used to treat high blood pressure
- disopyramide, quinidine, and other medicines used to treat irregular heart beat (arrhythmias)
- · insulin, and oral medicines to treat diabetes
- medicines used to treat high blood pressure, chest pain (angina pectoris), disturbances of heart rhythm
- digoxin, a medicine used to treat heart failure
- digitalis glycosides
- medicines commonly used during surgery or in emergency situations, such as dopamine, noradrenaline, and certain anaesthetics

- medicines containing adrenaline or similar substances that raise blood pressure, such as those found in some nose and eye drops, cough medicines, or remedies for the common cold
- non-steroidal anti-inflammatory drugs (known as NSAIDs), which are medicines used to relieve pain or inflammation or to treat arthritis
- ergot alkaloids, a class of medicines used in the prevention and treatment of migraine headaches
- monoamine oxidase inhibitors, a class of medicines used to treat depression
- cimetidine, a medicine used to relieve heartburn and gastrointestinal ulcers

You may need to take different amounts of your medicines or to take different medicines while you are taking Visken. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

How to take Visken

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

These directions 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.

How much to take

The dose of this medicine will be different for different patients. Also, the number of doses you take each day and the time allowed between doses depend on the condition for which you are taking Visken.

Treatment is usually started with the lowest dose. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

To treat high blood pressure, the usual dose is from 10 to 30 mg each day. Doses up to 15 mg are usually taken as a single dose in the morning. Doses above 15 mg are divided into two or three smaller doses.

To prevent angina, the usual dose is from 7.5 to 20 mg each day, divided into three doses.

To treat irregular heart beat, the usual dose is from 10 to 30 mg each day, divided into three doses.

Follow your doctor's instructions carefully. Do not exceed the recommended dose.

How to take it

Swallow the tablet with a full glass of water. You can take Visken with a meal or on an empty stemach

If your stomach is upset after taking the tablet, take it with a meal or after a snack.

How long to take it

Do not stop taking this medicine without first checking with your doctor.

Your doctor may want to gradually reduce the amount of medicine you are taking before stopping it completely. This helps to reduce the chance of your condition becoming worse and to prevent other unwanted effects on your heart.

Continue taking Visken as your doctor tells you.

Your doctor will check your progress to make sure the medicine is working and will discuss with you how long your treatment should continue.

If you forget to take it

If it is almost time for your next dose (e.g. within 2 or 3 hours), skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the dose 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 the one that you missed.

This may increase the chance of you getting an unwanted side effect.

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

Taking Visken at the same time each day will help you remember when to take your medicine.

If you take too much

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Visken. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

Some of the symptoms of an overdose may include:

- feeling sick and vomiting
- dizziness or light headedness (signs of very low blood pressure)
- · abnormally slow or irregular heart beat
- fainting
- sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, or having a fast, pounding heart beat (signs of low blood sugar)
- shortness of breath, and swelling of the feet or legs due to fluid build-up (signs of heart failure)
- shortness of breath
- difficulty breathing with wheezing or coughing
- convulsions, fits or seizures.

While you are taking Visken

Things you must do

If you have an allergic reaction to another medicine, a food or an insect sting while you are taking Visken, tell your doctor immediately.

Visken could make the allergic reaction worse or harder to treat.

If you become pregnant while taking Visken, tell your doctor.

Your doctor can discuss with you the risks and benefits of taking it while you are pregnant.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

This helps your doctor to give you the best treatment and to prevent unwanted side effects from happening.

If you are being treated for diabetes, make sure you check your blood sugar regularly and report any problems to your doctor.

Visken may change how well your diabetes is controlled. It may also prevent some of the warning signs of low blood sugar, such as fast heart beat, and may make low blood sugar last longer. The dose of your diabetes medicines may need to be changed.

If you plan to have surgery and will need an anaesthetic, tell your doctor or dentist that you are taking Visken.

This will help your doctor to prevent unwanted side effects such as a sudden drop in blood pressure.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Visken.

Tell any other doctor, dentist or pharmacist who treats you that you are taking Visken.

If this medicine makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.

These symptoms may be due to a sudden fall in your blood pressure.

If this problem does not go away, talk to your doctor.

To avoid symptoms of low blood pressure, here are some hints that may help:

- Stand up slowly to help 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, breathe deeply and bend forward with your head between your knees
- Take extra care when exercising, driving or standing for long periods, especially in hot weather. Drink plenty of fluids, especially if you sweat a lot.

Things you must not do

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Do not take it to treat any other complaints unless your doctor tells you to.

Do not suddenly stop the treatment with Visken without asking your doctor for advice, because this may cause worsening of your condition.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking Visken until you know how it affects you.

As with other beta-blocker medicines, Visken may cause dizziness, light-headedness or decreased alertness in some people. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Be careful to dress warmly during cold weather, especially if you will be outside for a long time.

Visken may make you more sensitive to cold temperatures, especially if you have problems with your blood circulation. These medicines tend to decrease blood circulation in the skin, fingers and toes.

If you experience eye problems (dry, gritty, or burning eyes), talk to your doctor.

Visken can be used by older people at the same dose as for younger people. Older people may experience more side effects than young people, and so might be monitored closely by their

Things that may help your condition

- Alcohol your doctor may advise you to limit your alcohol intake.
- Diet eat a healthy low-fat diet which includes plenty of fresh vegetables, bread, fruits, cereals and fish. Eat less sugar, salt and fat. To reduce your salt intake you should avoid using salt in cooking or at the table.

- Exercise regular exercise helps to reduce blood pressure and allows you to do more without getting angina. Try regular walking, swimming, cycling or games such as tennis and golf. Before starting any exercise, ask your doctor about the best kind of programme for you.
- Smoking your doctor may advise you to stop smoking or at least cut down.
- Weight your doctor may suggest losing some weight to help lower your blood pressure and help lessen the amount of work your heart has to do. Some people may need a dietician's help to lose weight.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Visken.

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects. If you are over 65 years of age, you may have an increased chance of getting side effects.

Do not be alarmed by these lists of possible side effects. You may not experience any of them.

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

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

- · tiredness, drowsiness, decreased alertness
- dizziness or light-headedness (sometimes with fainting), especially on standing up
- · shakiness or trembling
- · headache or other aches and pains
- disturbed sleep, vivid dreams
- feeling depressed
- stomach upset (mainly nausea or feeling sick) or vomiting
- · diarrhoea or abdominal discomfort
- · runny, itchy, red, dry or irritated eyes
- excess sweating
- · sleep disturbances
- muscle cramps

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

- skin reactions (rash, itching, hives, flaking of skin, worsening of psoriasis)
- abnormal thinking, or hallucinations (seeing or hearing things that are not there)
- numbness

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following side effects happen to you:

- serious signs of allergy such as swelling of the face, lips or tongue which may cause problems with swallowing or breathing
- coldness, burning, tingling or numbness in arms and legs
- changes in heart rate, such as abnormally slow heart beat (called bradycardia), irregular heart beat or palpitations
- disturbed heart rhythm (called cardiac conduction disorder)
- weakness, hunger, trembling, flushing or paleness
- · convulsions, fits or seizures
- chest tightness, wheezing, rattly breathing
- sudden, oppressive chest pain

- shortness of breath, sometimes with tiredness, weakness and reduced ability to exercise, swelling of the feet or legs due to fluid build up
- difficulty breathing with coughing or wheezing

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet.

After taking Visken

Storage

- Keep your medicine in the original container until it is time to take it.
- · Store it in a cool dry place.
- Do not store Visken or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

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 Visken or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Visken 15 mg tablets are white, marked with a score line and JU on one side; packs of 50 tablets.

Ingredients

Visken tablets contain 15 mg pindolol as the active ingredient. The tablets also contain:

- colloidal anhydrous silica
- magnesium stearate
- pregelatinised maize starch
- microcrystalline cellulose

Visken does not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Visken is supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

North Ryde NSW 2113

Telephone 1 800 671 203

® = Registered Trademark

This leaflet was prepared in July 2011

Australian Registration Number

Visken 15 mg AUST R 13393

For internal use only:

(CMI vis291111c based on PI vis291111i)