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**Consumer Medicine Information**

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**What is in this leaflet**

This leaflet answers some common questions about Irbesartan Winthrop.

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 benefits of you taking this medicine against the risks it will have for you.

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

**Keep this leaflet with your medicine.**

You may need to read it again.

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**What Irbesartan Winthrop is used for**

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Irbesartan Winthrop is used to lower high blood pressure, which doctors call hypertension.

Everyone has blood pressure. This pressure helps get your blood all around your body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are often no symptoms of high blood pressure. The only way of knowing that you have high blood pressure is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems, such as stroke, heart disease and kidney failure. Irbesartan Winthrop is also used in the treatment of kidney disease in patients with high blood pressure and type 2 diabetes.

**How Irbesartan Winthrop works**

Irbesartan Winthrop belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin II is a substance produced in the body that causes blood vessels to narrow. Irbesartan Winthrop blocks angiotensin-II and therefore widens your blood vessels, making it easier for your heart to pump blood throughout your body. This helps to lower your blood pressure.

Irbesartan Winthrop also slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Your doctor may have prescribed Irbesartan Winthrop for another reason. Ask your doctor if you have any questions about why Irbesartan Winthrop has been prescribed for you.

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

There is no evidence that this medicine is addictive.

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**Before you take Irbesartan Winthrop**

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**When you must not take it**

**Do not take Irbesartan Winthrop if:**

- **you are pregnant (or think you may be pregnant) or are planning to become pregnant;**  
Irbesartan Winthrop may affect your developing baby if you take it during pregnancy.

- **you are breast-feeding;**  
It is not known if Irbesartan Winthrop passes into breast milk, therefore it is recommended that you not take it while you are breast-feeding;
- **you are allergic to irbesartan or to any of the ingredients listed at the end of this leaflet;**
- **you are diabetic or have kidney problems and are being treated with an ACE inhibitor, any aliskiren-containing medicines or a group of medicines known as AIIRAs (medicines also used to treat high blood pressure);**
- **the packaging is torn or shows signs of tampering;**
- **the expiry date on the pack has passed;**  
If you take this medicine after the expiry date has passed, it may not work.

**If you are not sure if you should start taking Irbesartan Winthrop, talk to your doctor.**

**Irbesartan Winthrop should not be given to children.**

*Before you start to take it*

**Tell your doctor if you have any allergies to:**

- any of the ingredients listed at the end of this leaflet, including lactose
- any other medicines
- any other substances, such as foods, preservatives or dyes

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

**Tell your doctor if you are breast feeding or plan to breastfeed.**

**Tell your doctor if you have or have had any medical conditions, especially the following:**

- **recent excessive vomiting or diarrhoea;**
- **kidney problems, or you have had a kidney transplant or dialysis**
- **heart problems,**
- **liver problems, or have had liver problems in the past**
- **high levels of potassium in your blood**
- **you are strictly restricting your salt intake.**

**Tell your doctor if you plan to have surgery (even at the dentist) that needs a general anaesthetic.**

**If you have not told your doctor about any of the above, tell them before you take Irbesartan Winthrop.**

**Taking other medicines**

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

Some medicines may affect the way others work. Also, some other medicines used to treat high blood pressure may have an additive effect with Irbesartan Winthrop in lowering blood pressure. This may happen with diuretics (fluid tablets). As a result you

may need different amounts of your medicines.

It is important to tell your doctor if you are taking or plan to take any of the following:

- potassium supplements, potassium-containing salt substitutes (you may need to have blood tests done regularly)
- diuretics (fluid tablets)
- medicines containing lithium (you may need to have blood tests done regularly).
- anti-inflammatory medicines such as non-steroidal anti-inflammatory agents (for example diclofenac, ibuprofen) and COX-2 inhibitors (for example celecoxib) used to relieve pain, swelling and other symptoms of inflammation including arthritis. Taking Irbesartan Winthrop and an anti-inflammatory medicine alone or with a thiazide diuretic (fluid tablet) may damage your kidneys. It may also reduce the effect Irbesartan Winthrop has on lowering blood pressure.
- a medicine containing aliskiren. Taking Irbesartan Winthrop with aliskiren may affect your blood pressure, electrolyte balance and your kidney function.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Irbesartan Winthrop.

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**How to take Irbesartan Winthrop**

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**How much to take**

Your doctor will tell you how many tablets to take each day.

Usually patients start with one 150 mg tablet once a day. However, some patients may need a lower starting dose. Your doctor will tell you if this is necessary. The full blood pressure lowering effect of Irbesartan Winthrop should be reached about 4-6 weeks after starting treatment.

Depending on how your blood pressure responds, your daily dose of Irbesartan Winthrop may need to be increased. Most patients take either 150 mg or 300 mg each day.

In patients with high blood pressure and type 2 diabetes, 300 mg once daily is the preferred maintenance dose for slowing the progression of associated kidney disease.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly how much to take.

**Follow the instructions they give you.**

**How to take it**

**Swallow the tablet whole with a glass of water.**

It does not matter whether you take Irbesartan Winthrop tablets before or after food.

**When to take it**

**Take Irbesartan Winthrop at about the same time each day.**

Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.

**How long to take it**

**Continue taking Irbesartan Winthrop until your doctor tells you to stop.**

Irbesartan Winthrop helps to control your high blood pressure, but it does not cure it. Therefore Irbesartan Winthrop must be taken every day.

To help you remember to take your tablets each day, Irbesartan Winthrop tablets are supplied in a Calendar pack with the foil backing marked with the days of the week. This is just a way to help you to remember to take your tablets. All of the tablets in the pack are the same.

**When you start a new strip of tablets, take the tablet marked "START" at the end of the blister strip. On the next day, take the tablet marked with the relevant day of the week.**

**Continue taking your tablets each day until all of the tablets are taken.**

**Commence the next strip at "START" and continue as before.**

*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 go back to taking your tablets as you would normally.**

**Do not take a double dose to make up for the dose you missed.**

This may increase the chance of you getting any unwanted side effects.

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to take your tablets, ask your pharmacist for some hints.**

*If you take too much (overdose)*

**Immediately telephone your doctor or Poisons Information Centre (telephone: 13 11 26) or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Irbesartan Winthrop. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

If you take too many Irbesartan Winthrop tablets you will probably feel light-headed or dizzy.

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While you are using Irbesartan Winthrop

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*Things you must do*

**Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Irbesartan Winthrop.**

**If you become pregnant while taking Irbesartan Winthrop tell your doctor immediately.**

**Have your blood pressure checked when your doctor tells you to, to make sure Irbesartan Winthrop is working.**

**If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Irbesartan Winthrop.**

**If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Irbesartan Winthrop.**

Your blood pressure may drop suddenly.

**Make sure you drink enough water during exercise and hot weather when you are taking Irbesartan Winthrop, especially if you sweat a lot.**

If you do not drink enough water while taking Irbesartan Winthrop, you may faint or feel light-headed or sick. This is because your body does not have enough fluid and your blood pressure is low. If you continue to feel unwell, tell your doctor.

**If you have excessive vomiting and/or diarrhoea while taking Irbesartan Winthrop, tell your doctor.**

You may lose too much water and salt and your blood pressure may drop too much.

**If you feel light headed or dizzy after taking your first dose of Irbesartan Winthrop, or when your dose is increased, tell your doctor immediately.**

*Things you must not do*

**Do not give Irbesartan Winthrop tablets to anyone else, even if they have the same condition as you.**

**Do not take Irbesartan Winthrop to treat any other complaints unless your doctor or pharmacist tells you to.**

**Do not stop taking Irbesartan Winthrop, or lower the dosage, without checking with your doctor.**

*Things to be careful of*

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

**Be careful driving or operating machinery until you know how Irbesartan Winthrop affects you.**

As with many other medicines used to treat high blood pressure, Irbesartan Winthrop may cause dizziness or light-headedness in some people.

**If this occurs do not drive.**

Make sure you know how you react to Irbesartan Winthrop before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or light-headed.

If you drink alcohol, dizziness or light-headedness may be worse.

*Things that would be helpful for lowering your blood pressure*

Some self help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- **Alcohol** - your doctor may advise you to limit your alcohol intake.
- **Weight** - if you are overweight, 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.
- **Diet** - your doctor may advise you to eat a healthy low-fat diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish.

- **Salt** - your doctor may advise you to watch the amount of salt in your diet. 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 helps get the heart fitter, but it is important not to overdo it. Walking is good exercise, but try to find a route that is reasonably flat. 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.

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## Side effects

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

Irbesartan Winthrop helps most people with high blood pressure, but it may have unwanted side effects in a few 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 side effects.

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

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

- headache
- dizziness or light-headedness (vertigo)
- unusual tiredness or weakness, fatigue
- nausea/vomiting.

These are common side effects. They are generally mild and do not normally require treatment to be interrupted.

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

- skin rash or itchiness
- aching muscles, not caused by exercise
- muscle pain or weakness
- buzzing, ringing or other persistent noise in the ear
- yellowing of the skin and/or eyes, also called jaundice
- symptoms that may indicate kidney disease, such as passing little or no urine, drowsiness, nausea, vomiting, breathlessness, loss of appetite and weakness
- symptoms that may indicate high potassium levels in the blood, such as nausea, diarrhoea, muscle weakness, change in heart rhythm
- symptoms that may indicate liver disease such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine
- symptoms that may indicate low platelet count such as easy or excessive bruising, bleeding from gums or nose, prolonged bleeding from cuts and blood in urine or stools.

These are serious side effects. Skin rash and itchiness may be symptoms of an allergic reaction. You may need medical attention.

These side effects are not common.

**If any of the following happen, stop taking Irbesartan Winthrop and either tell your doctor immediately or go to Accident and Emergency Department at your nearest hospital:**

- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing;
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash.

These are very serious side effects.

You may need urgent medical attention or hospitalisation.

These side effects are very rare.

**Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

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## After using Irbesartan Winthrop

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### *Storage*

**Keep your Irbesartan Winthrop tablets in the blister pack until it is time to take them.**

If you take the tablets out of the blister pack they may not keep well.

**Keep Irbesartan Winthrop tablets in a cool dry place where the temperature stays below 25°C.**

**Do not store Irbesartan Winthrop or any other medicine in the bathroom or near a sink. Do not leave them near a radiator, in a car on hot days or on a window sill.**

Heat and dampness can destroy some medicines.

**Keep all medicines out of the reach of children.**

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 Irbesartan Winthrop or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.**

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## Product description

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### *What it looks like*

Irbesartan Winthrop 75 mg tablets: white, oval shaped film-coated tablets with a heart shape imprinted on one side and "2871" engraved on the other side. Blister pack sizes include: 3\*, 5\*, 7\*, 14\*, 28\*, 30, 56\* and 98\* tablets.

Irbesartan Winthrop 150 mg tablets: white, oval shaped film-coated tablets with a heart shape imprinted on one side and "2872" engraved on the other side. Blister pack sizes include: 3\*, 5\*, 7\*, 14\*, 28\*, 30, 56\* and 98\* tablets.

Irbesartan Winthrop 300 mg tablets: white, oval shaped film-coated tablets with a heart shape imprinted on one side and "2873" engraved on the other side. Blister pack sizes include: 3\*, 5\*, 7\*, 14\*, 28\*, 30, 56\* and 98\* tablets.

\* presentations currently not marketed.

### *Active ingredients*

Irbesartan Winthrop 75 mg tablets: 75 mg irbesartan per tablet.

Irbesartan Winthrop 150 mg tablets: 150 mg irbesartan per tablet.

Irbesartan Winthrop 300 mg tablets: 300 mg irbesartan per tablet.

### *Other Ingredients*

Irbesartan Winthrop tablets also contain carnauba wax, croscarmellose sodium, hypromellose, lactose, macrogol 3000, magnesium stearate, microcrystalline cellulose, silicon dioxide, and titanium dioxide

### *Supplier*

Irbesartan Winthrop is supplied in Australia by:

sanofi-aventis australia Pty Ltd  
12-24 Talavera Road  
Macquarie Park, NSW 2113.

Irbesartan Winthrop is a registered trademark of sanofi-aventis

Australian registration number(s):

Irbesartan Winthrop 75mg AUST R 196947

Irbesartan Winthrop 150mg AUST R 196948

Irbesartan Winthrop 300mg AUST R 196949

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