

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Irbesartan HCT 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.

### What Irbesartan HCT Winthrop is used for

Irbesartan HCT 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.

#### *How Irbesartan HCT Winthrop works*

Irbesartan HCT Winthrop contains irbesartan and hydrochlorothiazide. Both medicines reduce blood pressure in different ways. Irbesartan 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 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.

Hydrochlorothiazide belongs to the class of medicines known as diuretics. Diuretics cause an increase in the volume of urine. They also help with lowering blood pressure particularly when combined with other blood pressure reducing medicines.

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

### Before you take Irbesartan HCT Winthrop

*When you must not take it*

**Do not take Irbesartan HCT Winthrop if:**

- you are pregnant (or think you may be pregnant) or are planning to become pregnant.  
Irbesartan HCT Winthrop may affect your developing baby if you take it during pregnancy.
- you are breast-feeding or are planning to breast-feed.
- you are allergic to irbesartan or hydrochlorothiazide or to sulfonamide derived medicines (commonly known as sulfur drugs), or to any of the ingredients listed under 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).
- you are not producing urine.
- 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 HCT Winthrop, talk to your doctor.**

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

*Before you start to take it*

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

- any of the ingredients listed at the end of this leaflet including lactose
- any other medicines, including sulfonamide derived medicines (commonly known as sulfur drugs)
- 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 or think you are dehydrated
- kidney problems, or have had a kidney transplant or dialysis
- heart problems
- liver problems, or have had liver problems in the past
- diabetes
- gout or have had gout in the past
- lupus erythematosus
- high or low levels of potassium or sodium or other electrolytes in your blood
- primary aldosteronism
- you are strictly restricting your salt intake
- you have had a sympathectomy
- you have been taking diuretics
- you have a history of allergy or asthma

**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 HCT 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.**

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

- other medicines for high blood pressure
- other fluid tablets or diuretics
- lithium or lithium-containing medicines (for example lithium carbonate)
- potassium tablets
- potassium-containing salt substitutes
- 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 HCT 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 HCT Winthrop has on lowering blood pressure
- a medicine containing aliskiren. Taking Irbesartan HCT Winthrop with aliskiren may affect your blood pressure, electrolyte balance and your kidney function
- alcoholic drinks
- sleeping tablets
- strong pain killing medicines such as codeine or morphine
- medicines for diabetes (oral tablets or capsules or insulins)
- calcium supplements or medicines containing calcium
- Vitamin D
- medicines for gout
- powder or granules used to help reduce cholesterol (cholestyramine or colestipol hydrochloride)
- heart medicines such as digoxin or antiarrhythmic medicines (for example sotalol hydrochloride)
- corticosteroid medicines such as prednisone, cortisone or ACTH
- medicines used to treat cancer (cytotoxic medicines)
- amantadine, a medicine used to treat Parkinson's disease or to prevent influenza
- anticholinergic medicines, these can be used to treat Parkinson's disease, to relieve stomach cramps or spasms or used to prevent travel sickness
- carbamazepine, an anticonvulsant medication
- medicines used during surgery

- medicines used in an emergency situation such as adrenaline

Your doctor will decide whether your treatment needs to be altered or whether you should have check-ups more frequently.

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

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## How to take Irbesartan HCT Winthrop

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### *How much to take:*

Irbesartan HCT Winthrop will usually be prescribed by your doctor if previous treatment does not produce a sufficient drop in your blood pressure. Your doctor will tell you how to switch from your previous treatment to Irbesartan HCT Winthrop.

The usual dose of Irbesartan HCT Winthrop is one tablet a day. The full blood pressure lowering effect should be reached 6-8 weeks after beginning treatment. If your blood pressure is not satisfactorily reduced with Irbesartan HCT Winthrop, your doctor may prescribe another medicine to be taken with Irbesartan HCT Winthrop.

### *How to take it*

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

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

### *When to take it*

**Take Irbesartan HCT 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 HCT Winthrop until your doctor tells you to stop.**

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

To help you remember to take your tablets each day, Irbesartan HCT 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". 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 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 HCT 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 HCT Winthrop tablets, you will probably feel lightheaded or dizzy.

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## While you are using Irbesartan HCT 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 HCT Winthrop.**

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

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

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

**If you plan to have surgery or other treatment (even at the dentist) that needs an anaesthetic, make sure that you tell your doctor or dentist that you are taking Irbesartan HCT Winthrop.**

Your blood pressure may drop suddenly.

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

If you do not drink enough water while taking Irbesartan HCT 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 HCT 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 HCT Winthrop, or when your dose is increased, tell your doctor immediately.**

### *Things you must not do*

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

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

**Do not stop taking Irbesartan HCT 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 HCT Winthrop affects you. As with many other medicines used to treat high blood pressure, Irbesartan HCT 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 HCT 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.

The hydrochlorothiazide contained in this medicine could produce a positive analytical result in an antidoping test.

### *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 HCT Winthrop.**

Irbesartan HCT 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
- pain in the stomach or gut nausea and/or vomiting
- sexual problems

These 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 or sore joints, not caused by exercise
- muscle pain or weakness
- buzzing, ringing or other persistent noise in the ears
- changes in heart rhythm
- you are not urinating (passing water) as much as normal
- numbness or tingling in fingers or toes
- painful, swollen joints that may be symptoms of gout
- fainting
- yellowing of the skin and/or eyes, also known as jaundice
- symptoms that may occur if you have developed diabetes, such as excessive thirst, passing greatly increased amounts of urine, increased appetite with weight loss, feeling tired, drowsy, weak, depressed, irritable and generally unwell
- 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 and changes 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
- disturbances in your vision (such as blurred vision and seeing haloes around lights) and eye pain.

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 HCT Winthrop and either tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- swelling to the face, lips, tongue or throat, which may cause difficulty in swallowing or breathing.
- severe and a 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 HCT Winthrop

### Storage

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

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

**Keep Irbesartan HCT Winthrop tablets in a cool dry place where the temperature stays below 25°C. Do not store Irbesartan HCT Winthrop or any other medicine in the bathroom near a sink. Do not leave them near a radiator, in a car on a hot day 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 HCT 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

### What it looks like

Irbesartan HCT Winthrop 150/12.5 tablets - peach, oval shaped film-coated tablet with a heart shape imprinted on one side and "2875" engraved on the other side. Blister pack sizes include: 3\*, 5\*, 7\*, 14\*, 28\*, 30, 56\* and 98\* tablets.

Irbesartan HCT Winthrop 300/12.5 tablets - peach, oval shaped film-coated tablet with a heart shape imprinted on one side and "2876" engraved on the other side. Blister pack sizes include: 3\*, 5\*, 7\*, 14\*, 28\*, 30, 56\* and 98\* tablets.

Irbesartan HCT Winthrop 300/25 tablets - pink, oval shaped film-coated tablet with a heart shape imprinted on one side and "2788" 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 HCT Winthrop 150/12.5 tablets - 150 mg Irbesartan and 12.5 mg Hydrochlorothiazide per tablet.

Irbesartan HCT Winthrop 300/12.5 tablets - 300 mg Irbesartan and 12.5 mg Hydrochlorothiazide per tablet.

Irbesartan HCT Winthrop 300/25 tablets - 300 mg Irbesartan and 25 mg Hydrochlorothiazide per tablet.

### Other Ingredients

Irbesartan HCT Winthrop 150/12.5 & 300/12.5 tablets also contain carnauba wax, croscarmellose sodium, hypromellose, lactose, iron oxide red CI 77491, iron oxide yellow CI 77492, macrogol 3000, magnesium stearate, microcrystalline cellulose, silicon dioxide, and titanium dioxide.

Irbesartan HCT Winthrop 300/25 tablets also contain carnauba wax, croscarmellose sodium, hypromellose, lactose, iron oxide red CI 77491, iron oxide yellow CI 77492,

iron oxide black CI 77499, macrogol 3350, magnesium stearate, microcrystalline cellulose, silicon dioxide, pregelatinised maize starch, and titanium dioxide.

### Manufacturer

Irbesartan HCT Winthrop is supplied in Australia by

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

Irbesartan HCT Winthrop is a registered sanofi-aventis trademark.

Australian registration number(s):

Irbesartan HCT Winthrop 150/12.5 AUST R 196956

Irbesartan HCT Winthrop 300/12.5 AUST R 196957

Irbesartan HCT Winthrop 300/25 AUST R 196958

This leaflet was prepared in March 2017  
irbesartan-hct-winthrop-ccds14-cmiv4-27feb17