

AVAPRO(R) HCT Tablets

Irbesartan plus Hydrochlorothiazide

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking AVAPRO HCT. This leaflet answers some common questions about AVAPRO HCT. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. Do not throw this leaflet away. You may need to refer to it again later.

Always follow the instructions that your doctor and pharmacist give you about AVAPRO HCT. If you have any concerns about taking AVAPRO HCT, ask your doctor or pharmacist.

What is AVAPRO HCT

AVAPRO HCT is a trade name (manufacturer's name). AVAPRO HCT tablets contain two medicines, irbesartan and hydrochlorothiazide. Both these medicines are in the tablets your doctor has prescribed for you.

What AVAPRO HCT is used for

AVAPRO HCT lowers high blood pressure, which doctors call hypertension.

Your doctor measured your blood pressure and found it to be too high. 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) which means your blood pressure stays high, even when you are calm and relaxed.

There are usually no symptoms of high blood pressure. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. High blood pressure, if not treated, can damage blood vessels in several organs such as the heart, the kidneys, the brain and the eyes. This may lead to heart attacks, heart or kidney failure, strokes, or blindness. There are usually no symptoms of high blood pressure before damage occurs, so your doctor needs to measure your blood pressure to see if it is too high.

High blood pressure can be treated and controlled with medicines such as AVAPRO HCT. Your doctor may also have recommended that you adjust your lifestyle to help to lower your high blood pressure (losing weight, avoiding smoking, reducing alcohol consumption and restricting the amount of salt in the diet). Your doctor may also have encouraged the practice of regular, mild (not strenuous) exercise such as walking, swimming, etc.

What AVAPRO HCT does and how it works

AVAPRO HCT 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 which causes blood vessels to tighten. Irbesartan blocks angiotensin-II and therefore relaxes your blood vessels. 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 AVAPRO HCT for another use. If you want more information, ask your doctor.

When you must not take AVAPRO HCT

Do not take AVAPRO HCT if :

- * you are pregnant (or think you may be pregnant) or are planning to become pregnant

Your baby may absorb this medicine in the womb and there is a possibility of harm to the baby.

- * you are breast-feeding.
- * you are allergic to irbesartan or hydrochlorothiazide or to sulfonamide derived medicines, or to any of the ingredients listed under Product Description at the end of this leaflet.
- * 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 AVAPRO HCT, talk to your doctor.

AVAPRO HCT should not be given to children.

Before you start to take AVAPRO HCT

Tell your doctor if:

- * you are or intend to become pregnant or plan to breast-feed AVAPRO HCT should not be used during pregnancy or while breast-feeding
- * you have recently had excessive vomiting or diarrhoea or think you are dehydrated
- * you suffer from any medical conditions especially-
 - 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 are lactose intolerant or have had any allergies to any other medicine or any other substances, such as foods, preservatives or dyes.
- * have had a sympathectomy
- * you you have been taking diuretics
- * you have a history of allergy or asthma

Be sure you tell your doctor about any of these things before you take any AVAPRO HCT.

Taking AVAPRO HCT with 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.

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

- * other tablets for high blood pressure.
- * other water tablets or diuretics.
- * lithium or lithium-containing medicines (for example Lithicarb(R)).
- * potassium tablets (for example Span-K(R), Slow-K(R), Mag-K(R)).
- * potassium containing salt substitutes (for example Pressor-K(R)).
- * anti-inflammatory medicines (these are used to relieve pain, swelling and other symptoms of inflammation, including arthritis) and include nonsteroidal anti-inflammatory agents - NSAIDS (for example Voltaren(R), Indocid(R)) and COX-2 inhibitors (for example Celebrex(R)). Taking a combination of Avapro HCT and an anti-inflammatory medicine may damage your kidneys.
- * alcoholic drinks
- * sleeping tablets

- * strong pain killing medicines such as codeine or morphine
- * medicines for diabetes (oral tablets or capsules or insulins)
- * calcium supplements, medicines containing calcium or calcium sparing drugs (for example Vitamin D therapy).
- * medicines for gout.
- * powder or granules used to help reduce cholesterol (Questran Lite or Colestid Granules).
- * heart medicines such as digoxin or antiarrhythmic medicines (for example Sotacor(R)).
- * corticosteroid medicines such as prednisone, cortisone or ACTH.
- * medicines used to treat cancer (cytotoxic medicines).
- * amantadine (Symmetrel), 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.
- * 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.

How to take AVAPRO HCT

The tablets should be taken regularly as directed by your doctor. The tablets should be swallowed with a drink of water.

How much to take:

AVAPRO HCT 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 AVAPRO HCT.

The usual dose of AVAPRO HCT 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 AVAPRO HCT, your doctor may prescribe another medicine to be taken with AVAPRO HCT.

When to take it:

You should always take your daily dose of AVAPRO HCT at about the same time each day. Taking your AVAPRO HCT tablets at the same time each day will have the best effect.

To help you remember to take your tablets each day, AVAPRO HCT 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.

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

How long to take it:

AVAPRO HCT helps to control your high blood pressure, but does not cure it. Therefore AVAPRO HCT must be taken every day. Continue taking AVAPRO HCT until your doctor tells you to stop.

If you miss a dose:

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.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

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

If you take too much AVAPRO HCT (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone: 131126) or go to the Accident and Emergency Department at your nearest hospital, if you or anyone else may have taken too much AVAPRO HCT.

Do this even if there are no signs of discomfort or poisoning.

If you take too many AVAPRO HCT tablets, you will probably feel lightheaded or dizzy.

While you are using AVAPRO HCT

Things you must do:

- * If you become pregnant while taking AVAPRO HCT tell your doctor immediately.
- * Have your blood pressure checked when your doctor tells you to, to make sure AVAPRO HCT is working.
- * If you are about to start on any new medicine, tell your doctor and pharmacist that you are taking AVAPRO HCT.
- * Get up slowly when getting out of bed or standing up. You may feel light-headed or dizzy while taking AVAPRO

HCT. This may become worse if you stand up quickly as your blood pressure may fall. 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 it occurs talk to your doctor.

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

If you do not drink enough water while taking AVAPRO HCT, 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 AVAPRO HCT, tell your doctor. This can also mean that you are losing too much water and your blood pressure may become too low.

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

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

Things you must not do:

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

Things to be careful of:

- * Be careful driving or operating machinery until you know how AVAPRO HCT affects you. As

with many other medicines used to treat high blood pressure, AVAPRO HCT may cause dizziness or light-headedness in some people. Make sure you know how you react to AVAPRO HCT 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.

Side effects

AVAPRO HCT 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.

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

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

- * headache
- * dizziness or light-headedness
- * 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 aching joints, not caused by exercise
- * muscle pain, weakness or paralysis of muscles
- * 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 which 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

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 AVAPRO HCT and tell your doctor immediately or go to casualty at your nearest hospital -

- * swelling to the face, lips, tongue or throat, which may cause difficulty in swallowing or breathing. If you have them, you may have a serious allergic reaction to AVAPRO HCT
- * severe and a sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash. If you have them, you may have a serious allergic reaction to AVAPRO HCT
- * symptoms that may indicate liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine.

These are 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. If you notice any other unwanted effects, you should tell your doctor or pharmacist and ask for their advice.

After using AVAPRO HCT

Storage:

Keep your AVAPRO HCT 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 AVAPRO HCT tablets in a cool dry place where the temperature stays below 25 degrees C. Do not store AVAPRO HCT 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 AVAPRO HCT or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

Starting from January 2006 the manufacturer will be supplying a new formulation of Avapro HCT tablets with some different inactive ingredients. Therefore, until all stocks of the original formulation have been used up, your pharmacist may give you either the original formulation or the new one. There is only a slight difference between the appearance of the original and the new tablets (see below).

There is no difference between the two formulations in the active ingredient or how well Avapro HCT tablets work.

Original formulation

AVAPRO HCT 150/12.5 tablets - peach, oval tablet with a heart shape on one side and "2775" on the other. Pack size: 30 tablets. AUST R 68971

AVAPRO HCT 300/12.5 tablets - peach, oval tablet with a heart shape on one side and "2776" on the other. Pack size : 30 tablets. AUST R 68973

New formulation

AVAPRO HCT 150/12.5 tablets - peach, oval, film-coated tablet with a heart shape on one side and "2875" on the other. Pack size: 30 tablets. AUST R 102017

AVAPRO HCT 300/12.5 tablets - peach, oval, film-coated tablet with a heart shape on one side and "2876" on the other. Pack size : 30 tablets. AUST R 102086

New strength

AVAPRO HCT 300/25 tablets – pink, oval, film-coated tablet with a heart shape on one side and "2788" on the other. Pack size: 30 tablets. AUST R 129436.

Active Ingredients

AVAPRO HCT 150/12.5 tablets - 150 mg Irbesartan and 12.5 mg Hydrochlorothiazide per tablet.

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

AVAPRO HCT 300/25 tablets – 300 mg Irbesartan and 25 mg Hydrochlorothiazide per tablet.

Other Ingredients

Original formulation

AVAPRO HCT tablets also contain microcrystalline cellulose, croscarmellose sodium, lactose, magnesium stearate, silicon dioxide, pregelatinised maize starch, and red and yellow iron oxides

New formulation

AVAPRO HCT 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.

New strength

AVAPRO HCT 300/25 tablets also contain carnauba wax, microcrystalline cellulose, croscarmellose sodium, lactose, magnesium stearate, silicon dioxide, pregelatinised maize starch, hypromellose, titanium dioxide, macrogol 3350 and red, yellow & black iron oxides.

Who makes AVAPRO HCT

AVAPRO HCT is made available by Bristol-Myers Squibb Australia Pty Ltd, A.C.N. 004 333 322, 556 Princes Highway, Noble Park VIC 3174, Australia.

AVAPRO is a registered sanofi-aventis Trademark.

This information in no way replaces the advice of your doctor or pharmacist.

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How current is this information

This leaflet was produced based on information known by Bristol-Myers Squibb Australia Pty Ltd June 2007. You need to consult your doctor regularly as your doctor has access to information on any changes which may affect you.