

ABISART HCT

contains the active ingredient irbesartan/hydrochlorothiazide

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about ABISART HCT.

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 ABISART HCT against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What ABISART HCT is used for

ABISART HCT is used to treat hypertension (i.e. high blood pressure). ABISART HCT is a trade name (manufacturer's name). ABISART HCT tablets contain two medicines, irbesartan and hydrochlorothiazide.

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 ABISART HCT.

One of the active ingredients in ABISART HCT is irbesartan which belongs to a class of medicines called 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.

The other active ingredient in ABISART HCT is hydrochlorothiazide which belongs to a 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 also have recommended that you adjust your life style 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.

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.

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

This medicine may affect your ability to drive a car or operate machinery.

Before you take ABISART HCT

When you must not take it

Do not take ABISART HCT if you are:

- allergic to irbesartan or hydrochlorothiazide or to sulfonamide derived medicines
- allergic to any of the ingredients listed at the end of this leaflet

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 this medicine if you are not producing urine.

Do not take this medicine if you are pregnant (or think you may be pregnant) or are planning to become pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

It is not known if ABISART HCT passes into breast milk, therefore it is not recommended to be taken while you are breast-feeding.

Do not give this medicine to children.

Safety and effectiveness in children have not been established.

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

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- you have recently had excessive vomiting or diarrhea 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 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 ABISART HCT.

If you have not told your doctor about any of the above, tell him/her before you start taking ABISART HCT.

Taking ABISART HCT with other medicines

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

Some medicines and ABISART HCT may interfere with each other. It is 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®)
- potassium tablets (for example Span-K®, Slow-K®, Mag-K®)
- potassium containing salt substitutes (for example Pressor-K®)
- 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®, Indocid®) and COX-2 inhibitors (for example Celebrex®). Taking a combination of ABISART® HCT with 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®)
- 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
- carbamazepine (Tegretol), an anticonvulsant medication.
- medicines used during surgery
- medicines used in an emergency, such as adrenaline.

These medicines may be affected by ABISART HCT or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines or whether you should have check-ups or blood test more frequently.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take ABISART HCT

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 box, ask your doctor or pharmacist for help.

How much to take

ABISART 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 ABISART HCT.

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

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

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

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

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

How long to take it

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

Therefore ABISART HCT must be taken every day.

Continue taking ABISART HCT until your doctor tells you to stop.

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 then go back to taking your medicine 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 an unwanted side effect.

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

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) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much ABISART HCT. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include feeling lightheaded or dizzy.

While you are taking ABISART HCT

Things you must do

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

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

Get up slowly when getting out of bed or standing up.

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.

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

If you do not drink enough water while taking ABISART HCT, you may faint or feel lightheaded 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 diarrhea while taking ABISART HCT, tell your doctor.

This can also mean that you are losing too much water and your blood pressure may become too low.

Things you must not do

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

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

Do not stop taking your medicine or change the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen.

Things to be careful of

Be careful driving or operating machinery until you know how ABISART HCT affects you.

As with many other medicines used to treat high blood pressure, ABISART HCT may cause dizziness or light-headedness in some people. Make sure you know how you react to ABISART HCT before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or lightheaded.

Be careful when drinking alcohol while you are taking this medicine.

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

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

Hydrochlorothiazide contained in this medicine could produce a positive analytical result in antidoping test.

Lifestyle measures that help reduce heart disease risk

By following these simple measures, you can further reduce the risk from heart disease.

- Quit smoking and avoid second-hand smoke.
- Limit alcohol intake.
- Enjoy healthy eating by:
 - eating plenty of vegetables and fruit;
 - reducing your saturated fat intake (eat less fatty meats, full fat dairy products, butter, coconut and palm oils, most take-away foods, commercially-baked products).
- Be active. Progress, over time, to at least 30 minutes of moderate-intensity physical activity on 5 or more days each week. Can be accumulated in shorter bouts of

10 minutes duration. If you have been prescribed anti-angina medicine, carry it with you when being physically active.

- Maintain a healthy weight.
- Discuss your lifestyle and lifestyle plans with your doctor.
- For more information and tools to improve your heart health, call Heartline, the Heart Foundation's national telephone information service, on 1300 36 27 87 (local call cost).

Know warning signs of heart attack and what to do:

- Tightness, fullness, pressure, squeezing, heaviness or pain in your chest, neck, jaw, throat, shoulders, arms or back.
- You may also have difficulty breathing, or have a cold sweat or feel dizzy or light headed or feel like vomiting (or actually vomit).
- If you have heart attack warning signs that are severe, get worse or last for 10 minutes even if they are mild, call triple zero (000). Every minute counts.

Side effects

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

This medicine helps most people with high blood pressure, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of 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 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

The above list includes the more common side effects of your medicine. They are usually 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 called 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 change in heart rhythm

- symptoms that 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 see haloes around lights) and eye pain.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, stop taking ABISART HCT and 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. If you have them, you may have a serious allergic reaction to ABISART HCT.
- severe and 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 ABISART 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

Other side effects not listed above may also occur in some people.

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

After taking ABISART HCT

Storage

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

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

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

Do not store ABISART HCT or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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 this medicine 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

ABISART HCT 150/12.5 tablet contains 150 mg of irbesartan and 12.5 mg of hydrochlorothiazide -

A pink film-coated, oval, biconvex tablet debossed with "M" on one side of the tablet and "I33" on the other side. Available in blister packs of 30 tablets.

ABISART HCT 300/12.5 tablet contains 300 mg of irbesartan and 12.5 mg of hydrochlorothiazide -

A pink film-coated, oval, biconvex tablet debossed with "M" on one side of the tablet and "I34" on the other side. Available in blister packs of 30 tablets.

ABISART HCT 300/25 tablet contains 300 mg of irbesartan and 25 mg of hydrochlorothiazide -

A reddish-brown film-coated, oval, biconvex tablet debossed with "M" on one side of the tablet and "I35" on the other side. Available in blister packs of 30 tablets.

Ingredients

ABISART HCT contains irbesartan and hydrochlorothiazide as the active ingredients.

It also contains the following inactive ingredients:

- colloidal anhydrous silica
- magnesium stearate
- sodium lauryl sulfate
- microcrystalline cellulose
- pregelatinized maize starch
- povidone
- lactose
- croscarmellose sodium
- quinoline yellow aluminium lake
- Opadry II complete film coating system 32F540072 pink (ARTG no. 109229) (150/12.5 mg and 300/12.5 mg)
- Opadry II complete film coating system 32F500006 purple (ARTG no. 109227) (300/25 mg)

Supplier

ABISART HCT is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.mylan.com.au

Australian registration numbers:

ABISART HCT 150/12.5:

Blister pack AUST R 215942

ABISART HCT 300/12.5:

Blister pack AUST R 215944

ABISART HCT 300/25:
Blister pack AUST R 215946

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