

KSART HCT

contains the active ingredients irbesartan and hydrochlorothiazide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about KSART HCT.

It does not contain all of 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 KSART HCT against the benefits they expect it will have 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 KSART HCT is used for

KSART HCT lowers high blood pressure, also called 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) 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 KSART 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.

KSART HCT contains two medicines, 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 KSART HCT for another reason. Ask your doctor if you have any questions about why KSART HCT has been prescribed for you.

KSART HCT is not recommended for children.

Before you take KSART HCT

When you must not take it

Do not take KSART HCT if you are allergic to:

- irbesartan
- hydrochlorothiazide
- sulphonamide derived medicines
- any of the ingredients listed at the end of this leaflet

Do not take KSART HCT if you are pregnant or planning to become pregnant.

KSART HCT may harm your developing baby if you take it during pregnancy.

Do not take KSART HCT if you are breast feeding.

Do not take KSART HCT if you are not producing urine.

Do not take KSART HCT if the expiry date (Exp.) printed on the pack has passed.

Do not take KSART HCT if the packaging is torn or shows signs of tampering.

Before you start to take it

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

Tell your doctor if you plan to become pregnant or breastfeed.

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

- kidney problems
- kidney transplant or dialysis
- heart problems
- liver problems
- 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
- recent excessive vomiting or diarrhoea

Tell your doctor if you are restricting salt intake in your diet.

Tell your doctor if you have had a sympathectomy.

Tell your doctor if you have been taking diuretics.

Tell your doctor if you have a history of allergy or asthma.

If you have not told your doctor about any of the above, tell them before you start taking KSART HCT.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines may be affected by KSART HCT, or may affect how well it works. These include:

- other medicines for high blood pressure
- fluid tablets or diuretics
- lithium or lithium containing medicines (e.g. Lithicarb)
- potassium tablets (e.g. Span-K, Slow-K, Mag-K)
- potassium containing salt substitutes (e.g. Pressor-K)
- anti-inflammatory medicines, used to relieve pain, swelling and other symptoms of inflammation, including arthritis. These include nonsteroidal anti-inflammatory agents – NSAIDS (e.g.

Voltaren, Indocid) and COX-2 inhibitors (e.g. Celebrex)

- alcoholic drinks
- sleeping tablets
- strong pain killing medicines such as codeine or morphine
- medicines for diabetes (oral tablets or capsules or insulin)
- calcium supplements, medicines containing calcium or calcium sparing drugs (e.g. 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 (e.g. 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
- medicines used during surgery
- medicines used in an emergency situation such as adrenaline.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take KSART HCT

How much to take

KSART 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 KSART HCT.

The usual starting dose is one tablet once 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 KSART HCT, your doctor may prescribe another medicine to be taken with KSART HCT.

Follow all directions given to you by your pharmacist carefully.

How to take KSART HCT

Swallow the tablets with a glass of water.

Take your daily dose of KSART HCT at about the same time each day.

Taking your KSART HCT tablets at the same time each day will have the best effect.

If you forget to take KSART HCT

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

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

How long to take KSART HCT for

KSART HCT helps control your high blood pressure but does not cure it. To properly control your

condition, KSART HCT must be taken every day.

Keep taking KSART HCT for as long as your doctor recommends.

If you take too much KSART HCT (overdose)

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

You may need urgent medical attention.

If you take too much KSART HCT, you may feel dizzy or lightheaded.

While you are taking KSART HCT

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking KSART HCT.

Tell all doctors, dentists and pharmacists who are treating you that you are taking KSART HCT.

If you become pregnant while taking KSART HCT, tell your doctor immediately.

If you plan to have surgery, including dental surgery, that needs a general anaesthetic, tell your doctor or dentist that you are taking KSART HCT.

Visit your doctor regularly so they can monitor your blood pressure and ensure that KSART HCT is working for you.

Things you must not do

Do not use KSART HCT to treat any other conditions unless your doctor tells you to.

Do not give KSART HCT 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 KSART HCT affects you.

KSART HCT may cause drowsiness, dizziness or lightheadedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

If you drink alcohol, dizziness or lightheadedness may be worse.

Be careful getting up from a sitting or lying position.

Dizziness, lightheadedness or fainting may occur, especially when you get up quickly. Getting up slowly may help. 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.

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

If you do not drink enough water while taking KSART 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 KSART HCT, tell your doctor.

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

The hydrochlorothiazide contained in KSART HCT could produce a positive analytical result in an antidoping test.

Side effects

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

Like all other medicines, KSART HCT may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list 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 and they worry you:

- headache
- dizziness or light-headedness
- unusual tiredness or weakness, fatigue
- pain in the stomach, nausea/vomiting
- sexual problems

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 or aching joints, not caused by exercise
- muscle pain or weakness
- buzzing, ringing or other persistent noise in the ears
- changes in heart rhythm
- 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 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 high potassium levels in the blood such as nausea, diarrhea, muscle weakness and change in heart rhythm
- 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.

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

If any of the following happen, stop taking KSART HCT and tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- swelling to 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
- 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 very rare but serious side effects. If you have them you have had a serious allergic reaction to KSART HCT. You may need urgent medical attention or hospitalisation.

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

After using KSART HCT

Storage

Keep KSART HCT 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.

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

Do not store KSART HCT or any other medicine in the bathroom or near a sink.

Do not leave KSART HCT in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking KSART HCT, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

KSART HCT comes in 3 strengths of tablets:

- KSART HCT 150/12.5 - Pink, oval tablet with 'H' on one side and 'I' on the other side
- KSART HCT 300/12.5 - Pink, oval tablet with 'H' on one side and 'I' on the other side
- KSART HCT 300/25 – Dark pink, oval tablet with 'H' on one side and 'I' on the other side.

Each pack contains 30 tablets.

Ingredients

The active ingredients in KSART HCT are irbesartan and hydrochlorothiazide.

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

- each KSART HCT 300/12.5 tablet contains 300 mg of irbesartan and 12.5 mg of hydrochlorothiazide
- each KSART HCT 300/25 tablet contains 300 mg of irbesartan and 25 mg of hydrochlorothiazide.

The tablets also contain:

- mannitol
- povidone
- microcrystalline cellulose
- croscarmellose sodium
- colloidal anhydrous silica
- magnesium stearate
- Opadry II 85F34353 Pink (ARTG 107713, 150/12.5 mg tablet only)
- Opadry II 85F34229 Pink (ARTG 107715, 300/12.5 mg tablet only)
- Opadry II 85F34230 Pink (ARTG 107714, 300/25 mg tablet only).

The tablets do not contain lactose, gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel Street
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