

ASARTAN HCT™ 16/12.5, 32/12.5 & 32/25

Candesartan cilexetil and hydrochlorothiazide tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about ASARTAN HCT.

It does not contain all the information that is known about ASARTAN HCT. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ASARTAN HCT against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What ASARTAN HCT is used for

ASARTAN HCT is used to treat high blood pressure.

Candesartan cilexetil is a type of medicine called an angiotensin II - receptor antagonist (or blocker). It mainly works by causing relaxation of blood vessels.

Hydrochlorothiazide is a type of medicine called a diuretic. It works by reducing the amount of excess fluid in the body.

Using these two medicines together will lower your blood pressure more than using either one on its own.

Your doctor will have explained why you are being treated with ASARTAN HCT and told you what dose to take.

You must follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use.

Ask your doctor if you want more information.

ASARTAN HCT is not known to be addictive.

ASARTAN HCT is only available with a doctor's prescription.

Before you take it

When you must not take it

Do not take ASARTAN HCT if you have an allergy to:

- any medicine containing candesartan cilexetil or hydrochlorothiazide;
- any of the ingredients listed at the end of the leaflet;
- any medicine containing an angiotensin II receptor antagonist (or blocker); or
- any sulphur drugs (sulphonamides) such as some antibiotics or some medicines to treat diabetes.

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; or
- rash, itching or hives on the skin.

Do not take ASARTAN HCT if you have:

- severe kidney or liver disease;
- conditions associated with impaired bile flow (cholestasis); or
- gout.

Do not use ASARTAN HCT if you are taking blood pressure medicine containing aliskiren, especially if you have diabetes mellitus or have kidney problems.

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

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

Do not take ASARTAN HCT if you are breastfeeding.

Your baby can take in components of ASARTAN HCT from breast milk if you are breastfeeding.

Do not give ASARTAN HCT to children.

There is no information about its use in children.

Do not take ASARTAN HCT after the use by (expiry) date printed on the pack has passed.

It may have no effect at all or an unexpected effect if you take it after the expiry date.

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

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

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else.

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 any of the following medical conditions:

- kidney problems;
- liver problems;
- heart problems;
- diabetes;
- recent excessive vomiting or diarrhoea;
- Systemic Lupus Erythematosus (SLE), a disease affecting the skin, joints and kidneys;
- a salt restricted diet;
- a condition called primary hyperaldosteronism; or
- a past operation known as sympathectomy.

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

Taking other medicines

Tell your doctor or pharmacist 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 and ASARTAN HCT may interfere with each other. These include:

- other blood pressure lowering medicines;
- medicines containing potassium, including salt substitutes;
- digoxin, a medicine used to treat heart failure;
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling

and other symptoms of inflammation, including arthritis;

- colestipol and cholestyramine, medicines used to treat high blood cholesterol levels;
- lithium, a medicine used to treat mood swings and some types of depression;
- alcohol;
- strong pain killers such as codeine, morphine, dextropropoxyphene;
- barbiturates, used to treat epilepsy, such as phenobarbitone;
- medicines like insulin that are used to treat diabetes;
- calcium supplements, or medicines containing calcium;
- medicines to treat irregular heartbeats;
- corticosteroids such as prednisone, cortisone, dexamethasone;
- laxatives;
- medicines used to treat cancer such as cyclophosphamide;
- methotrexate a medicine used to treat arthritis and some cancers; or
- amantadine, a medicine used to treat Parkinson's disease.

These medicines may be affected by ASARTAN HCT or may affect how it works. You may need different amounts of your medicines, or may need to take different medicines.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. If you have not told your doctor about any of these things, tell them before you take any ASARTAN HCT.

How to take it

Follow all directions given to you by your doctor or 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

The usual dose is one tablet once daily, taken whole with a glass of water.

How and when to take it

Take ASARTAN HCT once a day, at about the same time each day.

Keeping a regular time for taking ASARTAN HCT will help to remind you to take it.

It does not matter whether you take ASARTAN HCT with food or on an empty stomach.

How long to take it

ASARTAN HCT helps control your condition, but does not cure it.

Therefore you must take ASARTAN HCT every day.

Continue taking the tablets for as long as your doctor tells you to.

If you forget to take it

If you miss a dose take it as soon as you remember, as long as it is 12 hours before the next dose is due.

Then go back to taking it as you would normally.

If it is less than 12 hours to the next dose do not take the dose you have missed.

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

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

If you have trouble remembering when 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 ASARTAN HCT. Do this even if there are no signs of discomfort or poisoning.

If you take too many ASARTAN HCT tablets you may get a headache, feel sick (nausea), dizzy, thirsty and very tired.

While you are taking it

Things you must do

Take ASARTAN HCT exactly as your doctor has told you to.

Your blood pressure will not be well controlled if you do not.

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

Tell your doctor if you have excessive vomiting or diarrhoea while taking ASARTAN HCT.

You may lose too much water and your blood pressure may become too low.

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

If you go into hospital, please let the medical staff know you are taking ASARTAN HCT.

Tell your doctor immediately if you become pregnant or plan to become pregnant while you are taking ASARTAN HCT.

You should not use ASARTAN HCT if you are pregnant or thinking about becoming pregnant. Your doctor can discuss different treatment options with you.

If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking ASARTAN HCT.

Tell your doctor if you plan to have an examination such as an X ray or a scan requiring an injection of iodinated contrast (dye) that you are taking ASARTAN HCT.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may want to take some tests (eg blood tests, blood pressure) from time to time. These tests may help to prevent side effects.

Things you must not do

Do not use it to treat any other complaints unless your doctor says to.

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

Do not stop taking ASARTAN HCT or lower the dosage, without checking with your doctor.

Things to be careful of

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

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

You may feel dizzy when you start taking ASARTAN HCT due to the drop in your blood pressure.

Drink plenty of water while you are using ASARTAN HCT, especially if you sweat a lot.

Please talk to your doctor or pharmacist about these possibilities if you think they may bother you.

Side effects

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

ASARTAN 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. You may need medical treatment 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 or pharmacist if you notice any of the following and they worry you:

- headache or dizziness;
- flu-like symptoms or infections;
- chest, throat or sinus infections;
- feeling sick (nausea) or vomiting;
- back pain;
- urinary tract infection;
- feeling tired; or
- stomach ache.

These side effects are usually mild.

The following side effects have been reported very rarely by patients taking candesartan: palpitations, agitation, anxiety, depression, trouble sleeping (insomnia), drowsiness (somnolence), nervousness, nightmare and sleep disorder. It is not known if these side effects are caused by candesartan.

Tell your doctor as soon as possible if you notice any of the following:

- rapid heartbeats; or
- aching muscles, tenderness or weakness in the muscles.

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 ASARTAN HCT and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, tongue or throat;
- swelling of the hands, feet or ankles.;
- harsh sounds when breathing;
- rash, itching or hives;
- easy bruising or bleeding more easily than normal;
- feel extremely tired;

- yellowing of the skin and eyes;
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers;
- worsening of the kidney function including passing little or no urine, drowsiness, nausea, vomiting, breathlessness, loss of appetite and weakness (especially in patients with existing kidney problems or heart failure);
- changes in your potassium, sodium and red or white blood cell levels may occur. Such changes are usually detected by a blood test; or
- symptoms that may indicate high potassium levels in the blood include nausea, diarrhoea, muscle weakness and changes in heart rhythm.

These are very serious side effects. If you have them, you may have had a serious reaction to ASARTAN HCT. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

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

Some people may get other side effects while taking ASARTAN HCT.

After taking it

Storage

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

If you take ASARTAN HCT out of the blister foil, it will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it where young 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

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Product description

What ASARTAN HCT looks like

ASARTAN HCT 16/12.5*, 32/12.5* & 32/25* mg tablets are supplied in blister packs containing 7* (1x7) or 30* (3x10) tablets.

ASARTAN HCT 16/12.5
Pink, uncoated capsule shaped tablets debossed with 'J' and '05' separated by score line on one side and plain with score line on the other side.

ASARTAN HCT 32/12.5
Yellow, uncoated oval shaped tablets debossed with 'J' and '07' separated by score line on one side and plain with score line on the other side.

ASARTAN HCT 32/25
Pink, uncoated oval shaped tablets debossed with 'J' and '15' separated by score line on one side and plain with score line on the other side.

*Some of these presentations and pack sizes may not be marketed.

Ingredients

Active ingredients:

Candesartan cilexetil and hydrochlorothiazide.

Other ingredients:

- carmellose calcium;
- hydroxypropylcellulose;
- lactose;
- magnesium stearate;

- aluminium magnesium silicate;
- propylene glycol;
- iron oxide red; and
- iron oxide yellow (16/12.5 mg & 32/25 mg tablets only).

Sponsor/Marketing Authorisation Holder

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