STARVAL HCT TABLETS

Valsartan/Hydrochlorothiazide (80/12.5 mg, 160/25mg)

What is in this leaflet

1. What STARVAL HCT is used for
2. How STARVAL HCT works
3. Before you use STARVAL HCT
4. How to use STARVAL HCT
5. While you are using STARVAL HCT
6. Side effects
7. Storage and Disposal of STARVAL HCT
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What STARVAL HCT is used for

STARVAL HCT contains an angiotensin-II receptor antagonist and a diuretic, which help control high blood pressure.

STARVAL HCT is used to treat high blood pressure. High blood pressure increases the workload of the heart and arteries (blood vessels). If it continues for a long time, it can damage the blood vessels of the brain, heart, kidneys, and may result in a stroke, heart failure, or kidney failure. High blood pressure increases the risk of heart attacks. Lowering your blood pressure to normal reduces the risk of developing these disorders.

How STARVAL HCT works

Angiotensin II is a natural substance in the body that causes blood vessels to tighten, thus causing your blood pressure to increase. Valsartan in STARVAL HCT blocks the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered. Diuretics reduce the amount of salt and water in the body by increasing the flow of urine. With longer use this helps to reduce and control blood pressure.

If you have any questions about how STARVAL HCT works or why this medicine has been prescribed for you, ask your doctor.

Before you use STARVAL HCT

You may take STARVAL HCT only after a medical examination. STARVAL HCT may not be suitable for all patients. Follow your doctor's instructions carefully. They may differ from the general information contained in this leaflet.

Inform your healthcare providers before taking STARVAL HCT if you have had skin cancer or if you develop an unexpected skin lesion during the treatment.

Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking STARVAL HCT.

Before taking STARVAL HCT, tell your doctor:

- if you experience breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past.
- If you develop any severe shortness of breath or difficulty breathing after taking STARVAL HCT, seek medical attention immediately.

When you must not use it

- If you have had any unusual or allergic reaction to valsartan or to hydrochlorothiazide or sulfonamides or to any other component of this product listed at the end of this leaflet. If you are not sure which medicines to avoid, ask your doctor or pharmacist;
- If you suffer from severe kidney disease with being unable to produce urine (anuria)
- If you suffer from liver disorders or from a severe liver disease with destruction of the small bile ducts within the liver (biliary cirrhosis) leading to the builds up bile in the liver (cholestasis).
- If your doctor has told you that you have low levels of potassium in your blood (with or without symptoms such as muscle weakness, muscle spasms, abnormal heart rhythm).
- If your doctor has told you that you have low levels of sodium in your blood (with or without symptoms such as tiredness, confusion, muscle twitching, convulsions).
- If your doctor has told you that you have high levels of calcium in your blood (with or without symptoms such as nausea, vomiting, constipation, stomach pain, frequent urination, thirst, muscle weakness and twitching).
- If your doctor has told you that you have high levels of uric acid in the blood.
- If you are pregnant or planning to become pregnant.
- If you have high level of sugar in the blood and you are suffering from type 2 diabetes (also called non- insulin dependent diabetes mellitus) while you are taking a blood pressure lowering medicine called aliskiren

If either of these applies to you, tell your doctor without taking STARVAL HCT

Pregnant and breast-feeding

Do not take STARVAL HCT if you are pregnant or planning to become pregnant. Use of similar medicines may cause serious harm to the unborn child. It is therefore important to check with your doctor immediately if you think you may
have become pregnant or are planning to become pregnant.

Your doctor will discuss with you the potential risk of taking STARVAL HCT during pregnancy.

It is also advisable not to take STARVAL HCT during breast-feeding. The diuretic component of STARVAL HCT passes into the breast milk and may also reduce your milk supply. If you are breast-feeding, avoid using STARVAL HCT unless recommended by your doctor.

Before you start to use it

Take special care with STARVAL HCT

- If you suffer from kidney disorders;
- If you have previously experienced angioedema (swelling of the face, lips, throat and/or tongue) with valsartan or other medicines like ACE inhibitors;
- If you suffer from high blood pressure with renal artery stenosis which is the narrowing of the blood vessels of the kidneys;
- If you suffer from diabetes (high blood sugar in your blood);
- If you have fever, rash, and joint pain, which may be signs of lupus erythematosus (or a history of this disease);
- If you are suffering from allergy or

STARVAL HCT TABLETS

Valsartan/Hydrochlorothiazide (80/12.5 mg, 160/25mg)

asthma;
- If your doctor has told you that you have high levels of cholesterol or triglycerides in your blood;
- If you are suffering from vomiting or diarrhoea, or taking high doses of a diuretic (water pill);
- If you are breast feeding;
- If you experience a decrease in vision or eye pain. These could be symptoms of an increase of pressure in your eye and can happen within hours to weeks of taking STARVAL HCT. This can lead to permanent vision impairment, if not treated;
- If you are suffering from heart failure or have experienced a heart attack, follow your doctor's instruction for the starting dose carefully. Your doctor may also check your kidney function;
- If you are treated with an ACE-inhibitor or aliskiren for high blood pressure;
- If you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking STARVAL HCT. Regularly check your skin for any new lesions and promptly report any suspicious skin lesions to your doctor.

If any of these apply to you, tell your doctor before taking STARVAL HCT. If you get any of the described symptoms, tell your doctor straight away.

Older people (age 65 and over)
You can also use STARVAL HCT if you are 65 years of age or older.

Children and adolescents
There is no experience with STARVAL HCT in children.

Taking other medicines
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. Remember also those not prescribed by a doctor. It may be necessary to change the dose or, in some
cases, for you to stop taking one of the medicines. This applies to both prescription and non-prescription (over- the-counter) medicines, especially:

- Other medicines used to lower blood pressure, especially ACE-inhibitors or aliskiren;
- Potassium-sparing medicines, potassium supplements, or salt substitutes containing potassium; Your doctor may check the amount of potassium in your blood periodically;
- Some antibiotics (rifamycin group), a medicine used to protect against transplant rejection (ciclosporin) or an antiretroviral medicine used to treat HIV/AIDS infection (ritonavir). These medicines may increase the effect of STARVAL HCT;
- Lithium, antidepressants, antipsychotics, medicines used to treat some psychological conditions;
- Medicines used to relieve pain or inflammation, especially non-steroidal anti-inflammatory agents (NSAIDs), including Selective Cyclooxygenase-2 Inhibitors (Cox-2 inhibitors); your doctor may also check your kidney function;
- Cortisone-like medicines, steroids, carbenoxolone (a medicine used to treat ulceration and inflammation), antibiotics such as penicillin G, amphothericine, antiarrhythmics (medicines used to treat heart problems) These medicines may decrease the blood potassium level if used together with STARVAL HCT;
- Digoxin or other digitalis glycosides (medicines used to treat heart problems);
- Muscle relaxant medicines; (medicines used during operations)
- Allopurinol (medicine used to treat gout);
- Amantadine (medicine to treat Parkinson's disease and also used to treat or prevent certain illnesses caused by viruses);

Including certain cancer medicines;
- Anticholinergic agents (medicines used to treat a variety of disorders such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms, Parkinson's disease and as an aid to anaesthesia);
- Ciclosporin (a medicine used in transplantation and in autoimmune disorders);
- Insulin or antidiabetic medicines taken by mouth (medicines used to treat high levels of sugar in your blood);
- Cholestyramine, colestipol or other resins (medicines used mainly to treat high levels of fats in the blood);
- Vitamin D and calcium salts;
- Diazoxide (a medicine used to treat high blood pressure or low sugar level in the body);
- Antiepileptics, such as carbamazepine (medicines used to treat convulsions);
- Barbiturates, narcotics (medicines with sleep-inducing properties) and alcohol;
- Pressor amines, such as noradrenaline (substances that raise blood pressure).

How to use STARVAL HCT
Follow your doctor's instructions carefully. Do not exceed the recommended dose.

Patients who have high blood pressure often do not notice any signs of this problem. Many may feel quite normal. This makes it all the more important for you to take your medicine exactly as the doctor or pharmacist tells you and to keep your appointments with the doctor even if you are feeling well.
STARVAL HCT is for oral use only.

How much to use
Your doctor will tell you exactly how many tablets of STARVAL HCT to take.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.
The usual dose is one STARVAL HCT (80/12.5 mg) or STARVAL HCT (160/25 mg) tablet once a day.

Do not change the dose or stop treatment without talking to your doctor.

STARVAL HCT TABLETS

Valsartan/Hydrochlorothiazide (80/12.5 mg, 160/25mg)

When to take STARVAL HCT
Taking STARVAL HCT at the same time each day will help you remember when to take your medicine. You can take STARVAL HCT with or without food. Swallow your tablet with a glass of water.

How long to use STARVAL HCT
Continue to take STARVAL HCT as your doctor tells you. If you have questions about how long to take STARVAL HCT, talk to your doctor or your pharmacist.

If you forget to use STARVAL HCT
It is advisable to take your medicine at the same time each day, preferably in the morning. However, if you forget to take a dose of this medicine, take it as soon as possible. If it is almost time for the next dose, skip the missed dose and carry on with the next one at the usual time. Do not double dose.

If you use more STARVAL HCT than you should (overdose)
If you experience severe dizziness and/or fainting, unusual tiredness, weakness or muscle cramps, or irregular heartbeats, tell your doctor as soon as possible.

While you are using STARVAL HCT

Things you must do

- It is important for your doctor to check your progress at regular visits to make sure that this medicine is working properly.
- You might have regular blood tests before and during treatment with STARVAL HCT. These will monitor the amount of electrolytes (such as potassium, sodium, calcium or magnesium) in your blood and may also monitor your kidney function, especially if you are over 65 years old, have certain heart, liver and kidney diseases, or are taking potassium supplements. Your doctor will advise you about this.

Things you must not do
Stopping your treatment with STARVAL HCT may cause your disease to get worse. Do not stop taking your medicine unless instructed by your doctor.

Things to be careful of

Driving and using machines
Like many other medicines used to treat high blood pressure, STARVAL HCT may cause effects such as dizziness or fainting in some patients. So before you drive a vehicle, use machinery, or do other things that need concentration, make sure you know how you react to the effects of STARVAL HCT.

Side effects
As with all medicines, patients taking STARVAL HCT can experience side effects although not everybody gets them.

Some side effects could be serious *(frequency unknown: frequency cannot be estimated from the available data)*

- Breathlessness (possible symptoms of non cardiogenic pulmonary edema)
- Sudden loss of consciousness
- (possible symptoms of syncope)
- Severely decreased urine output (possible symptoms of impaired kidney function)
- Fever, sore throat or mouth ulcers
- due to infections (possible symptoms of neutropenia)
- Muscle weakness, muscle spasms, abnormal heart rhythm (possible symptoms of low level of potassium in blood)
- Tiredness, confusion, muscle twitching, convulsions (possible symptoms of hyponatremia)

If you get any of these, tell your doctor immediately.

Some side effects are uncommon (*these side effects may affect between 1 and 10 in every 1,000 patients)*

- Thirst, low urine output, dark urine, dry flushed skin, irritability (possible symptoms of dehydration)
- Tingling or numbness (possible symptoms of paraesthesia)
- Vision disorders
- Tiredness
- Cough
- Muscle pain
- Noises in ears
- Dizziness, light headedness (possible symptoms of hypotension

Also reported (*frequency unknown: frequency cannot be estimated from the available data)*

- Uric acid, creatinine, urea nitrogen in the blood increase. (abnormal kidney function test results)
- Bilirubin in the blood increase. (abnormal liver function test result

The following effects have also been observed with STARVAL HCT:

- Abdominal pain, upper abdominal pain
- anxiety, insomnia
- back pain, muscle strain, muscle spasms, ligament sprain, joint pain and stiffness (arthritis), weakness (asthenia)
- cough with phlegm together with chest pain and fever (bronchitis or bronchitis acute)
- chest pain
- fainting on standing up
- stomach discomfort after meal (dyspepsia)
- dry mouth
- nose bleeds (epistaxis)
- inability to achieve or maintain an erection (erectile dysfunction)
- inflammation of the stomach and intestines (gastroenteritis)
- headache
- excessive sweating (hyperhidrosis),
- decreased skin sensitivity (hypoesthesia)
- flu (influenza)
- blocked nose (nasal congestion), common cold (nasopharyngitis),
- neck pain
- swelling (edema), swollen hands, ankles or feet (edema peripheral),
- ear infection (otitis media),
- pain in extremity
- palpitations, fast heart beat (tachycardia)
- sore throat (pharyngolaryngal pain),
- excessive frequent urination (pollakiuria)
- fever (pyrexia)
- feeling of pressure pain in the cheeks and forehead (sinusitis), sinus congestion,
- drowsiness (somnolence),
- upper respiratory tract infections, urinary tract infections, viral infections,
- spinning sensation (vertigo),
- vision disturbance.

STARVAL HCT TABLETS

Valsartan/Hydrochlorothiazide (80/12.5 mg, 160/25mg)

If any of these affects you severely, tell your doctor.

The following, other possibly serious, additional undesirable effects have been reported with other products containing either valsartan or hydrochlorothiazide alone.

Valsartan

- abdominal pain
- spinning sensation (vertigo)
- decrease of level of hemoglobin and decrease of the percentage of red blood cells in the blood (which can, in severe cases, lead to anaemia)
- unusual bleeding or bruising (thrombocytopenia), rash, itching, together with some of the following signs or symptoms: fever, joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms (other hypersensitivity/allergic reactions including serum sickness)
- muscle spasms
- abnormal heart rhythm (increase of serum potassium)
- purplished-red spots, fever, itching (vasculitis)
- elevation of liver function values
- allergic reaction with symptoms such as rash, itching, dizziness, swelling of face or lips or tongue or throat, difficulty breathing or swallowing (angioedema)
- blistering skin (sign of dermatitis bullous), rash, itching (pruritus)
- severely decreased urine output (kidney failure)

Hydrochlorothiazide

- Some side effects could be serious (frequency unknown: frequency cannot be estimated from the available data): Skin and lip cancer (non-melanoma skin cancer-appearance of a lump or discoloured patch on the skin that continues to persist after a few weeks, and slowly progresses over months or sometimes years or cancerous lumps that are red/pink and firm and sometimes turn into ulcers, while cancerous lumps are usually flat and scaly; often develops on areas of skin regularly exposed to the sun, such as the face, ears, hands, shoulders, upper chest and back).
- Side effects that are very rate to occur; Acute respiratory distress (signs include severe shortness of breath, fever, weakness and confusion).
- Skin rash with or without difficulties in breathing (possible signs of hypersensitivity reactions
- facial rash, joint pain, muscle disorder, fever (possible signs of Systemic Lupus Erythematosus)
- rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (possible signs of Toxic Epidermal Necrolysis, erythema multiforme) confusion, tiredness, muscle twitching and spasm, rapid breathing (possible signs of hypochloraemic alkalosis)
- gastrointestinal disturbances, such as nausea, vomiting, constipation, stomach pain, frequent urination, thirst, muscle weakness and
- twitching (possible signs of hypercalcemia)
- severe upper stomach pain (possible signs of pancreatitis)
- severe or persistent vomiting or diarrhea
- irregular heart beat (possible signs of arrythmia)
- purple skin patches (possible signs of thrombocytopenia, purpura)
- fever, sore throat, more frequent infections (possible signs of agranulocytosis)
- fever, sore throat or mouth ulcers due to infections (possible signs of leucopenia)
- weakness, bruising and frequent infections (possible signs of pancytopenia, bone marrow depression)
- pale skin, tiredness, breathlessness, dark urine (possible signs of hemolytic anemia)
- an abnormal building of liquid in your eye that may result in vision changes (choroidal effusion), sudden nearsightedness or blurred vision (acute myopia), a rapid increased pressure in eyes, eye pain. If left untreated, it may lead to permanent vision loss (possible signs of acute angle-closure glaucoma)
- high levels of lipids and uric acid in your blood (hyperlipidemia, hyperuricaemia)
- low levels of magnesium in your blood (hypomagnesaemia)
- itchy rash or other forms of rash (urticaria)
- decreased appetite, mild nausea and vomiting
- dizziness, fainting on standing up (orthostatic hypotension)
- inability to achieve or maintain an erection (impotence)
- high levels of sugar in your blood or in your urine (hyperglycemia, glycosuria)
- increased sensitivity of the skin to sun (photosensitivity)
- abdominal discomfort, constipation or diarrhea
- yellow eyes and skin (cholestasis or jaundice)
- headache
- sleep disorder
- depression
- tingling or numbness (paraesthesia)
- vision disorder (visual impairment)
- muscle spasm
- fever (pyrexia)
- weakness (asthenia)

If any of these affects you severely, tell your doctor.
If you notice any other side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers →Reporting Side Effects to Medicines (ConSERF)).

Storage and disposal of STARVAL HCT

Storage

- Keep out of the reach and sight of children.
- Do not store above 30°C
- Store your tablets in the original package.
- Do not take STARVAL HCT after the expiry date shown on the pack.

Disposal

- Any unused product or waste material should be disposed of in accordance with local requirements.

STARVAL HCT TABLETS

Valsartan/Hydrochlorothiazide (80/12.5 mg, 160/25mg)

Product Description

What it looks like

STARVAL HCT is supplied as film-coated- tablets in two strengths:

- STARVAL HCT tablets (80/12.5 mg) are white to off white, film coated, oval shaped tablets debossed with 'VH 1' on one side and plain on the other side.

- STARVAL HCT tablets (160/25 mg) are white to off white, film coated, oval shaped tablets debossed with 'VH 3' on one side and plain on the other side.

Ingredients

- Active ingredients
  The active substances of STARVAL HCT are valsartan (80 mg or 160 mg) and hydrochlorothiazide (12.5 mg or 25 mg)

- Inactive ingredients
  The other ingredients are microcrystalline cellulose, colloidal anhydrous silica, crospovidone, purified talc, magnesium stearate, pregelatinized maize starch, purified water, opadry white

MAL Number

STARVAL HCT 80/12.5mg Tablets: MAL11115008AZ

STARVAL HCT 160/25mg Tablets: MAL11115009AZ

Manufacturer

Sun Pharmaceutical Ind. Ltd
Paonta Sahib, Dist. Sirmour
Himachal Pradesh, 173 025,
India

Product Registration Holder

Ranbaxy (Malaysia) Sdn Bhd
(A SUN PHARMA Company)
Lot 23, Bakar Arang Industrial Estate,
08000, Sungai Petani, Kedah,
Malaysia.

Date of revision

April 2025

Serial Number

NPRA(R2/1)250411/1451