

PACKAGE LEAFLET: INFORMATION FOR THE USER

VALZAP™ HCT 80 mg/12.5 mg film-coated tablets
VALZAP™ HCT 160 mg/12.5 mg film-coated tablets
VALZAP™ HCT 160 mg/25 mg film-coated tablets
Valsartan/Hydrochlorothiazide

ZENTIVA
A SANOFI COMPANY

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What VALZAP™ HCT is and what it is used for
2. Before you take VALZAP™ HCT
3. How to take VALZAP™ HCT
4. Possible side effects
5. How to store VALZAP™ HCT
6. Further information

1. WHAT VALZAP™ HCT IS AND WHAT IT IS USED FOR

VALZAP™ HCT film-coated tablets contain two active substances called valsartan and hydrochlorothiazide. Both of these substances help to control high blood pressure (hypertension).

- **Valsartan** belongs to a class of medicines known as “angiotensin II receptor antagonists”, which help to control high blood pressure. Angiotensin II is a substance in the body that causes vessels to tighten, thus causing your blood pressure to increase. Valsartan works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.
- **Hydrochlorothiazide** belongs to a group of medicines called thiazide diuretics (also known as “water tablets”). Hydrochlorothiazide increases urine output, which also lowers blood pressure.

VALZAP™ HCT is used to treat high blood pressure which is not adequately controlled by a single substance alone.

High blood pressure increases the workload of the heart and arteries. If not treated, it can damage the blood vessels of the brain, heart, and 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.

2. BEFORE YOU TAKE VALZAP™ HCT

Do not take VALZAP™ HCT

- if you are allergic (hypersensitive) to valsartan, hydrochlorothiazide, sulphonamide derivatives (substances chemically related to hydrochlorothiazide) or to any of the other ingredients of VALZAP™ HCT
- • if you are **more than 3 months pregnant** (it is also better to avoid VALZAP™ HCT in early pregnancy – see pregnancy section).
- if you have severe liver disease.
- if you have severe kidney disease.
- if you are unable to urinate.
- if you are treated with an artificial kidney.
- if the level of potassium or sodium in your blood is lower than normal, or if the level of calcium in your blood is higher than normal despite treatment.
- if you have gout.

If any of the above apply to you, do not take this medicine and speak to your doctor.

Take special care with VALZAP™ HCT

- if you are taking potassium-sparing medicines, potassium supplements, salt substitutes containing potassium or other medicines that increase the amount of potassium in your blood such as heparin. Your doctor may need to check the amount of potassium in your blood regularly.
- if you have low levels of potassium in your blood.
- if you have diarrhoea or severe vomiting.
- if you are taking high doses of water tablets (diuretics).
- if you have severe heart disease.
- if you suffer from a narrowing of the kidney artery.
- if you have recently received a new kidney.
- • if you suffer from hyperaldosteronism. This is a disease in which your adrenal glands make too much of the hormone aldosterone. If this applies to you, the use of VALZAP™ HCT is not recommended.
- if you have liver or kidney disease.
- if you have fever, rash and joint pain, which may be signs of systemic lupus erythematosus (SLE, a so-called autoimmune disease).
- if you have diabetes, gout, high levels of cholesterol or fats in your blood.
- if you have had allergic reactions with the use of other blood pressure-lowering agents of this class (angiotensin II receptor antagonists) or if you have allergy or asthma.
- it may cause increased sensitivity of the skin to sun.

The use of VALZAP™ HCT in children and adolescents (below the age of 18 years) is not recommended.

You must tell your doctor if you think you are (or might become) pregnant. VALZAP™ HCT is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The effect of the treatment can be influenced if VALZAP™ HCT is taken together with certain other medicines. It may be necessary to change the dose, to take other precautions, or in some cases to stop taking one of the medicines. This especially applies to the following medicines:

- lithium, a medicine used to treat some types of psychiatric illness
- medicines that affect or can be affected by potassium blood levels, such as digoxin, a medicine to control the heart rhythm, some antipsychotic medicines
- medicines that may increase the amount of potassium in your blood, such as potassium supplements, potassium-containing salt substitutes, potassium-sparing medicines, heparin
- medicines that may reduce the amount of potassium in your blood, such as corticosteroids, some laxatives
 - diuretics (water tablets), medicines for the treatment of gout, such as allopurinol, therapeutic vitamin D and calcium supplements, medicines for the treatment of diabetes (oral agents or insulins)
 - other medicines to lower your blood pressure, such as beta blockers or methyldopa, or medicines that tighten your blood vessels or stimulate your heart, such as noradrenaline or adrenaline
- medicines to increase blood sugar levels, such as diazoxide
- medicines to treat cancer, such as methotrexate or cyclophosphamide
- pain killers
- arthritis medicines
- muscle relaxing medicines, such as tubocurarine

- anti-cholinergic medicines, such as atropine or biperiden
- amantadine (a medicine used to prevent influenza)
- cholestyramine and colestipol (medicines used to treat high levels of fats in the blood)
- ciclosporin, a medicine used for organ transplant to avoid organ rejection
- some antibiotics (tetracyclines), anaesthetics and sedatives
- carbamazepine, a medicine used to treat seizure conditions

Taking VALZAP™ HCT with food and drink

You can take VALZAP™ HCT with or without food. Avoid taking alcohol until you have talked to your doctor. Alcohol may make your blood pressure fall more and/or increase the risk of you becoming dizzy or feeling faint.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

You must tell your doctor if you think that you are (or might become) pregnant

Your doctor will normally advise you to stop taking VALZAP™ HCT before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of VALZAP™ HCT. VALZAP™ HCT is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if it is used after the third month of pregnancy.

Tell your doctor if you are breast-feeding or about to start breast-feeding

VALZAP™ HCT is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

Before you drive a vehicle, use tools or operate machines or carry out other activities that require concentration, make sure you know how this medicine affects you. Like many other medicines used to treat high blood pressure, VALZAP™ HCT may occasionally cause dizziness and affect the ability to concentrate.

Important information about some of the ingredients of VALZAP™ HCT

VALZAP™ HCT contains lactose and sorbitol, both sugars. If your doctor has told you that you suffer from intolerance to some sugars, consult him or her before taking this medicine.

This medicinal product contains less than 1 mmol sodium (23 mg) per dose; i.e. essentially “sodium-free”.

3. HOW TO TAKE VALZAP™ HCT

Always take VALZAP™ HCT exactly as your doctor has told you. This will help you to get the best results and lower the risk of side effects. You should check with your doctor or pharmacist if you are not sure.

People with 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 keep your appointments with your doctor even if you are feeling well.

Your doctor will tell you exactly how many tablets of VALZAP™ HCT to take. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

- The usual dose of VALZAP™ HCT is one tablet per day.
- Do not change the dose or stop taking the tablets without consulting your doctor.

- The medicine should be taken at the same time each day, usually in the morning.

- You can take VALZAP™ HCT with or without food.
- Swallow the tablet with a glass of water.

If you take more VALZAP™ HCT than you should

If you experience severe dizziness and/or fainting, lay down and contact your doctor immediately. If you have accidentally taken too many tablets, contact your doctor, pharmacist or hospital.

If you forget to take VALZAP™ HCT

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten dose.

If you stop taking VALZAP™ HCT

Stopping your treatment with VALZAP™ HCT may cause your high blood pressure to get worse. Do not stop taking your medicine unless your doctor tells you to.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, VALZAP™ HCT can cause side effects, although not everybody gets them.

These side effects may occur with certain frequencies, which are defined as follows: very common: affects more than 1 user in 10 common: affects 1 to 10 users in 100 uncommon: affects 1 to 10 users in 1,000 rare: affects 1 to 10 users in 10,000 very rare: affects less than 1 user in 10,000 not known: frequency cannot be estimated from the available data

Some side effects can be serious and need immediate medical attention:

You should see your doctor immediately if you experience symptoms of angioedema, such as:

- swollen face, tongue or pharynx
- difficulty in swallowing
- hives and difficulties in breathing

Other side effects include:

Uncommon

- cough
- low blood pressure
- light-headedness
- dehydration (with symptoms of thirst, dry mouth and tongue, infrequent urination, dark colored urine, dry skin)
- muscle pain
- tiredness
- tingling or numbness
- blurred vision
- noises (e.g. hissing, buzzing) in ears

Very rare

- dizziness
- diarrhoea
- joint pain

Not known

- breathing difficulty
- severely decreased urine output
- low level of sodium in the blood (sometimes with nausea, tiredness, confusion,

- malaise, convulsions)
- low level of potassium in the blood (sometimes with muscle weakness, muscle spasms, abnormal heart rhythm)
- low level of white cells in the blood (with symptoms such as fever, skin infections, sore throat or mouth ulcers due to infections, weakness)
- the level of bilirubin increased in blood (which can, in severe cases, trigger yellow skin and eyes)
- the level of blood urea nitrogen and creatinine increased in blood (which can indicate abnormal kidney function)
- the level of uric acid in blood increased (which can, in severe cases, trigger gout)
- syncope (fainting)

Side effects reported with valsartan or hydrochlorothiazide alone, but not observed with VALZAP™ HCT:

Valsartan

Uncommon

- spinning sensation
- abdominal pain

Not known

- skin rash with or without itching together with some of the following signs or symptoms: fever, joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms
- rash, purplish-red spots, fever, itching (symptoms of inflammation of blood vessels)
- low level of blood platelets (sometimes with unusual bleeding or bruising)
- high level of potassium in the blood (sometimes with muscle spasms, abnormal heart rhythm)
- allergic reactions (with symptoms such as rash, itching, hives, difficulty breathing or swallowing, dizziness)
- swelling mainly of the face and throat; rash; itching
- elevation of liver function values
- the level of haemoglobin decreased and the percentage of red cells decreased in the blood (which both can, in severe cases, trigger an anaemia).
- kidney failure

Hydrochlorothiazide

Common

- itchy rash and other types of rash
- reduced appetite
- mild nausea and vomiting
- faintness, fainting on standing up
- impotence

Rare

- swelling and blistering of the skin (due to increased sensitivity to sun)
- constipation, discomfort of the stomach or bowels, liver disorders (yellow skin or eyes)
- irregular heart beat
- headache
- sleep disturbances
- sad mood (depression)
- low level of blood platelets (sometimes with bleeding or bruising underneath the skin)

Very rare

- inflammation of blood vessels with symptoms such as rash, purplish-red spots, fever
- itching or red skin
- blistering of the lips, eyes or mouth
- skin peeling
- fever
- facial rash associated with joint pain
- muscle disorder
- fever (cutaneous lupus erythematosus)
- severe upper stomach pain; lack or low levels of different blood cells
- severe allergic reactions
- difficulty breathing
- lung infection; breathlessness

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE VALZAP™ HCT

- Keep out of the reach and sight of children.
- Do not use VALZAP™ HCT after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.
- Store below 30°C. Store in the original package in order to protect from moisture.
- Do not use any VALZAP™ HCT pack that is damaged or shows signs of tampering.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What VALZAP™ HCT contains

The active substances are valsartan and hydrochlorothiazide.

Each VALZAP™ HCT 80 mg/12.5 mg film-coated tablet contains 80 mg valsartan and 12.5 mg hydrochlorothiazide.

Each VALZAP™ HCT 160 mg/12.5 mg film-coated tablet contains 160 mg valsartan and 12.5 mg hydrochlorothiazide.

Each VALZAP™ HCT 160 mg/25 mg film-coated tablet contains 160 mg valsartan and 25 mg hydrochlorothiazide.

Other excipients are:

- Tablet Core: Cellulose, microcrystalline, Silica, colloidal anhydrous, Sorbitol (E420), Magnesium carbonate, pregelatinised starch, Povidone K-25, Sodium stearyl fumarate, Sodium laurylsulphate, Crospovidone (Kollidon CL). Coating: Lactose monohydrate, Hypromellose, Macrogol 4000, Titanium dioxide (E171), Iron oxide yellow (E172) (only the 160 mg/25 mg strength), Mixture of black, red and yellow iron oxide (E172) (only the 160 mg/25 mg and 160 mg/12.5 mg strengths), Iron oxide red (E172) (only the 80 mg/12.5 mg and 160 mg/12.5 mg strengths)

What VALZAP™ HCT looks like and contents of the pack

VALZAP™ HCT 80 mg/12.5 mg film-coated tablets: Pink, cylindrical shaped, biconvex, film coated tablet.

VALZAP™ HCT 160 mg/12.5 mg film-coated tablets: Red, cylindrical shaped, biconvex, film coated tablet.

VALZAP™ HCT 160 mg/25 mg film-coated tablets: Brown, cylindrical shaped, biconvex, film coated tablet.

The tablets are supplied in blister packs of 28 film-coated tablets.

Manufactured by:

ZENTIVA, k.s., Prague, Czech Republic

Packed by Benta S.A.L, Dbayeh-Lebanon

This leaflet was last approved in 19. 9. 2012.