VALZAP™ 80 mg film-coated tablets
VALZAP™ 160 mg film-coated tablets

ZENTIVA
A SANOFI COMPANY

Valsartan

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

VALZAP™ belongs to a class of medicines known as angiotensin II receptor antagonist, 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. VALZAP™ works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.
VALZAP™ **80 160 mg film-coated tablets can be used for three different conditions**:
- **to treat high blood pressure in adults and in children and adolescents 6 to 18 years of age.** High blood pressure increases the workload on 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.
- **to treat adult patients after a recent heart attack** (myocardial infarction). "Recent" here means between 12 hours and 10 days.
- **to treat symptomatic heart failure in adult patients.** VALZAP™ is used when a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors (a medication to treat heart failure) cannot be used or it may be used in addition to ACE inhibitors when beta blockers (another medication to treat heart failure) cannot be used. Heart failure symptoms include shortness of breath, and swelling of the feet and legs due to fluid build-up. It is caused when the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE VALZAP™

Do not take VALZAP™:
- if you are allergic to valsartan or any of the other ingredients of this medicine (listed in section 6).
- if you have severe liver disease.
- if you are more than 3 months pregnant (it is also better to avoid VALZAP™ in early pregnancy - see pregnancy section).

If any of these apply to you, do not take VALZAP™.

Warnings and precautions
Talk to your doctor or pharmacist before taking VALZAP™:
- if you have liver disease.
- if you have severe kidney disease or if you are undergoing dialysis.
- if you are suffering from a narrowing of the kidney artery.
- if you have recently undergone kidney transplantation (received a new kidney).
- if you are treated after a heart attack or for heart failure, your doctor may check your kidney function.
- if you have severe heart disease other than heart failure or heart attack.
- if you are taking medicines that increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin. It may be necessary to check the amount of potassium in your blood at regular intervals.
- if you are below 18 years of age and you take VALZAP™ in combination with other medicines that inhibit the renin angiotensin aldosterone system (medicines that lower blood pressure), your doctor may check your kidney function and the amount of potassium in your blood at regular intervals.
- if you suffer from aldosteronism. 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™ is not recommended.
- if you have lost a lot of fluid (dehydration) caused by diarrhoea, vomiting, or high doses of water pills (diuretics).

You must tell your doctor if you think you are (or might become) pregnant. VALZAP™ 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).

If any of these apply to you, tell your doctor before you take VALZAP™.

Other medicines and VALZAP™
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The effect of the treatment can be influenced if VALZAP™ 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 applies to both prescription and non-prescription medicines, especially:
- other medicines that lower blood pressure, especially water pills (diuretics).
- medicines that increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin.
- certain type of pain killers called non-steroidal anti-inflammatory medicines (NSAIDs).
- lithium, a medicine used to treat some types of psychiatric illness.

In addition:
- if you are being treated after a heart attack, a combination with ACE inhibitors (a medication to treat heart attack) is not recommended.
- if you are being treated for heart failure, a triple combination with ACE inhibitors and beta blockers (medications to treat heart failure) is not recommended.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Pregnancy
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™ before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of VALZAP™. VALZAP™ 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.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. VALZAP™ 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 VALZAP™ affects you. Like many other medicines used to treat high blood pressure, VALZAP™ may in rare cases cause dizziness and affect the ability to concentrate.

VALZAP™ contains lactose monohydrate, sorbitol and sodium. This medicine contains lactose monohydrate and sorbitol (E420), both sugars. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
This medicinal product contains less than 1 mmol sodium (23 mg) per dose; i.e. essentially "sodium-free".

3. HOW TO TAKE VALZAP™

Always take this medicine exactly as your doctor or pharmacist has told you in order to get the best results and reduce the risk of side effects. 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 the doctor even if you are feeling well.

Adult patients with high blood pressure: The usual dose is 80 mg daily. In some cases your doctor may prescribe higher doses (e.g. 160 mg or 320 mg). He may also combine VALZAP™ with an additional medicine (e.g. a diuretic).

Children and adolescents (6 to 18 years of age) with high blood pressure:
In patients who weigh less than 35 kg the usual dose is 40 mg of valsartan once daily.
In patients who weigh 35 kg or more the usual starting dose is 80 mg of valsartan once daily.
In some cases your doctor may prescribe higher doses (the dose can be increased to 160 mg and to a maximum of 320 mg).

Adult patients after a recent heart attack: After a heart attack the treatment is generally started as early as after 12 hours, usually at a low dose of 20 mg twice daily. You obtain the 20 mg dose by dividing the 40 mg tablet. Your doctor will increase this dose gradually over several weeks to a maximum of 160 mg twice daily. The final dose depends on what you as an individual patient can tolerate. VALZAP™ can be given together with other treatment for heart attack, and your doctor will decide which treatment is suitable for you.

Adult patients with heart failure: Treatment starts generally with 40 mg twice daily. Your doctor will increase the dose gradually over several weeks to a maximum of 160 mg twice daily. The final dose depends on what you as an individual patient can tolerate. VALZAP™ can be given together with other treatment for heart failure, and your doctor will decide which treatment is suitable for you.

You can take VALZAP™ with or without food. Swallow VALZAP™ with a glass of water.
Take VALZAP™ at about the same time each day.
The tablet can be devided into equal doses.

If you take more VALZAP™ **than you should**
If you experience severe dizziness and/or fainting, contact your doctor immediately and lie down. If you have accidentally taken too many tablets, contact your doctor, pharmacist, or hospital.

If you forget to take VALZAP™
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™
Stopping your treatment with VALZAP™ may cause your disease 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 medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some symptoms need immediate medical attention:
You may experience symptoms of angioedema (a specific allergic reaction), such as
- swollen face, lips, tongue or throat
- difficulty in breathing or swallowing
- hives, itching

If you get any of these, see a doctor immediately.

Side effects include:
Common (may affect up to 1 in 10 people):
- dizziness,
- low blood pressure with or without symptoms such as dizziness and fainting when standing up
- decreased kidney function (signs of renal impairment)

Uncommon (may affect up to 1 in 100 people):
- angioedema (see section "Some symptoms need immediate medical attention")
- sudden loss of consciousness (syncope)
- spinning sensation (vertigo)
- severely decreased kidney function (signs of acute renal failure)
- muscle spasms, abnormal heart rhythm (signs of hyperkalaemia)
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- headache
- cough
- abdominal pain
- nausea
- diarrhoea
- tiredness
- weakness

Not known (frequency cannot be estimated from the available data):
- allergic reactions with rash, itching and hives; symptoms of fever, swollen joints and joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms may occur (signs of serum sickness)
- purplish-red spots, fever, itching (signs of inflammation of blood vessels also called vasculitis)
- unusual bleeding or bruising (signs of thrombocytopenia)
- muscle pain (myalgia)
- fever, sore throat or mouth ulcers due to infections (symptoms of low level of white blood cells also called neutropenia)
- decrease of level of haemoglobin and decrease of the percentage of red blood cells in the blood (which can,lead to anaemia in severe cases)
- increase of level of potassium in the blood (which can trigger muscle spasms and abnormal heart rhythm in severe cases)
- decreased levels of sodium in the blood
- elevation of liver function values (which can indicate liver damage) including an increase of bilirubin in the blood (which can, trigger yellow skin and eyes in severe cases)
- increase of level of blood urea nitrogen and increase of level of serum creatinine (which can indicate abnormal kidney function)

The frequency of some side effects may vary depending on your condition. For example, side effects such as dizziness, and decreased kidney function, were seen less frequently in adult patients treated with high blood pressure than in adult patients treated for heart failure or after a recent heart attack.

Side effects in children and adolescents are similar to those seen in adults.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE VALZAP™

Keep this medicine out of the sight and reach of children.

Do not use VALZAP™ after the expiry date which is stated on the carton/blister after EXP. The expiry date refers to the last day of that month.

Store below 30ºC. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What VALZAP™ contains
The active substance is valsartan.
VALZAP™ 80 mg film-coated tablets: Each film-coated tablet contains 80 mg of valsartan,
VALZAP™ 160 mg film-coated tablets: Each film-coated tablet contains 160 mg of valsartan.

The other ingredients are: Cellulose, microcrystalline, Silica, colloidal anhydrous, Sorbitol (E420), Magnesium carbonate, Starch, pregelatinised, Povidone K-25, Sodium stearyl fumarate, Sodium laurylsulphate, Crospovidone (Kollidon CL), Lactose monohydrate, Hypromellose, Titanium dioxide (E 171), Macrogol 4000
VALZAP™ 80 mg contains the colouring agent Iron oxide red (E 172).
VALZAP™ 160 mg contains the colouring agents Iron oxide yellow (E 172) and Mixture of black, red and yellow iron oxide (E 172).

What VALZAP™ **looks like and contents of the pack**
VALZAP™ 80 mg film-coated tablets: cylindrical, scored on one side, pink film-coated tablets.
VALZAP™ 160 mg film-coated tablets: cylindrical, scored on one side, ochre film-coated tablets.
The tablets can be divided into equal doses.

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

Manufactured by:
ZENTIVA, k.s., Prague, Czech Republic

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

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Packed by
Benta SAL, Dbayeh- Lebanon
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