

Package leaflet: Information for the user

Valsartan Teva 40 mg Film-coated Tablets
Valsartan Teva 80 mg Film-coated Tablets
Valsartan Teva 160 mg Film-coated Tablets
Valsartan Teva 320 mg Film-coated Tablets
Valsartan

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

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- 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. See section 4.

What is in this leaflet:

1. What Valsartan Teva is and what it is used for
2. What you need to know before you take Valsartan Teva
3. How to take Valsartan Teva
4. Possible side effects
5. How to store Valsartan Teva
6. Contents of the pack and other information

1. What Valsartan Teva is and what it is used for

Valsartan Teva 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. Valsartan works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

Valsartan Teva 40 mg film-coated tablets **can be used for three different conditions:**

- **to treat high blood pressure 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.** Valsartan Teva 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 other medications 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.

Valsartan Teva 80 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.** Valsartan Teva 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 other medications 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.

Valsartan Teva 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.** Valsartan Teva 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 other medications 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.

Valsartan Teva 320 mg film-coated tablets **can be used**

- **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.

2. What you need to know before you take Valsartan Teva

Do not take Valsartan Teva

- 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 Valsartan Teva in early pregnancy - see section 2: Pregnancy, breast-feeding and fertility).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing **aliskiren**

If any of these apply to you, do not take Valsartan Teva

Warnings and precautions

Talk to your doctor or pharmacist before taking Valsartan Teva.

- if you have liver disease
- if you have a severe kidney disease or if you are undergoing dialysis
- if you are suffering from a narrowing of the kidney artery
- if you have recently had a 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 Valsartan Teva 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 Valsartan Teva is not recommended.
- if you have lost a lot of fluid (dehydration) caused by diarrhoea, vomiting, or high doses of water tablets (diuretics).
- if you have ever experienced swelling of the tongue and face caused by an allergic reaction called angioedema when taking another drug (including ACE inhibitors), tell your doctor. If these symptoms occur when you are taking Valsartan Teva, stop taking Valsartan Teva immediately and never take it again (see section 4, "Possible side effects").
- you must tell your doctor if you think you are (or might become) pregnant. Valsartan Teva 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 section 2: Pregnancy, breast-feeding and fertility).
- if you are taking any of the following medicines used to treat high blood pressure:
 - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems
 - aliskiren
- if you are being treated with an ACE-inhibitor together with certain other medicines to treat your heart failure, which are known as mineralocorticoid receptors antagonists (MRA) (for example spironolactone, eplerenone) or betablockers (for example metoprolol)

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading 'Do not take Valsartan Teva'.

If any of these apply to you, tell your doctor before you take Valsartan Teva.

Other medicines and Valsartan Teva

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 Valsartan Teva 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 tablets** (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.

Your doctor may need to change your dose and/or to take other precautions:

If you are taking an ACE-inhibitor or aliskiren (see also information under the headings 'Do not take Valsartan Teva' and 'Warnings and precautions').

If you are being treated with an ACE-inhibitor together with certain other medicines to treat your heart failure, which are known as mineralocorticoid receptors antagonists (MRA) (for example spironolactone, eplerenone) or betablockers (for example metoprolol).

Valsartan Teva with food and drink

You can take Valsartan Teva with or without food.

Pregnancy, breast-feeding and fertility

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

Ask your doctor or pharmacist for advice before taking any medicine

- **You must tell your doctor if you think you are (or might become) pregnant.** Your doctor will normally advise you stop taking Valsartan Teva before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Valsartan Teva. Valsartan Teva 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.** Valsartan Teva 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 Valsartan Teva affects you. Like many other medicines used to treat high blood pressure, Valsartan Teva may in rare cases cause dizziness and affect the ability to concentrate.

Valsartan Teva[320 mg] contains sunset yellow FCF (E110)

This medicinal product contains sunset yellow FCF (E110) and may cause allergic reactions.

3. How to take Valsartan Teva

Always take this medicine Valsartan Teva exactly as your doctor has told you. 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.

[80 mg, 160 mg and 320 mg]

Adults with high blood pressure: The recommended 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 Valsartan Teva with an additional medicine (e.g. a diuretic).

[40 mg, 80 mg, 160 mg and 320 mg]

Use in 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).

[40mg, 80 mg and 160 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.

Valsartan Teva 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.

Valsartan Teva can be given together with other treatment for heart failure, and your doctor will decide which treatment is suitable for you.

You can take Valsartan Teva with or without food. Swallow Valsartan Teva with a glass of water.

Take Valsartan Teva at about the same time each day.

The tablet can be divided into equal doses.

If you take more Valsartan Teva 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 Valsartan Teva

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 Valsartan Teva

Stopping your treatment with Valsartan Teva 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 Valsartan Teva can cause side effects, although not everybody gets them.

These side effects may occur with certain frequencies, which are defined as follows:

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|--------------|---|
| Very common: | may affect more than 1 in 10 people |
| Common: | may affect up to 1 in 10 people |
| Uncommon: | may affect up to 1 in 100 people |
| Rare: | may affect up to 1 in 1000 people |
| Very rare: | may affect up to 1 in 10,000 people |
| Not known: | frequency cannot be estimated from the available data |

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 :

- dizziness
- low blood pressure with or without symptoms such as dizziness and fainting when standing up
- decreased kidney function (signs of renal impairment)

Uncommon:

- 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:

- 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)
- 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)
- low level of sodium in the blood (which can trigger tiredness, confusion, muscle twitching and/or convulsions in severe cases)

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 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Valsartan Teva

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

Do not use tValsartan Teva after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from moisture.

Do not use Valsartan Teva if you notice that the pack is damaged or shows signs of tampering.

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 Valsartan Teva contains

- The active substance is valsartan.
40 mg: Each film-coated tablet contains 40 mg of valsartan
80 mg: Each film-coated tablet contains 80 mg of valsartan
160 mg: Each film-coated tablet contains 160 mg of valsartan
320 mg: Each film-coated tablet contains 320 mg of valsartan
- The other ingredients are colloidal anhydrous silica, sodium starch glycolate (type A), crospovidone, microcrystalline cellulose, maize starch, magnesium stearate, hypromellose, macrogol, titanium dioxide (E171), talc, 40 and 160 mg: yellow iron oxide (E172), 80 and 160 mg: red iron oxide (E172), 320 mg: red iron oxide (E172), indigotine (E132), sunset yellow FCF (E110).

What Valsartan Teva looks like and contents of the pack

Valsartan Teva 40 mg Film-coated Tablets are yellow, oval-shaped, film-coated tablets, scored on one side and debossed with “V” on one side of the score line and “40” on the other side of the score line.]

Valsartan Teva 80 mg Film-coated Tablets are pink, oval-shaped, film-coated tablets, scored on one side and debossed with “V” on one side of the score line and “80” on the other side of the score line.]

Valsartan Teva 160 mg Film-coated Tablets are yellow, oval-shaped, film-coated tablets, scored on one side and debossed with “V” on one side of the score line and “160” on the other side of the score line.]

Valsartan Teva 320 mg Film-coated Tablets are purple, oval-shaped, film-coated tablets, scored on one side and debossed with “V” on one side of the score line and “320” on the other side of the score line.

Valsartan Teva 40 mg Film-coated Tablets are available in pack size of 1, 7, 14, 15, 28, 30, 56, 60, 84, 90, 98, 100 and 280 film-coated tablets. Hospital pack: 50, 56 (56 x 1), 98 (98 x 1) and 280 (280 x 1) film-coated tablets.

Valsartan Teva 80 mg Film-coated Tablets are available in pack size of 1, 14, 15, 28, 30, 56, 60, 84, 90, 98, 100 and 280 film-coated tablets. Hospital pack: 50 film-coated tablets. Calendar pack of 28 and 98 tablets.

Valsartan Teva 160 mg Film-coated Tablets are available in pack size of 1, 14, 15, 28, 30, 56, 60, 84, 90, 98, 100 and 280 film-coated tablets. Hospital pack: 50 film-coated tablets. Calendar pack of 28 and 98 tablets.

Valsartan Teva 320 mg Film-coated Tablets are available in pack size of 1, 7, 10, 14, 15, 20, 28, 30, 50, 56, 84, 90, 98, 100, 280 film-coated tablets. Hospital pack: 50, 56 x 1, 98 x 1 and 280 x 1 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva Pharma B.V.
Computerweg 10
3542 DR Utrecht
The Netherlands

Manufacturer(s):

TEVA Pharmaceutical Works Private Limited Company, Pallagi út 13, 4042 Debrecen, Hungary

TEVA Pharmaceutical Works Private Limited Company, Táncsics Mihály út 82, H-2100 Gödöllő, Hungary

TEVA UK Ltd., Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG, UK

Pharmachemie BV, Swensweg 5, P.O. Box 552, 2003 RN Haarlem, The Netherlands

TEVA SANTÉ SAS, Rue Bellocier, 89107 Sens, France

Teva Czech Industries s.r.o., Ostravská 29, č.p. 305, 747 70 Opava-Komárov, Czech Republic

Merckle GmbH, Ludwig-Merckle-Straße 3, 89143 Blaubeuren-Weiler, Germany

Teva Operations Poland Sp. z o.o. Mogilska 80 Str., 31-546 Krakow, Poland

This medicinal product is authorised in the member states of the EEA under the following names:

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| Austria: | Valsartan Teva 40mg, 80mg, 160mg, 320mg Filmtabletten |
| Belgium: | Valsartan TEVA 40mg, 80mg, 160mg, 320mg filmomhulde tabletten |
| Czech Republic: | Valsartan - Teva 40mg, 80mg, 160mg |
| Denmark: | Valsartan Teva 40mg, 80mg, 160mg, 320mg |
| Germany: | Valsartan Teva ® 40mg, 80mg, 160mg, 320mg Filmtabletten |
| Estonia: | Valsartan Teva 40mg, 80mg, 160mg, 320mg |
| Greece: | Valsartan Teva 40mg, 80mg, 160mg, 320mg Επικαλυμμένα με λεπτό υμένιο δισκία |
| Spain: | Valsartan Teva 40mg, 80mg, 160mg, 320mg comprimidos recubiertos con película EFG |
| Finland: | Valsartan Teva 40mg, 80mg, 160mg, 320mg tabletti, kalvopäällysteinen |
| France: | Valsartan TEVA, 40mg, 80mg, 160mg comprimé pelliculé |
| Hungary: | Valsartan -Teva 40mg, 80mg, 160mg, 320mg filmtablett |
| Ireland: | Valsartan Teva 40mg, 80mg, 160mg, 320mg Film-coated Tablets |
| Italy: | Valsartan Teva 40mg, 80mg, 160mg, 320mg compresse rivestite con film |
| Lithuania: | Valsartan Teva 40mg, 80mg, 160mg, 320mg plėvele dengtos tabletės |
| Luxembourg: | Valsartan Teva 40mg, 80mg, 160mg, 320mg comprimés pelliculés |
| Latvia: | Valsartan Teva 40mg, 80mg, 160mg, 320mg apvalkotās tabletes |
| Netherlands: | Valsartan PCH, 40mg, 80mg, 160mg, 320mg filmomhulde tabletten |
| Norway: | Valsartan Teva 40mg, 80mg, 160mg, 320mg tablett, filmdrasjerte |
| Poland: | Bespres 40mg, 80mg, 160mg, 320mg |
| Portugal: | Valsartan Teva 40mg, 80mg, 160mg, 320mg |
| Sweden: | Valsartan Teva 40mg, 80mg, 160mg, 320mg filmdragerade tablett |
| Slovenia: | Valsartan Teva 40mg, 80mg, 160mg, 320mg filmsko obložene tablete |
| Slovakia: | Valsartan Teva 40mg, 80mg, 160mg, 320mg |
| United Kingdom: | Valsartan 40mg, 80mg, 160mg, 320mg Film-coated Tablets |

This leaflet was last revised in November 2014