**contents of the pack and other information**

What Valsartan Capsules contain:

- The active substance is valsartan.
  - 40 mg: Each hard capsule contains 40 mg of valsartan.
  - 80 mg: Each hard capsule contains 80 mg of valsartan.
  - 160 mg: Each hard capsule contains 160 mg of valsartan.
- The other ingredients are silica colloidal anhydrous, sodium starch glycolate (type A), croscopovidone, cellulose microcrystalline, maize starch and magnesium stearate inside the capsule.
- The capsule shell is made of titanium dioxide, gelatin, black iron oxide, 80 mg and 160 mg strengths only: red iron oxide, 160 mg strength only: yellow iron oxide. The printing ink contains shellac, propylene glycol and black iron oxide.

What Valsartan Capsules look like and contents of the pack:

- Capsule, hard
- 40 mg strength: Hard-gelatin capsule with grey opaque body and flesh opaque cap, filled with off-white to yellowish powder with small agglomerates, imprinted V40 on body and cap.
- 80 mg strength: Hard-gelatin capsule with grey opaque body and flesh opaque cap, filled with off-white to yellowish powder with small agglomerates, imprinted V80 on body and cap.
- 160 mg strength: Hard-gelatin capsule with grey opaque body and flesh opaque cap, filled with off-white to yellowish powder with small agglomerates, imprinted V160 on body and cap.

Transparent PVC/PE/PVDC - Aluminium blister packs:

- Pack sizes: 40 mg capsules: 1, 7, 14, 15, 28, 30, 56, 84, 90, 98, 100 and 280 capsules.
- 80 & 160 mg capsules: 1, 14, 15, 28, 30, 56, 84, 90, 98, 100 and 280 capsules.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Teva UK Limited, Eastbourne, BN22 9AG, United Kingdom

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## HOW TO TAKE VALSARTAN CAPSULES

Always take Valsartan Capsules 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. For doses not realisable/practicable with this strength, other strengths and pharmaceutical forms of this medicinal product are available.

Valsartan 80 mg and 160 mg capsules:

- **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/she may also combine Valsartan Capsules with an additional medicine (e.g. a diuretic).

Valsartan 40 mg, 80 mg and 160 mg capsules:

- **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 valsalteran 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 may obtain the 20 mg dose by dividing a 40 mg valsartan 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.

- **Adult patients with heart failure:**
  - Treatment starts generally as soon as possible for the first six months. In some cases your doctor may prescribe higher doses (e.g. 160 mg or 320 mg). He/she may also combine Valsartan Capsules with an additional medicine (e.g. a diuretic).

- **Muscle spasms, abnormal heart rhythm (signs of heart failure)**
  - The recommended dose is 80 mg 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).

### POSSIBLE SIDE EFFECTS

Like all medicines, Valsartan Capsules can cause side effects, although not everybody gets them.

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

- **Common:** may affect more than 1 in 10 people
- **Uncommon:** may affect up to 1 in 10 people
- **Rare:** may affect up to 1 in 1,000 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:

- **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

### Frequency 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).