

## Patient package insert according to Pharmacists' Regulations (Preparations) - 1986

This medicine can be sold with a physician's prescription only

# VALSARTAN DEXCEL 40, 80, 160, TABLETS

**Each tablet contains** Valsartan at a dosage of 40, 80 or 160 mg respectively.

**Inactive ingredients and allergens in the medicine** - see section 6 "Additional information".

**Read this entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have additional questions, refer to the doctor or pharmacist.

This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them, even if it seems their illness is the same as yours.

## 1. What is the medicine intended for?

**Valsartan Dexcel 40** is intended for the treatment of heart failure and to reduce hospitalizations in patients with intolerance to angiotensin converting enzyme inhibitors (ACEi). For treatment following myocardial infarction, to improve survival.

**Valsartan Dexcel 80 and 160** are intended for the treatment of hypertension. For the treatment of heart failure and to reduce hospitalizations in patients with intolerance to angiotensin converting enzyme inhibitors (ACEi). For treatment following myocardial infarction, to improve survival.

- Hypertension increases the workload of the heart and arteries. If the hypertension is not treated, the blood vessels of the brain, heart and kidneys could be damaged. The result may cause a stroke, heart failure or kidney failure. Hypertension increases the risk of heart attacks. Lowering blood pressure to normal levels reduces the risk of developing these disorders.
  - For the treatment of adult patients following a heart attack (myocardial infarction), in order to improve survival and reduce additional heart problems.
  - For the treatment of symptomatic heart failure in adult patients. Heart failure includes shortness of breath, swelling of the legs and feet due to fluid build-up. Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed by the body.
- Therapeutic group:**  
Angiotensin II receptor antagonist.  
Valsartan belongs to a class of medicines

that block the angiotensin II receptor, which helps control hypertension. Angiotensin II is a natural substance in the body that causes blood vessels to tighten, thus causing blood pressure to increase. Valsartan works by blocking the effect of angiotensin II, as a result, blood vessels relax and blood pressure is lowered.

## 2. Before using the medicine

Do not use the medicine if you:

- Are sensitive (allergic) to the active ingredient (valsartan) or to any of the other ingredients this medicine contains (see section 6).
- Suffer from a severe liver dysfunction.
- Are more than 3 months pregnant (it is also preferable to avoid Valsartan in early pregnancy, see "Pregnancy and breastfeeding" section).
- Are being treated with blood pressure lowering medicine containing aliskiren because you are a diabetic or suffer from impaired kidney function.

**If one of these conditions applies to you, notify the doctor without taking Valsartan.**

## Special warnings regarding the use of this medicine

**Before treatment with Valsartan Dexcel tell your doctor if you:**

- Have a liver disease.
- Have a severe kidney disease or you are undergoing dialysis.
- Are suffering from narrowing of the kidney artery.
- Have recently undergone a kidney transplantation.
- Have a severe heart disease, other than heart failure or heart attack.
- Have ever had swelling of the tongue and face caused by an allergic reaction called angioedema, when you took another medicine (including ACE inhibitors), tell your doctor. If these symptoms occur while taking Valsartan, **stop taking the medicine immediately and never take Valsartan again.** (See also section 4 "Side Effects").
- Are taking medicines that increase the amount of potassium in the blood. This includes potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin. You may be required to check the amount of potassium in your blood at regular intervals.
- Suffer from aldosteronism, a disease in which there is excess production of the aldosterone hormone by the adrenal gland.

In this case the use of Valsartan is not recommended.

- Suffer from loss of fluids (dehydration) due to diarrhoea and vomiting or high doses of diuretics.
- Are taking any of the following medicines used to treat high blood pressure:
  - An ACE (angiotensin converting enzyme) inhibitor (e.g., enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
  - Aliskiren.
  - If you are being treated with an ACE inhibitor in combination with other medicines to treat heart failure, known as mineralocorticoid receptor antagonists (MRA) (e.g., spironolactone, eplerenone) or beta blockers (e.g., metoprolol).

See also the information in section "Do not use the medicine if you".

Tell your doctor if you think you are pregnant or if you may be pregnant. Taking Valsartan is not recommended during early pregnancy, **do not** take Valsartan if you are more than 3 months pregnant, as serious harm could be caused to the fetus if the medicine is used at that stage (See "pregnancy and breastfeeding" section).

## Children and adolescents

This medicine is not intended for infants, children and adolescents under 18 years of age.

## Tests and follow-up

- Your doctor may check your kidney function, blood pressure and the amount of electrolytes (such as potassium) in your blood at regular intervals.
- Usually, patients with hypertension do not notice signs of the problem. Many feel well. Therefore, it is very important to persist with your visits to the doctor, even if you feel well.

## Drug interactions

**If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** The treatment can be affected if **Valsartan Dexcel** is taken together with certain medicines. It may be necessary to change the dosage, to take precautions or in some cases, stop taking one of the medicines. Especially notify the doctor or pharmacist if you are taking the following medicines:

- Other medicines used to reduce blood pressure,** mainly diuretics, ACE inhibitors (such as: enalapril, lisinopril, etc.) or aliskiren (see sections "Do not use the medicine if you" and "Special warnings

regarding the use of this medicine").

- 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 nonsteroidal anti-inflammatory drugs (NSAIDs).
- Certain antibiotics (from the rifamycin group), a medicine used to protect against transplant rejection (cyclosporin) or antiretroviral medicine used to treat HIV/AIDS infection (ritonavir). These medicines may increase the effect of Valsartan.
- Lithium,** a medicine used for the treatment of certain types of psychiatric illnesses.

## In addition:

- If you are being treated **after a heart attack,** the combination with ACE inhibitors (a medicine to treat heart attack) is not recommended.
- If you are being treated for **heart failure,** a triple combination with: **ACE inhibitors, other medicines to treat heart failure known as mineralocorticoid receptor antagonists (MRA) (with blocking activity)** (e.g., spironolactone, eplerenone) or **beta blockers** (e.g., metoprolol) is **not recommended.**

## Use of the medicine and food:

The medicine can be taken with or without food.

## Pregnancy and breastfeeding:

- You must tell the doctor if you think you are pregnant (or may be pregnant). It can be assumed that your doctor will advise you to stop taking Valsartan before you become pregnant or as soon as you know you are pregnant, he will advise you to take another medicine instead of Valsartan. Valsartan is not recommended during early pregnancy and **must not** be used beyond third month of pregnancy, as the medicine may cause serious harm to your baby if taken after the third month of pregnancy.

- Tell your doctor if you are breastfeeding or are planning to breastfeed.** Valsartan is not recommended for mothers who are breastfeeding, and your doctor will presumably choose another treatment for you if you wish to breastfeed, especially if your baby was just born, or born prematurely.

## Driving and using machines:

Before driving a vehicle, operating machinery or performing any activity that requires

concentration, make sure you know how the medicine affects you. Like many other medicines used to treat high blood pressure, Valsartan may cause dizziness and impairment of concentration.

## Important information about some of the ingredients of the medicine

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

## 3. How to use the medicine?

Always use the medicine according to the doctor's instructions.

Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only. The usual recommended dosage depends on the indication for which it was prescribed.

The medicine can be used in patients aged 65 and above.

This medicine is not intended for infants, children and adolescents under the age of 18.

## Do not exceed the recommended dose.

### Method of administration:

**Valsartan Dexcel 40/80:** May be halved.

**Valsartan Dexcel 160:** Do not halve the tablet since there is no score line.

There is no information regarding crushing or chewing.

Swallow the medicine with a glass of water. Take the medicine at the same time each day.

## If you have accidentally taken a higher dosage

If you experience severe dizziness and/or fainting, refer to your doctor immediately and lie down. If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

## If you forgot to take the medicine

If you forgot to take a dose, take it as soon as you remember. If it is almost time for your next dose, skip the forgotten dose. Do not take a double dose. Take the next dose at the scheduled time and consult the doctor. Continue with the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop taking this medicine without consulting the doctor. Stopping the treatment may worsen your illness. Before stopping, discuss the implications of stopping with the doctor or pharmacist.

**Do not take medicines in the dark! Check the label and the dose each time you take**

**a medicine. Wear glasses if you need them.**

**If you have further questions on the use of this medicine, consult the doctor or pharmacist.**

## 4. Side effects

Like any medicine, the use of **Valsartan Dexcel** may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

**Certain side effects can be serious and need immediate medical intervention:**

**Refer to the doctor immediately** if you have symptoms of angioedema (a certain allergic reaction) such as:

- Swelling of the face, tongue or throat
- Breathing and swallowing difficulties
- Itching and hives.

**If you experience any of the symptoms mentioned, stop taking the medicine and contact your doctor immediately (see also section "Special warnings regarding use of the medicine").**

### Additional side effects:

**Common side effect** (effects that occur in 1-10 out of 100 users):

- Dizziness
- Low blood pressure with or without symptoms such as dizziness or fainting upon standing up
- Decreased kidney function (signs of renal impairment)

**Uncommon side effects** (effects that occur in 1-10 out of 1,000 users):

- Allergic reaction (angioedema); see section "Special warnings regarding use of the medicine". Refer to the doctor immediately for medical assistance
- Sudden loss of consciousness (syncope)
- Spinning sensation (vertigo)
- Severely decreased kidney function (signs of acute renal failure)
- Muscle spasms, abnormal heart rhythm (signs of hyperkalemia)
- Breathlessness, breathing difficulties when lying down, swelling of the feet or legs (signs of heart failure)
- Headache
- Cough
- Abdominal pain
- Nausea
- Diarrhoea
- Tiredness
- Weakness

**Side effects with unknown frequency** (effects for which a frequency has not yet been determined):

- Blisters on the skin (sign of a bullous skin

inflammation [dermatitis])

- Allergic reactions accompanied by rash, itching and hives, symptoms of fever, swollen joints and joint pain, muscle pain, symptoms of swollen lymph nodes and/ or flu-like symptoms may occur (signs of serum sickness)
- Purple-red spots, fever, itching (signs of blood vessels inflammation also called vasculitis)
- Unusual bleeding or bruising (signs of thrombocytopenia - low blood platelets level)
- Muscle pain (myalgia)

Fever, sore throat or mouth ulcers resulting from infections (symptoms of a low level of white blood cells, called neutropenia)

Decrease in haemoglobin level and decrease in the percentage of red blood cells in the blood (which can, in severe cases, lead to anaemia)

Increase in blood potassium levels (which can, in severe cases, trigger muscle spasms and irregular heart rhythm)

Elevation of liver function values (which can indicate liver damage) including an increase of bilirubin in the blood (which can, in severe cases, cause yellowing of the skin and eyes)

Increase in blood urea nitrogen level and increase in serum creatinine level (which can indicate abnormal kidney function)

Low blood sodium levels (which can trigger tiredness, confusion, muscle twitching and/ or convulsions in severe cases)

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

**If a side effect appears, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.**

Side effects can be reported to the Ministry of Health by clicking the link

"דיווח על תופעות לוואי עקב טיפול תרופתי"

found on the home page of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il))

directing to the online form for reporting side effects or by entering the link:

<https://sideeffects.health.gov.il>

## 5. How to store the medicine

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed

to do so by the doctor.

- Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package.
- The expiry date refers to the last day of that month.
- Storage conditions:** Store at a temperature below 25°C. Store in the original package.

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

## 6. Additional information

**In addition to the active ingredient, the medicine also contains:**

Mannitol, copovidone, croscarmellose sodium, silica colloidal anhydrous, magnesium stearate, hypromellose, titanium dioxide (E-171), talc, macrogol, iron oxide yellow (E-172; 40 mg and 160 mg only), iron oxide red (E-172; 80 mg only), carnauba wax.

**What the medicine looks like and what the package contains:**

**Valsartan Dexcel 40:** oblong biconvex yellow tablets with a score line on one side.

**Valsartan Dexcel 80:** oblong biconvex pink tablets with a score line on one side.

**Valsartan Dexcel 160:** oblong biconvex yellow tablets.

Approved package sizes: 7, 10, 14, 28, 30 tablets.

Not all package sizes may be marketed.

**Manufacturer's name and address:**  
Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel.

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**Drug registration numbers at the national medicine registry of the Ministry of Health:**

**Valsartan Dexcel 40:** 147 19 33424 00

**Valsartan Dexcel 80:** 147 20 33426 00

**Valsartan Dexcel 160:** 147 21 33427 00

### Registration holder:

**Dexcel Pharma Technologies Ltd.**  
1 Dexcel St., Or Akiva 3060000, Israel