

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

## VALSARTAN DEXCEL TABLETS 40, 80, 160mg

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

Inactive ingredients - see section 6.

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 similar to yours.

**Valsartan Dexcel** may be used in patients over 65 years of age. This medicine is not intended for infants, children and adolescents under 18 years of age.

### 1. What is the medicine intended for?

**Valsartan Dexcel 40, 80, 160** are intended for the treatment of heart failure and for treatment after a myocardial infarction.

**Valsartan 80 and 160** are also intended for the treatment of hypertension.

**Therapeutic group:** angiotensin II receptor antagonist. **Valsartan Dexcel** belongs to a class of medicines known as angiotensin II receptor antagonists, which helps control hypertension.

### 2. Before using the medicine

Do not use the medicine if:

- You are more than 3 months pregnant (it is also better to avoid taking **Valsartan Dexcel** in early pregnancy, see "Pregnancy and breastfeeding" section).
- You are hypersensitive (allergic) to the active ingredient (Valsartan) or to any of the other ingredients of this medicine, listed in section 6.
- You suffer from a severe liver disease, severe liver dysfunction, cirrhosis of the liver or biliary obstruction.
- You suffer from diabetes or impaired renal function and are concomitantly taking a blood pressure lowering medicine containing aliskiren.

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

### Special warnings regarding the use of this medicine

- **Before treatment with Valsartan Dexcel tell your doctor if:**
  - You have liver disease.
  - You have kidney disease, or if you are undergoing dialysis treatment.
  - You suffer from narrowing of the kidney artery or if you have recently undergone kidney transplantation.
  - You are taking the medicine aliskiren, or an ACE inhibitor (such as enalapril, lisinopril, ramipril) or an ACE inhibitor in combination with a beta blocker (a medicine that blocks  $\beta$  receptors such as metoprolol) or an ACE inhibitor in combination with MRA medicine (a medicine that blocks

mineralocorticoid receptors), such as spironolactone, eplerenone, for the treatment of heart failure.

- You suffer from loss of fluids due to vomiting or diarrhoea, or if you are taking high doses of diuretics.
- You are sensitive to any food or medicine.
- You suffer from heart failure or if you have had a myocardial infarction (heart attack). Follow the doctor's instructions precisely regarding initial dosage. The doctor may check your kidney function.
- You have a heart disease other than heart failure or heart attack.
- You have ever had swelling, mainly of the face, throat and tongue that was caused by an allergic reaction called angioedema while taking other medicines (including an ACE inhibitor). If these symptoms apply to you, **stop taking Valsartan Dexcel and contact the doctor immediately, do not take Valsartan Dexcel again (see section 4 "Side effects")**.
- You are taking medicines that increase blood potassium levels, such as potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium and heparin. Periodic blood tests of potassium levels may be required.

– You suffer from aldosteronism (a disease in which there is excess production of the aldosterone hormone by the adrenal gland). In this case, taking **Valsartan Dexcel** is not recommended.

### If you are taking or have recently taken, other medicines, including non-prescription medicines and food supplements tell your doctor or pharmacist.

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:

- Medicines used to reduce blood pressure or for heart problems, mainly diuretics, ACE inhibitors (such as enalapril, lisinopril) or aliskiren (see section 2 "Do not use the medicine if" and "Special warnings regarding the use of this medicine").
- Potassium-sparing diuretics such as: spironolactone, triamterene, amiloride, potassium supplements, salt substitutes containing potassium, heparin or other medicines that may increase potassium levels. The doctor may perform periodic blood tests of potassium levels.
- A certain type of analgesic called nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, naproxen or selective cyclooxygenase-2 inhibitors (COX-2 inhibitors). The doctor may also check your kidney function.
- Lithium (a medicine used for the treatment of certain types of psychiatric illnesses).
- Certain antibiotics (of the rifampicin group), a medicine used to protect against transplant rejection (ciclosporin) or antiretroviral

medicine used to treat HIV infection (AIDS (Itravir).

These medicines may increase the effect of **Valsartan Dexcel**.

#### Other medicines:

- Combination with an ACE inhibitor and a beta blocker (such as metoprolol) for treatment of heart failure is not recommended.
- Combination with an ACE inhibitor and MRA medicines (such as spironolactone, eplerenone).
- Combination with an ACE inhibitor for a post heart attack treatment is not recommended.

#### Use the medicine and food

**Valsartan Dexcel** can be taken with or without a meal.

#### Pregnancy and breastfeeding

Tell your doctor if you are pregnant, or think that you may be pregnant. Your doctor will normally advise you to stop taking the medicine before you become pregnant or as soon as you know that you are pregnant; and to take another medicine instead of **Valsartan Dexcel**. This medicine is not recommended during early pregnancy, and must not be used beyond third month of pregnancy since it may cause serious harm to your baby if taken after the third month of pregnancy.

Consult your doctor if you are breastfeeding, or are planning to breastfeed.

Breastfeeding newborns (during the first weeks after birth), especially premature babies, is not recommended while taking this medicine.

#### Driving and use of machinery

Like many other medicines used for the treatment of hypertension, **Valsartan Dexcel** may, in rare cases, cause dizziness and damage concentration. Therefore, before driving a vehicle, using machinery or performing any activity that requires concentration, make sure you know how you react to **Valsartan Dexcel**.

#### 3. How to use the medicine?

Always use according to doctor's instructions. Check with the doctor or pharmacist if you are uncertain. The dosage and administration will be determined by the doctor only.

**Do not exceed the recommended dose.**

**Valsartan Dexcel** may be used in patients above 65 years of age. This medicine is not intended for infants, children and adolescents under 18 years of age.

Use this medicine at set times as was determined by the attending doctor. It is recommended to take the medicine at the same time every day, preferably in the morning. Taking the medicine at the same time every day will help you remember when to take the medicine. Swallow the medicine with a glass of water.

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

**Valsartan Dexcel 160:** Do not halve the tablet.

There is no information regarding crushing and chewing.

#### Tests and follow up

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

It is important to take the medicine exactly according to the doctor's instructions in order to achieve the best results and reduce the risk for side effects.

If you have accidentally taken a higher dosage effects such as dizziness and/or fainting may occur. In this case, refer to a doctor immediately and lie down. If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

If you forget to take this medicine at the required time, do not take a double dose. Take the next dose at the usual 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 discontinue treatment with this medicine without consulting the doctor.

If you stop taking the medicine, your illness may get worse. Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine or regarding how long you should take **Valsartan Dexcel**, 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 may be serious.**

**Stop the use and refer to a doctor immediately if:**

- You have symptoms of angioedema (allergic reaction) such as: swelling of the face, tongue, throat or lips, swallowing difficulties, breathing difficulties, hives, itching.

**Refer to a doctor as soon as possible if:**

- Swelling of the feet, ankles, hands or an unexplained weight gain appears (may indicate kidney problems).
- You feel dizziness or fainting. In this case lie down and contact the doctor immediately.

**Additional side effects:**

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

- Dizziness; hypotension with or without symptoms such as dizziness or fainting when standing up.
- Decreased kidney function (signs of renal impairment).

**Uncommon side effect (effects that appear in 1-10 users out of 1000):**

- Allergic reaction with symptoms such as rash, itching, dizziness, swelling of the face, lips, tongue and/or throat, breathing or swallowing difficulties (symptoms of angioedema)- see also "Refer to a doctor as soon as possible".
- Sudden loss of consciousness, spinning sensation (vertigo).
- Severely decreased kidney function (signs of acute renal failure).
- Muscle spasms, abnormal heart rate (signs of hyperkalemia).
- Shortness of breath, difficulty breathing 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 whose frequency has not been determined yet):**

- Blisters on the skin (a sign of dermatitis bullosa).
- Allergic reaction with rash, itching and hives; along with some of the following signs or symptoms: fever, swollen joints, joint pain, muscle pain, swelling of the lymph nodes and/or flu-like symptoms (signs of serum sickness).
- Purple-red spots, fever, itching (signs of blood vessels inflammation – vasculitis).
- Unusual bleeding or bruising (signs of low platelets levels – thrombocytopenia).
- Muscle pain (myalgia)
- Fever, sore throat or mouth ulcers as a result of infections (symptoms of low level of white blood cells- neutropenia).
- Decrease in haemoglobin levels and decrease in the percentage of red blood cells in the blood (which can lead to anaemia in severe cases).
- Increase in blood potassium levels (which can stimulate muscle spasms and irregular heart rate in severe cases).
- Elevation of liver function values (that may indicate liver damage) including an increase of bilirubin in the blood (which can cause yellowing of the skin and eyes in severe cases).
- Increase in blood urea nitrogen level and increase in serum creatinine level (which can indicate abnormal kidneys function).
- Low blood sodium levels (may cause tiredness, confusion, muscle spasms 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 that were treated for hypertension as opposed to patients that were treated for heart failure or after a heart attack that occurred recently.

The following side effects were observed during clinical studies with a valsartan containing product, without the ability to determine whether caused by the medicine or by other factors: back pain, libido changes, sinus inflammation, insomnia, joint pain, pharyngitis, runny or stuffy nose, swollen palms, heels or feet, upper respiratory tract infection, viral infections.

If a side effect appears, if the side effects worsens or if you suffer from any side effect not listed in this leaflet, consult your doctor.

#### Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "דיווח על תופעות לוואי עקב טיפול תרופתי" that can be 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 of adverse events reporting or via the following link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

#### 5. How to store the medicine

- Avoid poisoning! This medicine and any other medicine must be stored in a safe place out of the reach 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 (exp. date) stated on the package. The expiry date refers to the last day of that month.

**Storage conditions:** do not store at a temperature above 25°C. Store in the original package.

#### 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), Taic, 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.

Every package contains: 7, 10, 14, 28, 30 tablets in blister packages. Not all packages sizes may be marketed.

**Manufacturer:** Dexel Ltd., 1 Dexcel St., Or-Akiva 3060000, Israel.

This leaflet was checked and approved by the Ministry of Health on: November 2016.

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

**Valsartan Dexcel 40:** 147193342400

**Valsartan Dexcel 80:** 147203342600

**Valsartan Dexcel 160:** 147213342700

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Registration holder:  
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