Applicant	**:**	Sandoz SA (Pty) Ltd
Proprietary name	**:**	Zomevek 80 & Zomevek 160
Dosage form and strength	**:**	Film-coated tablets. Each tablet contains 80 mg or 160 mg valsartan (26/08/2026)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ZOMEVEK® 80 Tablet (film-coated tablet)

ZOMEVEK® 160 Tablet (film-coated tablet)

Valsartan

The tablets are sugar free

Read all of this leaflet carefully before you start taking ZOMEVEK®.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ZOMEVEK® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

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1. What ZOMEVEK® is and what it is used for

ZOMEVEK® belongs to a class of medicines known as angiotensin-II receptor antagonists, which help to control high blood pressure. Angiotensin II is a substance in the body that causes blood vessels to tighten, thus causing your blood pressure to increase. ZOMEVEK® works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

ZOMEVEK® is used to treat high blood pressure

2. What you need to know before you take ZOMEVEK®

BEFORE YOU TAKE ZOMEVEK®:

Follow your doctor's instructions carefully.

Do not take ZOMEVEK®:

- If you have ever had an unusual or allergic reaction to valsartan or to any other ingredients of this product listed at the beginning of this leaflet. If you think you may be allergic, ask your doctor for advice.
- If you are pregnant.
- if you have moderate to serious liver disease;
- if you have moderate to serious kidney disease;
- if you have too low a level of potassium or sodium in your blood, or if you have too high a level of calcium in your blood despite treatment;
- if you have if you have gout (characterized by recurrent attacks of acute inflammatory arthritis—a red, tender, hot, swollen joint);
- if you have porphyria, (Porphyrias are a group of inherited or acquired disorders of certain enzymes or chemicals in the blood product manufacturing system);
- If you are pregnant or breastfeeding;

- If you have aortic stenosis (valvular heart disease caused by the incomplete opening of the aortic valve) or hypertrophic obstructive cardiomyopathy (is a disease of the myocardium (the muscle of the heart) in which a portion of the myocardium is hypertrophied (thickened).
- If you have a history of any type of angioedema (is the rapid swelling (oedema) of the skin);
- If you use lithium; and
- If you use potassium sparing diuretics (is any drug that elevates the rate of urination and thus provides a means of forced diuresis) such as spironolactone, triamterene, amiloride.

Warnings and precautions

Take special care with ZOMEVEK®:

- If you have a serious kidney or liver disease;
- If you are already taking an ACE-inhibitor (any of a group of antihypertensive medicines that relax arteries and promote kidney excretion of salt and water), together with a betablocker (is a group of anti-hypertensive medicines that relax arteries and promote heart function), to treat your heart failure;
- If you are suffering from vomiting or diarrhoea or are taking high doses of a diuretic (water pill); and
- If you are suffering from heart failure or have a history of myocardial infarction (commonly known as a heart attack, is the interruption of blood supply to part of the heart, causing heart cells to die). Follow your doctor's instruction for the starting dose carefully. Your doctor may also check your kidney function.
- Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking ZOMEVEK®. Your doctor will decide on further treatment. Do not stop taking ZOMEVEK® on your own.

If any of these apply to you, tell your doctor before you take ZOMEVEK®.

Older people (age 65 and over):

You can also use ZOMEVEK®: if you are 65 years of age or older.

Children and adolescents (below the age of 18 years):

Safety and efficacy have not been established in children and adolescents below the age of 18 years.

Other medicines and ZOMEVEK®:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

If you are taking medicines not prescribed by a doctor you may have to; change the dose; take other precautions; or in some cases you may have to stop taking one of these medicines.
This applies to both prescription and non-prescription medicines, especially:

- medicines used to lower blood pressure, especially diuretics (water pills);

potassium-sparing medicines (Please refer to the section “Do not take ZOMEVEK®” for more information) , potassium supplements, or salt substitutes containing potassium.

Pregnancy and breastfeeding:

Pregnant women:

Do not take ZOMEVEK®: if you are pregnant. ZOMEVEK®: may cause serious harm to the unborn child. It is therefore important to check with your doctor immediately if you think you may have become pregnant or are planning to become pregnant.

Breast-feeding mothers:

Do not take ZOMEVEK® while breast-feeding. Tell your doctor if you are breast-feeding.

If you are pregnant or breast-feeding your baby while taking ZOMEVEK®, please consult you doctor, pharmacist or other healthcare professional for advise.

Driving and using machines:

ZOMEVEK® may cause dizziness and affect the ability to concentrate. Before you drive a vehicle, use machinery, or carry out other activities that require concentration, make sure you know how you react to the effects of ZOMEVEK®.

It is not always possible to predict to what extent ZOMEVEK® may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ZOMEVEK® affects them.

3. How to take ZOMEVEK®

Do not share medicines prescribed for you with others.

Always take ZOMEVEK® exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Patients who have high blood pressure often do not notice or experience any signs or symptoms of this condition. Many may feel quite normal. Therefore it is all the more important for you to keep your appointments with the doctor, even if you are feeling well. It is also therefore very important that you take ZOMEVEK® exactly as your doctor tells you, in order to get the best results, and to reduce the risk of side-effects.

Do not exceed the recommended dosage.

ZOMEVEK® is for oral use only.

How much ZOMEVEK® to take:

Your doctor will tell you exactly how many tablets of ZOMEVEK® to take.

To treat high blood pressure the usual dosage is one 80 mg or 160 mg tablet once a day. In some cases, your doctor may prescribe a higher dose (e.g. 320 mg) or an additional medicine (e.g. a diuretic (water pill)).

When and how to take ZOMEVEK®:

Swallow ZOMEVEK® tablets with a glass of water. ZOMEVEK® tablets may be taken with or without food. Do not crush or chew the tablets.

How long to take ZOMEVEK®:

Your doctor will tell you exactly how long you will need to take the tablets.

If you take more* ZOMEVEK®*than you should:

You may experience severe dizziness and/or fainting, tell your doctor as quickly as possible.

***If you forget to take* ZOMEVEK®:**

It is advisable to take your medicine at the same time each day, preferably in the morning. However, if you forget to take a dose of ZOMEVEK®, carry on with the next one at the usual time. Do not take a double dose to make up for the forgotten tablet.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre.

Effects when treatment with ZOMEVEK® is stopped:

Stopping your treatment with ZOMEVEK® may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

4. Possible side effects

ZOMEVEK® can have side effects.

Some of these unwanted reactions may be similar to symptoms caused by your specific medical condition; others may not be reactions at all, being unrelated to your treatment.

Not all side-effects reported for ZOMEVEK® are included in this leaflet. Should your general health worsen while taking ZOMEVEK®, please consult your doctor, pharmacist or other health care professional for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- sudden loss of consciousness or fainting,
- shortness of breath, swelling of the feet or legs due to fluid build-up,
- Low blood platelet counts with symptoms such as bleeding or bruising more easily than normal,
- allergic reactions with symptoms such as swelling of the face, eyelids and lips,
- inflammation of the blood vessels,
- impaired kidney function,
- passing little or no urine, drowsiness, nausea, vomiting and breathlessness.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- viral infections,
- rhinitis (irritation and inflammation of some internal areas of the nose),
- dizziness standing up, especially when getting up from lying or sitting position,
- low blood pressure.

Less frequent side effects:

- upper respiratory tract infection,
- sore throat and discomfort when swallowing,
- inflammation of the sinus,
- high levels of potassium in the blood,
- sleep disturbance,
- change in libido,
- feeling of spinning,
- cough,
- diarrhoea,
- pain in the back or stomach,
- tiredness,

- weakness,
- swelling or accumulation of fluid,
- dizziness,
- headache,
- nausea,
- rash,
- itching,
- joint pains, and
- muscle pain.
- Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea.

If you notice any other effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ZOMEVEK®.

Suspected side effects can also be reported directly to the Holder of Certificate of Registration (HCR) via the website: https://pvi1j.solutions.iqvia.com or the e-mail address, adverse.event.sac@sandoz.com.

5. How to store ZOMEVEK®

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN

Store at or below 25 °C. Protect from moisture.

Keep the blisters in the outer carton until required for use, to protect the tablets from moisture.

Do not take ZOMEVEK® after the expiry date shown on the pack.

Do not use any ZOMEVEK® pack that is damaged or shows signs of tampering.

6. Contents of the pack and other information

What ZOMEVEK® contains

ZOMEVEK® comes in the form of a film-coated tablet. Each tablet contains the active substance valsartan (80 mg or 160 mg).

The other ingredients are colloidal anhydrous silica, crospovidone, hypromellose , macrogol 8000, magnesium stearate, Microcrystalline cellulose, red iron oxide (E172), titanium dioxide (E171), yellow iron oxide (E172).

What ZOMEVEK®looks like and contents of the pack

ZOMEVEK® 80 Tablet:

Pale red, round film-coated tablet with bevelled edges, one side with debossing ‘DV” and “NVR” on the reverse side of the tablet. Film-coating is intact and shows no signs of cracks.

ZOMEVEK® 160 Tablet:

Grey-orange, ovaloid film-coated tablet, slightly convex, one side with debossing **“**DX**”** and “NVR” on the reverse side of the tablet. Film-coating is intact and shows no signs of cracks.

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28 tablets in PVC/PE/PVDC aluminium foil blisters (Triplex) or PA/Al /PVC aluminium foil blisters (alu-alu or double-sided aluminium blisters) or PVC/PVDC with aluminium foil (Duplex) blisters. The aluminium foil is silver and the PVC/PVDC is clear, colourless transparent.

The outer container is a printed cardboard box.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd.[1]

72 Steel Road,

Spartan

Kempton Park,

1619.

This leaflet was last revised in

26 August 2026

Registration numbers

ZOMEVEK® 80 Tablet: 43/7.1.3/0036

ZOMEVEK® 160 Tablet: 43/7.1.3/0037

[1]Company Reg. No.: 1990/001979/07