SCHEDULING STATUS: **S3**

PROPRIETARY NAMES, STRENGTHS AND DOSAGE FORM:

ZOMEVEK 80 TABLET (film-coated tablet)

ZOMEVEK 160 TABLET (film-coated tablet)

Read all of this leaflet carefully before you start using ZOMEVEK.

Keep this leaflet. You may need to read it again.

This medicine has been prescribed only for you. Do not give it to anybody else or use it for any other illnesses.

If you have further questions, please ask your doctor or pharmacist.

WHAT ZOMEVEK CONTAINS:

Your medicine is called ZOMEVEK and 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: Microcrystalline cellulose, crospovidone, colloidal anhydrous silica, magnesium stearate, hypromellose, macrogol 8000, red iron oxide, yellow iron oxide, black iron oxide (160 mg only), titanium dioxide.

The tablets are sugar free.

WHAT ZOMEVEK 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.

BEFORE YOU TAKE ZOMEVEK:

Follow your doctor's instructions carefully. They may differ from the general instructions in this leaflet.

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 gout;
- if you have porphyria;
- If you are pregnant or breastfeeding;
- If you have aortic stenosis or hypertrophic obstructive cardiomyopathy;
- If you have a history of any type of angioedema;
- If you use lithium;
- If you use potassium sparing diuretics such as spironolactone, triamterene, amiloride.

Take special care with ZOMEVEK:

- If you have a serious kidney or liver disease
- If you are already taking an ACE-inhibitor together with a betablocker to treat your heart failure
- If you are suffering from vomiting or diarrhoea or are taking high doses of a diuretic (water pill).
- If you are suffering from heart failure or have a history of myocardial infarction. Follow your doctor's instruction for the starting dose carefully. Your doctor may also check your kidney function.

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.
Take ZOMEVEK with food and drink:
ZOMEVEK can be taken with or without food. Do not crush or chew the tablets, it should be swallowed whole with a glass of water.

Pregnancy and breastfeeding:
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.

Do not take ZOMEVEK while breastfeeding. Tell your doctor if you are breastfeeding.

Driving and using machinery:
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.

Taking other medicines with ZOMEVEK*:*

If you are taking medicines on a regular basis including complementary or traditional medicines, concomitant use of the medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional, for advice.

Remember also those not prescribed by a doctor. 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:

- medicines used to lower blood pressure, especially diuretics (water pills);
- potassium-sparing medicines, potassium supplements, or salt substitutes containing potassium.

HOW TO TAKE ZOMEVEK:
Do not share medicines prescribed for you with others.
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.

Patients who have 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. It is very important that you take this medicine exactly as your doctor tells you in order to get the best results and 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).

When and how to take ZOMEVEK:

Swallow ZOMEVEK tablets with a glass of water. ZOMEVEK tablets may be taken with or without food.

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:

If you have accidentally taken too many tablets of ZOMEVEK, talk to your doctor.

If you 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.

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.

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.

Some side-effects can be serious:

- 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, breathlessness

If you experience any of these, tell your doctor straight away.

Other possible side effects are:

- viral infections,
- dizziness standing up, especially when getting up from lying or sitting position.
- 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
- low blood pressure
- cough
- diarrhoea
- pain in the back or stomach
- tiredness
- weakness
- swelling or accumulation of fluid
- dizziness
- rhinitis
- headache
- nausea
- rash
- itching
- joint pains
- muscle pain

If any of these affect you severely, tell your doctor.

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

STORING AND DISPOSING OF ZOMEVEK:

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.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF ZOMEVEK:

7, 10, 14, 15, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100 or 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.

Not all pack sizes may be marketed.

IDENTIFICATION OF ZOMEVEK:

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.

REGISTRATION NUMBERS:

Zomevek 80 Tablet: 43/7.1.3/0036

Zomevek 160 Tablet: 43/7.1.3/0037

NAME AND ADDRESS OF REGISTRATION HOLDER:

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DATE OF PUBLICATION:

Date of registration: 23 July 2010

Date of most recent approval of patient information leaflet: 23 July 2010

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