

PACKAGE LEAFLET: INFORMATION FOR THE USER

ZOFECARD

Zofecard 7.5mg film-coated tablets

Zofecard 30mg film-coated tablets

ZOFENOPRIL

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What Zofecard is and what it is used for
2. What you need to know before you take Zofecard
3. How to take Zofecard
4. Possible side effects
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1. WHAT ZOFECARD IS AND WHAT IT IS USED FOR

Zofecard contains 7.5 or 30 mg zofenopril calcium which belongs to a group of blood pressure lowering medicines called angiotensin converting enzyme (ACE) inhibitors.

Zofecard is used to treat the following conditions:

- high blood pressure (hypertension).
- heart attack (acute myocardial infarction) in people who may or may not show signs and symptoms of heart failure, and who have not received treatment that helps dissolve blood clots (thrombolytic therapy).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ZOFECARD

Do not take Zofecard if you:

- are allergic (hypersensitive) to any of the ingredients in the product
- have had any previous allergic reaction to any other ACE inhibitor such as captopril or enalapril

- have a history of severe swelling and itching around the face, nose and throat (angioneurotic edema) associated with previous ACE inhibitor therapy, or if you suffer from hereditary/idiopathic angioneurotic oedema (rapid swelling of the skin, tissues, digestive tract and other organs)
- suffer from severe liver problems
- suffer from narrowing of the arteries to the kidneys
- are more than 3 months pregnant (It is also better to avoid Zofecard in early pregnancy – see pregnancy section.)
- are a woman of child-bearing age unless using effective contraception.
- have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren

Warnings and precautions

Talk to your doctor before taking Zofecard if you:

- have high blood pressure and liver or kidney problems
- have high blood pressure that is caused by a kidney problem or by narrowing of the artery leading to the kidney (renovascular hypertension)
- have recently had a kidney transplant
- are undergoing dialysis
- are on LDL apheresis (a procedure similar to kidney dialysis that clears your blood of harmful cholesterol)
- have abnormally high levels of the hormone aldosterone in your blood (primary aldosteronism)
- have a narrowing of the heart valve (aortic stenosis) or thickening of the heart walls (hypertrophic cardiomyopathy)
- suffer or have suffered from psoriasis (skin disease characterised by scaly pink patches)
- are receiving desensitization treatment ('allergy injections') for insect stings.
- are taking any of the following medicines used to treat high blood pressure:
 - an "angiotensin II receptor blocker" (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan, etc.), in particular if you have diabetes-related kidney problems.
 - aliskiren

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

See also information under the heading "Do not take Zofecard"

Your blood pressure may get too low with Zofecard, especially after the first dose (this is more likely if you are also taking diuretics, are dehydrated or on a low-salt diet). If this happens, tell your doctor immediately and then lie down on your back.

If you are having an operation, tell your anaesthetist that you are taking Zofecard before being anaesthetised. This will help him/her to control your blood pressure and heart rate during the procedure.

In addition if you suffer from heart attack (acute myocardial infarction) and you:

- have low blood pressure (< 100mmHg) or are in a state of circulatory shock (as a result of your heart problem) – Zofecard is not recommended for you
- are over 75 years of age – Zofecard should be used with special care.

You must tell your doctor if you think you are (or might become) pregnant. Zofecard is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section)

Children and adolescents

Do not give this medicine to children and adolescents under the age of 18 years because it is unlikely to be safe.

Other medicines and Zofecard

Tell your doctor if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor if you are taking:

- medicines that increase blood potassium levels (potassium sparing diuretics, such as spironolactone, triamterene, amiloride or potassium supplements), potassium-containing salt substitutes
- lithium (used to treat mood disorders)
- anaesthetics
- narcotic drugs (such as morphine)
- antipsychotic drugs (used to treat schizophrenia and similar illnesses)
- antidepressants of the tricyclic type, e.g. amitriptyline and clomipramine
- other high blood pressure medicines and vasodilators (including beta-blockers, alpha-blockers and diuretics such as hydrochlorothiazide, furosemide, torasemide)

Your doctor may need to change your dose and/or to take other precautions:

If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Zofecard” and “Warnings and precautions”)

- nitroglycerine and other nitrates used for chest pain (angina)
- antacids including cimetidine (used to treat heartburn and stomach ulcers)
- cyclosporin (used after organ transplants) and other immunosuppressant drugs (medicines that suppress your body’s defence)
- allopurinol (used to treat gout)
- insulin or oral anti-diabetic medicines
- cytostatic agents (used to treat cancer or diseases which affect the body’s defence system)
- corticosteroids (powerful anti-inflammatory drugs)
- procainamide (used to control an irregular heart beat)
- nonsteroidal anti-inflammatory drugs (NSAIDs, such as aspirin or ibuprofen)
- sympathomimetic drugs (medicines that act on the nervous system, including some used to treat asthma or hay fever and pressor amines, e.g. adrenalin).

Zofecard with food, drink and alcohol

Zofecard can be taken with food or on an empty stomach, but the tablet is best taken with water. Alcohol increases the hypotensive (lowering of blood pressure) effect of Zofecard; ask your doctor for further advice on drinking alcohol whilst on this medication.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant, if you think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will normally advise you to stop taking Zofecard before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Zofecard.

Zofecard is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

If you are breast-feeding or about to start breast-feeding ask your doctor for advice before taking this medicine. Zofecard is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

This medicine may cause dizziness or tiredness. If this happens to you, do not drive or operate machinery.

Zofecard contains lactose

This product contains lactose - if you know you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE ZOFECARD

Always take Zofecard exactly as your doctor has told you. Check with your doctor if you are not sure. Zofecard may be taken with food or on an empty stomach. The tablet is best taken with water.

Treatment of high blood pressure (hypertension)

The normal starting dose of Zofecard is 15mg, once a day. Your doctor will gradually adjust the dosage (usually at four weeks intervals) to find the dose that suits you best. Long-term antihypertensive effects are usually obtained with 30mg of Zofecard, once a day. The maximum dose is 60mg per day, taken in a single or two divided doses.

If you are dehydrated, have a salt deficiency or are taking diuretics (water pills), it may be necessary to start your treatment with 7.5mg of Zofecard.

Liver or kidney problems

If you have mild to moderate liver impairment or moderate to severe kidney impairment, your doctor will start your treatment with half the therapeutic dose of Zofecard (15mg). If you are receiving dialysis, one-quarter of the usual therapeutic dose (7.5mg) is needed at the start of your treatment.

Heart attack (acute myocardial infarction)

Zofecard treatment should begin within the first 24 hours after the onset of symptoms. You will receive Zofecard tablets twice a day in the morning and evening, as follows:

- 7.5mg twice a day, on the first and second day of treatment
- 15mg twice a day, on the third and fourth day of treatment
- From the fifth day onwards, the dose should be increased to 30mg, twice a day
- Your doctor may adjust your dose or the maximum dose you receive on the basis of your blood pressure measurements
- Treatment will then be continued for a further six weeks, or longer, if symptoms of heart failure persist.

If you take more Zofecard than you should

If you accidentally take too many tablets, contact your doctor or nearest Accident & Emergency department immediately (taking any remaining tablets, the carton or this leaflet with you if possible).

The most frequent symptoms and signs of an overdose are low blood pressure with fainting (hypotension), very slow heart beat (bradycardia), changes in blood chemicals (electrolytes) and kidney dysfunction.

If you forget to take Zofecard

If you miss a dose, take the next dose as soon as you remember. However if a long delay has occurred (e.g. several hours) so that the next due dose is near, skip the forgotten dose and take the next, scheduled, normal dose at the usual time. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Zofecard

Always consult your doctor before stopping Zofecard treatment, whether you are taking it for high blood pressure or following a heart attack.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Most side effects associated with ACE inhibitors are reversible and disappear after treatment is finished.

Common side effects (affecting less than 1 person in every 10 treated):

- fatigue (tiredness)
- nausea and/or vomiting
- dizziness
- headache
- cough.

Less common side effects (affecting less than 1 person in every 100 treated):

- general weakness
- muscle cramps
- skin rash.

Rare side effects (affecting less than 1 person in every 1000 treated):

- rapid swelling and itching, especially around the face, mouth and throat, with possible difficulty in breathing.

In addition to the side effects reported with Zofecard, the following have generally been reported with ACE inhibitors:

- Severe low blood pressure at the start of treatment or when the dosage is increased, with dizziness, impaired vision, fainting (syncope)
- Increased or irregular heartbeat, palpitations and chest pain (heart attack or angina pectoris)
- Impaired consciousness, sudden dizziness, suddenly impaired vision or weakness and/or loss of sense of touch on one side of the body (transient ischaemic attack or stroke)
- Peripheral oedema (accumulation of water in the limbs), low blood pressure on standing, chest pain, muscle aches and/or cramps
- Reduced kidney function, changes in the amount of daily urine, presence of proteins in the urine (proteinuria), impotence
- Abdominal pain, diarrhoea, constipation, dry mouth
- Allergic reactions like skin rash, hives (urticaria), itching, peeling, redness, loosening and blistering of the skin (toxic epidermal necrolysis), worsening of psoriasis (a skin disease characterised by scaly pink patches), hair loss (alopecia)
- Increased sweating and flushing
- Mood changes, depression, sleep disorders, altered skin sensations such as burning, prickling, or tingling (paraesthesia), disorders of balance, confusion, ringing in the ears (tinnitus), taste disturbances, blurred vision
- Difficulty in breathing, narrowing of the airways in the lung (bronchospasm), sinusitis, runny or stuffy nose (rhinitis), inflammation of the tongue (glossitis), bronchitis
- Yellowing of the skin (jaundice), inflammation of the liver or pancreas (hepatitis, pancreatitis), bowel obstruction (ileus)
- Changes in blood tests, such as red blood cell, white blood cell or platelet count or a reduction in all kinds of blood cells (pancytopenia). Contact your doctor if you find that you bruise easily or develop an unexplained sore throat or fever
- Increased blood levels of liver enzymes (transaminases) and bilirubin, increased blood urea and creatinine
- Anaemia due to rupture of red blood cells (haemolytic anaemia), which may occur if you suffer from G6PD (glucose-6-phosphate dehydrogenase) deficiency.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ZOFECARD

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not take Zofecard after the expiry date ('EXP') which is stated on the box and blister pack.

Do not throw away any medicines via wastewater . Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

This leaflet was last revised in 09/2014.