

## Package Leaflet: Information for the user

# OsvaRen® 435 mg / 235 mg film-coated tablets

Calcium acetate/Magnesium carbonate, heavy  
(this will be referred to as OsvaRen® throughout the leaflet)

### Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### In this leaflet:

1. What OsvaRen® is and what it is used for
2. Before you take OsvaRen®
3. How to take OsvaRen®
4. Possible side effects
5. How to store OsvaRen®
6. Further information

## 1. What OsvaRen® is and what it is used for

OsvaRen® is used to treat high blood phosphate levels in patients with chronic kidney impairment who are on dialysis (haemodialysis, peritoneal dialysis).

OsvaRen® belongs to a group of medicines known as phosphate binders. Phosphate is a mineral that affects the health of bones. When your kidney function is impaired you tend to have high phosphate levels in the blood. This can put you at risk of bone problems. OsvaRen® binds phosphate and thereby balances your phosphate levels.

## 2. Before you take OsvaRen®

### Do not take OsvaRen®

- if you are **hypersensitive** (allergic) to **calcium acetate, magnesium carbonate** or any of the other ingredients of OsvaRen®
- if your phosphate blood levels are too low
- if you have **raised calcium blood values**. This can arise due to vitamin-D overdose, tumours of the lung, breast, kidneys or blood, bone metastases, certain lung disorders (sarcoidosis) or from bone loss as a consequence of lack of exercise.
- if you have **raised magnesium values** in the blood and/or corresponding signs
- if you have the **heart rhythm disturbance** called 3rd degree AV-block.
- if you suffer from **muscular fatigue**, including that of the eye muscles and weakness of the muscles used in swallowing, chewing and breathing (myasthenia gravis).

## Take special care with OsvaRen®

Before you take OsvaRen® your doctor will talk to you about any changes in diet because of the effect it has on the phosphate levels in your body and depending on the kind of dialysis you receive.

- OsvaRen® is only to be taken with caution in view of calcium, magnesium and phosphate blood values in the following cases:
  - very high, non-treatable blood phosphate values
  - high, difficult to treat potassium blood values
  - low heart frequency or conduction defects of the heart, which are associated with a slow heart beat (2nd degree AV-block).
- if your calcium and magnesium blood values are too high, your doctor will lower the OsvaRen® dose according to the blood values or discontinue treatment. Adjustment of the amount of calcium and magnesium in the dialysate may be necessary.
- if you take high doses of OsvaRen® over a long time because your magnesium blood values may rise. Possible signs of high magnesium levels are stomach problems such as feeling sick, loss of appetite and constipation. If the magnesium levels are very high you might experience muscle weakness, low blood pressure or even fainting and coma.
- if you have chronic kidney impairment because you may develop high levels of calcium in the blood. Possible signs of high calcium levels are muscle weakness and stomach problems such as bellyache, constipation, feeling and being sick. Please talk to your doctor, if any of these signs occur.
- Be aware of possible symptoms of elevated calcium in your blood as given in section 4.
- if you take OsvaRen® for a long time because calcium deposits in tissue and hence tissue hardening may occur.
- if you develop constipation.
- if you want to take antacids (used to relieve heartburn) that contain calcium or

magnesium. Talk to your doctor before taking antacids because they might add to the amount of calcium and magnesium you are already taking with OsvaRen®.

- if you experience diarrhoea. In this case, please contact your doctor and take a lower dose of OsvaRen®.

Your doctor will regularly check your levels of phosphate, magnesium, calcium and the calcium-phosphate-product in your blood. If your calcium and magnesium blood values are too high, your doctor will lower the OsvaRen® dose according to the blood values or discontinue treatment. Adjustment of the amount of calcium and magnesium in the dialysate may be necessary.

## Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- The calcium value in the blood is to be monitored if the following are being taken:
  - **vitamin D**, as it increases the level of calcium in your body
  - **certain diuretic** substances (water pills), such as hydrochlorothiazide, as the calcium levels in your body may rise
- **oestrogens**, as female sex hormones, increase the calcium levels in your body
- OsvaRen® can lower the levels and hence the effect of the following medicines:
  - **antibiotics**, such as tetracycline, doxycycline, ciprofloxacin, norfloxacin, cefpodoxime, cefuroxime
  - **bisphosphonates**, such as alendronate and risedronate, medicines to treat bone diseases
  - **fluorides** to prevent and treat caries and bone disorders
  - **ketconazole**, a medicine to treat fungal infections
  - **estramustine**, a medicine to treat prostate cancer
  - **anticholinergics**, substances to treat Parkinson's disease and irritable bladder

- **zinc**
- **urso-** and **chenodesoxycholic acid**, substances to treat gall stones,
- **halofantrine**, a medicine to treat malaria
- **iron** preparations
- **digoxin** (a cardiac glycoside), a medicine to enhance the performance of the heart
- **nitrofurantoin**, a substance to treat urinary tract infections
- **penicillamine**, a medicine to treat chronic inflammation of the joints
- OsvaRen® can increase the levels and hence the effect of the following medicines:
  - **levothyroxine**, a drug used in impaired function of the thyroid gland
- OsvaRen® can increase the calcium values and hence the effect of the following agents:
  - **digitalis glycosides** (cardiac glycosides such as digoxin) as a medicine to enhance the performance of the heart
  - **adrenaline**, a substance to control allergic reactions and to treat shock. Possible consequences can even lead to severe disorders of heart rhythm.

If you need a medicine like digitalis glycosides (such as digoxin or digitoxin) your doctor will do ECG monitoring.

- OsvaRen® can reduce the effect of the following medicine:
  - **Calcium antagonists**, such as verapamil, an agent to lower blood pressure.

No other oral medicines mentioned in this leaflet should be taken within the period 2 hours before and 3 hours after the intake of OsvaRen®. Also if you take OsvaRen® as recommended, OsvaRen® may influence the effects of other medicines due its effect on the blood calcium levels.

## Taking OsvaRen® with food and drink

OsvaRen® should be taken with meals.

## Pregnancy and breast-feeding

There are no data available on the use of OsvaRen® during pregnancy and breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

### Pregnancy

You should take OsvaRen® only if your treating physician believes that the potential benefits outweigh the risk. Your calcium and magnesium levels will be checked regularly.

### Breastfeeding

Breastfeeding is not recommended if you take OsvaRen®.

## Driving and using machines

No particular precautions are necessary.

## Important information about some of the ingredients of OsvaRen®

This medicinal product contains sucrose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

OsvaRen® contains sodium. This has to be taken into consideration by patients on a controlled sodium diet.

### 3. How to take OsvaRen®

Always take OsvaRen® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

#### Use in children and adolescents:

Insufficient information on the use of OsvaRen® is available in these patient groups. Therefore, the administration of OsvaRen® is not recommended in children and adolescents below 18 years of age (see section 2).

#### Adults

The dosage to be taken should be prescribed and monitored by your doctor according to the level of phosphate values in your blood.

#### Recommended dose: 3 to 10 film-coated tablets

Maximum daily dose: 12 film-coated tablets

The recommended starting dose is 3 tablets daily. Take the tablets together with food.

The dose is then increased gradually until the desired phosphate levels in the blood are reached, unless you develop high blood calcium levels.

The film-coated tablets are to be taken at mealtimes. Do not crush or chew the tablets. If you cannot swallow the tablets whole, you may break them along the score line immediately before you take them.

Breaking the tablets immediately before taking will avoid the development of an unpleasant taste.

No other oral medicines mentioned in this leaflet should be taken within the period 2 hours before and 3 hours after the intake of OsvaRen®.

OsvaRen® can be used over a longer period, whereby your doctor should decide the exact length of time.

Please speak to your doctor or pharmacist if you have the impression that the effect of OsvaRen® is too strong or too weak.

#### If you take more OsvaRen® than you should

Consult your doctor, as the calcium and magnesium blood values will go up and can lead to serious side effects.

Typical signs of high calcium and magnesium blood values are gastric disorders, muscle weakness, low blood pressure, nausea, loss of appetite, constipation, heart rhythm disturbances and sleepiness. Typical signs of extremely high calcium blood values are loss of energy, unconsciousness and even coma.

Typical signs of extremely high magnesium blood values are low blood pressure and even coma.

#### If you forget to take OsvaRen®

In case of a missed dose, the next dose should be taken at the normal time (no attempt should be made to make up for the missed dose).

Always take the medicine with food.

#### If you stop taking OsvaRen®

Do not interrupt or stop taking OsvaRen® without consulting your doctor.

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

### 4. Possible side effects

Like all medicines, OsvaRen® can cause side effects, although not everybody gets them. The following frequencies have been used for the assessment of side effects:

very common	more than 1 in 10 people treated
common	less than 1 in 10, but more than 1 in 100 people treated
uncommon	less than 1 in 100, but more than 1 in 1000 people treated
rare	less than 1 in 1000, but more than 1 in 10 000 people treated
very rare	less than 1 in 10 000 people treated, not known (cannot be estimated from the available data)

#### common

- gastro-intestinal disorders such as
  - soft stools
  - nausea
  - loss of appetite
  - feeling of fullness
  - belching
  - constipation
  - diarrhoea
- increase in calcium blood level, which can occur without symptoms or in connection with symptoms such as
  - constipation
  - loss of appetite,
  - feeling sick
  - being sick
- increase in magnesium blood level, mostly without symptoms

#### uncommon

- moderate to severely increased calcium blood levels, which can be associated with the following complaints:
  - disturbed consciousness such as disorientation, unconsciousness (stupor) and even coma
  - weakness
  - confusion
  - increased excretion of calcium in the urine
  - hypo-acidification of the blood
  - heart rhythm disturbances
  - high blood pressure
  - hardening of tissues (deposit of calcium salts)
- moderate to severely increased magnesium blood levels, which can be associated with the following complaints:
  - tiredness
  - muscle weakness
  - sleepiness ranging to diminished consciousness
  - lowered pulse
  - drop in blood pressure

#### very rare

- raised potassium blood levels
- disturbed mineral balance of the bones

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### 5. How to store OsvaRen®

Keep out of the reach and sight of children. Do not use OsvaRen® after the expiry date which is stated on the container after 'EXP'. The expiry date refers to the last day of that month. After first opening of the container, use OsvaRen® within 3 months. Keep the container tightly closed in order to protect the contents from moisture. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### 6. Further information

#### What OsvaRen® contains

The **active substances** are **calcium acetate and magnesium carbonate, heavy**.

Each film-coated tablet contains 435 mg calcium acetate, equivalent to 110 mg calcium and 235 mg magnesium carbonate heavy, equivalent to 60 mg magnesium. Each film-coated tablet contains not more than 5.6 mg sodium and 50 mg sucrose.

The other ingredients are

- Tablet core: Starch, pregelatinised (from maize), maize starch, sucrose, gelatin, croscarmellose sodium and magnesium stearate
- Tablet film-coating: Castor oil, refined and hypromellose.

#### What OsvaRen® looks like and contents of the pack

White to weakly yellow, elongated, scored film-coated tablet. The score line only serves to divide the tablet in order to make it easier to swallow and not to divide it up into equal doses.

OsvaRen® is available in a polyethylene container with 180 film-coated tablets.

### Marketing Authorisation Holder

Fresenius Medical Care Nephrologica Deutschland GmbH  
61346 Bad Homburg v.d.H., Germany

### Manufacturer

Fresenius Medical Care Deutschland GmbH  
61346 Bad Homburg v.d.H., Germany

### Further information on this medicine, including package information in formats suitable for the blind and partially-sighted, is available from the local representative of the Marketing Authorisation Holder:

Fresenius Medical Care (UK) Ltd., Nunn Brook Road, Huthwaite  
Nottinghamshire NG17 2HU, England - Tel.: 0044 (0)1623 445100  
Fresenius Medical Care (Ireland) Ltd  
Grattan House, Malahide Road, Dublin 17, Ireland  
Pharma-Cos Ltd., Pharma-Cos House, Triq C. Portanier,  
Santa Venera SVR 1732, Malta, Tel: (+356) 21441870,  
Fax: (+356) 21441388, Email: info@pharma-cos.com

### This medicinal product is authorised in the Member States of the EEA under the following names:

A, CY, CZ, D, DK, E, EST, F, FIN, GR, H, I, IRL, IS, L,  
LT, LV, M, N, NL, P, PL, S, SK, SLO, UK: OsvaRen  
B: Renepho

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