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

OsvaRen® is a medicine used in patients with chronic kidney impairment who are on dialysis (haemodialysis, peritoneal dialysis), OsvaRen® is also used in patients with primary hyperparathyroidism (see below).

Parathyroid hormone is a hormone produced in the parathyroid glands. Parathyroid hormone is a hormone 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. What you need to know before you take OsvaRen®

Do not take OsvaRen®

- if you are allergic (are sensitive or have a bad reaction) to calcium carbonate, magnesium carbonate or any of the other ingredients of this medicine (listed in section 6).
- if you have phosphate blood levels too low.
- if you have calcium blood levels too high.
- if you have kidney impairment who are on dialysis. If your calcium and magnesium blood values are too high, your doctor will lower the dose of this drug or discontinue treatment. Adequate treatment in patients with kidney impairment is very limited amount of data on the use of OsvaRen® during pregnancy and breastfeeding.
- if you are pregnant or breastfeeding. Take OsvaRen® with food to reduce side effects.
- if you want to take antacids (used to relieve heartburn) that contain calcium or magnesium, you are already taking with OsvaRen®. Talk to your doctor before taking, because they might add to the amount of calcium-phosphate-product in your blood.
- if you have cataracts (clouding of the eye) or any of the following medicines:
- if you experience diarrhoea. In this case, please contact your doctor and take a medicine to treat diarrhoea.
- if you have diarrhoea. Talk to your doctor before taking, because they might add to the amount of calcium-phosphate-product in your blood.
- if you have high phosphate blood levels too high. Your doctor will check regularly.

Taking OsvaRen® with food

1. How should I take OsvaRen®

OsvaRen® can lower the levels and hence the effect of the following medicines:
- enalapril, an agent to lower blood pressure
- penicillamine, a substance to treat urinary tract infections
- metronidazole, a medicine to treat malaria
- calcium acetate, magnesium carbonate, calcium and magnesium phosphate products in your blood.
- if you have heart rhythm disturbances (see chapter 5.2.4).
- if you have heart rhythm disturbances (see chapter 5.2.4).
- if you need to take a diuretic (a substance to decrease water in the body) that increases the level of calcium in your body.
- if you have impaired function of the thyroid gland (see chapter 5.2.4).
- if you are drinking more than 3 glasses of alcohol a day for more than 1 month. Your calcium and magnesium levels will be checked regularly.
- if you take OsvaRen® for a long time because calcium deposits in tissue and hence can put you at risk of bone problems.
- if you have low phosphate blood levels too low. Your doctor will check regularly.
- if you experience heart rhythm disturbances (see chapter 5.2.4).

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

If you experience heart rhythm disturbances (see chapter 5.2.4).

1. How should I take OsvaRen®

- if you take OsvaRen® for a long time because calcium deposits in tissue and hence can put you at risk of bone problems.
- if you have heart rhythm disturbances (see chapter 5.2.4).

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

- if you develop constipation.
- if you have diabetes, you can only take OsvaRen® if your doctor will do ECG monitoring and control your calcium level during administration.
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3. How do I take OsvaRen®

- if you are pregnant or breastfeeding. Take OsvaRen® with food to reduce side effects.
- if you want to take antacids (used to relieve heartburn) that contain calcium or magnesium, you are already taking with OsvaRen®. Talk to your doctor before taking, because they might add to the amount of calcium-phosphate-product in your blood.
- if you have cataracts (clouding of the eye) or any of the following medicines:
- if you experience diarrhoea. In this case, please contact your doctor and take a medicine to treat diarrhoea.
- if you have diarrhoea. Talk to your doctor before taking, because they might add to the amount of calcium-phosphate-product in your blood.
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- if you take OsvaRen® for a long time because calcium deposits in tissue and hence can put you at risk of bone problems.
- if you have low phosphate blood levels too low. Your doctor will check regularly.
3. How to take OsvaRen®

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

Taking the medicine

Do not take OsvaRen® if you are allergic to calcium or magnesium. Do not take OsvaRen® if you have high blood calcium or magnesium levels. Other medicines can also cause side effects, although not everybody gets them.

Do not take OsvaRen® if you have the following:• raised potassium blood levels
• raised magnesium blood levels
• raised calcium blood levels, mostly without symptoms
• increased excretion of calcium in the urine
• hypo-acidification of the blood
• disturbed consciousness such as disorientation, unconsciousness (stupor) and even coma

If you have the impression that the effect of OsvaRen® is too strong or too weak, please talk to your doctor or pharmacist.

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

The recommended dose is 3 to 10 film-coated tablets daily. Keep the container tightly closed in order to protect the medicine from moisture. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. This medicine must be kept out of the sight and reach of children.

4. Possible side effects

Typical signs of high magnesium blood values are gastric disorders, weakness, loss of appetite, nausea, loss of appetite, constipation, heart rhythm disturbances and loss of consciousness. Typical signs of extremely high calcium blood values are loss of energy, unconsciousness and even coma. These measures will help to protect the environment.

Typical signs of extremely high magnesium blood levels are loss of blood pressure, nausea, loss of appetite, constipation, heart rhythm disturbances and loss of consciousness.

4.1. Common side effects

• nausea
• vomiting
• loss of appetite
• feeling of fullness
• bloating
• diarrhoea
• flatulence

If you take more OsvaRen® than you should

If you forget to take OsvaRen®

If you take more OsvaRen® than you should consult your doctor, as the calcium and magnesium blood values will go up and can cause serious side effects.

•  moderate to severely increased magnesium blood levels, which can be associated with the following complaints:
  - hardening of tissues (deposit of calcium salts)
  - high blood pressure
  - heart rhythm disturbances
  - constipation
  - hardening of the blood

5. How to store OsvaRen®

Keep this medicine in a cool, dry place and keep it tightly closed.

5.1. Substances and their uses

The medicine is available in a polyethylene container with 180 film-coated tablets. Wait at your pharmacy how to throw away medicines you no longer use. This medicine must be kept out of the sight and reach of children.

6. Contents of the pack and other information

What OsvaRen® contains

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. The active substances are calcium acetate and magnesium carbonate, refined and hypromellose.

What OsvaRen® looks like and contents of the pack

The following complaints:

6.1. How long does OsvaRen® last?

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