Renvela®
sevelamer carbonate

sanofi

genzyme
A SANOFI COMPANY

QUALITATIVE AND QUANTITATIVE COMPOSITION

~~RENVELA Film-coated tablet:~~ Each tablet contains 800 mg sevelamer carbonate

PHARMACEUTICAL FORM

~~RENVELA Film-coated tablet:~~ The white to off-white oval tablet, engraved with “RV800” on one side.

CLINICAL PARTICULARS

Therapeutic indications

Renvela is indicated for the control of hyperphosphatemia in adult patients receiving haemodialysis or peritoneal dialysis.

Renvela is also indicated for the control of hyperphosphataemia in adult patients with chronic kidney disease not on dialysis with serum phosphorus ≥1.78 mmol/l

Renvela should be used within the context of a multiple therapeutic approach, which could include calcium supplement, 1,25-dihydroxy Vitamin D3 or one of its analogues to control the development of renal bone disease.

Posology and method of administration

Posology

Starting dose

The recommended starting dose of sevelamer carbonate is 2.4 g or 4.8 g for adult per day based on clinical needs and serum phosphorus level. Renvela must be taken three times per day with meals.

Serum phosphorus level in patients	**Total daily dose of sevelamer carbonate to be taken over 3 meals per day**
1.78 – 2.42 mmol/l (5.5 – 7.5 mg/dl)	2.4 g*
>2.42 mmol/l (>7.5 mg/dl)	4.8 g*

*Plus subsequent titrating as per instructions

For patients previously on phosphate binders (sevelamer hydrochloride or calcium based), Renvela should be given on a gram for gram basis with monitoring of serum phosphorus levels to ensure optimal daily doses.

Titration and Maintenance

Serum phosphorus levels must be monitored and the dose of sevelamer carbonate titrated, every 2-4 weeks until an acceptable serum phosphorus level is reached, with regular monitoring thereafter.

Patients taking Renvela should adhere to their predscribed diets.

In clinical practice, treatment will be continuous based on the need to control serum phosphorus levels and the adult daily dose is expected to be an average of approximately 6 g per day.

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Paediatric population

Due to lack of data, the safety and efficacy of Renvela tablet has not been established in children. Renvela is not recommended in children.

Method of administration

~~Renvela Film-coated tablet:~~

Tablets should be swallowed intact and should not be crushed, chewed, or broken into pieces prior to administration. Renvela should be taken with food and not on an empty stomach.

Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in "*List of excipients"*
- Hypophosphataemia
- Bowel obstruction

Special warnings and precautions for use

Efficacy and safety of Renvela has not been studied in children below the age of 18 years.

The safety and efficacy of Renvela have not established in adult patients with chronic kidney disease not on dialysis with serum phosphorus < 1.78 mmol/l. Therefore, Renvela is currently not recommended for use in these patients.

The safety and efficacy of Renvela have not been established in patients with the following disorders:

- dysphagia
- swallowing disorders
- severe gastrointestinal motility disorders including untreated or severe gastroparesis, retention of gastric contents and abnormal or irregular bowel motion
- active inflammatory bowel disease
- major gastrointestinal tract surgery

~~t~~Therefore, caution should be exercised when Renvela is used in these patients.

Intestinal obstruction and ileus/sub-ileus

In very rare cases, intestinal obstruction and ileus/sub-ileus have been observed in patients during treatment with sevelamer hydrochloride, which contains the same active moiety as sevelamer carbonate. Constipation may be a preceding symptom. Patients who are constipated should be monitored carefully while being treated with Renvela. Renvela treatment should be re-evaluated in patients who develop severe constipation or other severe gastrointestinal symptoms.

Fat-soluble vitamins

Patients with CKD may develop low levels of fat-soluble vitamins A, D, E and K, depending on dietary intake and the severity of their disease. It cannot be excluded that Renvela can bind fat-soluble vitamins contained in ingested food. In patients not taking supplemental vitamins but on sevelamer, serum vitamin A, D, E and K status should be assessed regularly. It is recommended that vitamin supplements be given if necessary. It is recommended that CKD patients, not on dialysis are given vitamin D supplements (approximately 400 IU of native vitamin D daily) which can be part of a multivitamin preparation to be taken apart from their dose of Renvela. In patients undergoing peritoneal dialysis additional monitoring of fat-~~–~~soluble vitamins and folic acid is recommended, since vitamin A, D, E, and K levels were not measured in a clinical study in these patients.

Folate deficiency

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There is at present insufficient data to exclude the possibility of folate deficiency during long term Renvela treatment.

Hypocalcaemia/hypercalcaemia

Patients with CKD may develop hypocalcaemia or hypercalcaemia. Renvela does not contain any calcium. Serum calcium levels should therefore be monitored at regular intervals and elemental calcium should be given as a supplement if required.

Metabolic acidosis

Patients with chronic kidney disease are predisposed to developing metabolic acidosis. As part of good clinical practice, monitoring of serum bicarbonate levels s therefore recommended.

Peritonitis

Patients receiving dialysis are subject to certain risks for infection specific to dialysis modality. Peritonitis is a known complication in patients receiving peritoneal dialysis and in a clinical study with sevelamer hydrochloride, a greater number of peritonitis cases were reported in the sevelamer group than in the control group. Patients in peritoneal dialysis should be closely monitored to ensure the correct use of appropriate aseptic technique with the prompt recognition and management of any signs and symptoms associated with peritonitis.

Swallowing and choking difficulties

Uncommon reports of difficulty swallowing the Renvela tablet have been reported. Many of these cases involved patients with co-morbid conditions including swallowing disorders or oesophageal abnormalities. Caution should be exercised when Renvela is used in patients with difficulty swallowing.

Anti-arrhythmic and anti-seizure medicinal products

Caution should be exercised when prescribing Renvela to patients also taking anti-arrhythmias and anti-seizure medicinal products (see "Interaction with other medicinal products and other forms of interaction").

Hypothyroidism

Closer monitoring of patients with hypothyroidism co-administered with sevelamer carbonate and levothryroxine is recommended (see "Interaction with other medicinal products and other forms of interaction").

Long-term chronic treatment

In a clinical trial of one year, no evidence of accumulation of sevelamer was seen. However, the potential absorption and accumulation of sevelamer during long-term chronic treatment (> one year) cannot be totally excluded (see "Pharmacokinetic properties ").

Hyperparathyroidism

Renvela is not indicated for the control of hyperparathyroidism. In patients with secondary hyperparathyroidism Renvela should be used within the context of a multiple therapeutic approach, which could include calcium as supplements, 1,25 - di hydroxy Vitamin D3 or one of its analogues to lower the intact parathyroid hormone (iPTH) levels.

Inflammatory Gastrointestinal Disorders

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Cases of serious inflammatory disorders of different parts of the gastrointestinal tract (with complications including hemorrhage, perforation, ulceration, necrosis. colitis, and colonic/cecal mass) associated with the presence of sevelamer crystals have been reported (see “Undesirable effects — Post-marketing experience”).
Inflammatory disorders may resolve upon Renvela discontinuation.
Treatment with Renvela should be re-evaluated in patients who develop severe gastrointestinal symptoms.

Interaction with other medicinal products and other forms of interaction
Dialysis
Interaction studies have not been conducted in patients on dialysis.

Ciprofloxacin
In interaction studies in healthy volunteers, sevelamer hydrochloride, which contains the same active moiety as Renvela, decreased the bioavailability of ciprofloxacin by approximately 50% when co-administered with sevelamer hydrochloride in a single dose study. Consequently, Renvela should not be taken simultaneously with ciprofloxacin.

Ciclosporin. mycophenolate mofetil and tacrolimus in transplant patients
Reduced levels of ciclosporin, mycophenolate mofetil and tacrolimus have been ~~reporled~~reported in transplant patients when co-administered with sevelamer hydrochloride without any clinical consequences (i.e graft rejection). The possibility of an interaction cannot be excluded and a close monitoring of blood concentrations of ciclosporin, mycophenolate mofetil and tacrolimus should be considered during the use of combination and after its withdrawal.

Levothyroxine
Very rare cases of hypothyroidism have been repo ted in patients co-administered sevelamer hydrochloride, which contains the same active moiety as sevelamer carbonate. and levothyroxine.
Closer monitoring of thyroid stimulating hormone (TSH) levels is therefore recommended in patients receiving sevelamer carbonate and levothyroxine.

Anti-arhythmics and anti-seizure medicinal products
Patients taking anti-arrhythmic medicinal products for the control of arrhythmias and anti-seizure medicinal products for the control of seizure disorders were excluded from clinical trials. Caution should be exercised when prescribing Renvela to patients also taking these medicinal products.

Digoxin, warfarin, enalapril or metoprolol
In interaction studies in healthy volunteers, sevelamer hydrochloride, which contains the same active moiety as Renvela, had no effect on the bioavailabilily of digoxin, warfarin, enalapril or metoprolol.

Proton pump inhibitors
During postmarketing experience, very rare cases of increased phosphate levels have been reported in patients taking proton pump inhibitors co-administered with sevelamer carbonate.

Bioavailability
Renvela is not absorbed and may affect the bioavailability of other medicinal products. When administering any medicinal product where a reduction in the bioavailability could have a clinically

significant effect on safety or efficacy, the medicinal product should be administered at least one hour before or three hours after Renvela, or the physician should consider monitoring blood levels.

Fertility, pregnancy and lactation

Pregnancy

There are no data from the use of sevelamer in pregnant women. Studies in animals have shown some reproductive toxicity when sevelamer was administered to rats at high doses (see "Preclinical safety data".

Sevelamer has also been shown to reduce the absorption of several vitamins including folic acid (see "Special warnings and precautions for use" and "Preclinical safety data"). The potential risk to humans is unknown. Renvela should only be given to pregnant women if clearly needed and after a careful risk/benefit analysis has been conducted for both the mother and foetus.

Breast-feeding

It is unknown whether sevelamer is excreted in human breast milk. The non-absorbed nature of sevelamer indicates that excretion of sevelamer in breast milk is unlikely. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with Renvela should be made taking into account the benefit of breast-feeding to the child and the benefit of Renvela therapy to the woman.

Fertility

There are no data from the effect of sevelamer on fertility in humans. Studies in animals have shown that sevelamer did not impair fertility in male or female rats at exposures at a human equivalent dose 2 times the maximum clinical trial dose of 13 g/day, based on a comparison of relative body surface area.

Effects on ability to drive and use machines

Sevelamer has no or negligible influence on the ability to drive and use machines.

Undesirable effects

Summary of the safety profile

The most frequently occurring (25% of patients) undesirable effects possibly or probably related to sevelamer were all in the gastrointestinal disorders system organ class. Most of these adverse reactions were mild to moderate in intensity.

Tabulated list of adverse reactions

The safety of sevelamer (as either carbonate and hydrochloride salts) has been investigated in numerous clinical trials involving a total of 969 haemodialysis patients with treatment duration of 4 to 50 weeks (724 patients treated with sevelamer hydrochloride and 245 with sevelamer carbonate), 97 peritoneal dialysis patients with treatment duration of 12 weeks (all treated with sevelamer hydrochloride) and 128 patients with CKD not on dialysis with treatment duration of 8 to 12 weeks (79 patients treatment with sevelamer hydrochloride and 49 with sevelamer carbonate).

Data possibly or probably related to sevelamer from these studies are listed by frequency in the table below.

The reporting rate is classified as very common (= 1/ 10), common (> 1/ 100, < 1/10), uncommon (> 1/ 1,000, < 1/ 100), rare (= 1/10.000, < 1/1,000), very rare (< 1/ 10,000), not known (cannot be estimated from the available data).

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Gastrointestinal disorders
Very common: Nausea, vomiting, upper abdominal pain, constipation
Common: Diarhoea, dyspepsia, flatulence, abdominal pain, abdominal distension
Not known: Pruritus, rash, intestinal obstruction, ileus/sub-ileus, and intestinal perforation

Post-marketing experience: Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

During post-marketing experience, the following adverse events have been reported in patients receiving Renvela: Hypersensitivity, pruritus, rash, abdominal pain and uncommon cases of ileus. Intestinal obstruction and intestinal perforation.

Cases of serious inflammatory disorders of the gastrointestinal tract (with complications including hemorthage, perforation, ulceration, necrosis, colitis, and intestinal mass) associated with the presence of sevelamer crystals have been reported (see “Special warnings and precautions for use”).

Reporting suspected adverse effect

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Healthcare professionals are asked to report any suspected adverse reaction via farmakovigilans@kalventis.com and Pusat Farmakovigilans/MESO Nasional Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif Badan Pengawas Obat dan Makanan. Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560
Email: pvcenter@pom.go.id
Phone: +62-21-4244691 Ext.1079
Website: https://e-meso.pom.go.id/

Overdose

No cases of overdose have been reported. Sevelamer hydrochloride, which contains the same active moiety as sevelamer carbonate. has been given to normal healthy volunteers in doses of up to 14 grams per day for eight days with no undesirable effects. In CKD patients, the maximum average daily dose studied was 14.4 grams of sevelamer carbonate in a single daily dose.
In case of overdose, contact your physician immediately.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: Treatment of hyperphosphataemia.
ATC code: V03AE02.

Mechanism of action:

Renvela contains sevelamer, a non-absorbed phosphate binding crosslinked polymer. free of metal and calcium. Sevelamer contains multiple amines separated by one carbon from the polymer backbone which become protonated in the stomach. These protonated amines bind negatively charged ions such as dietary phosphate in the intestine. By binding phosphate in the gastrointestinal tract and decreasing absorption, sevelamer lowers the phosphorus concentration in the serum. Regular monitoring of serum phosphorus levels is always necessary during phosphate binder administration.

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In two randomised, cross over clinical studies, sevelamer carbonate in both tablet and powder formulations when administered three times per day has been shown to be therapeutically equivalent to sevelamer hydrochloride and therefore effective in controlling serum phosphorus in CKD patients on haemodialysis.
The first study demonstrated that sevelamer carbonate tablets dosed three times per day was equivalent to sevelamer hydrochloride tablets dosed three times per day in 79 haemodialysis patients treated over two randomised ~~8 week~~8-week treatment periods (mean serum phosphorus time-weighted averages were 1.5 + 0.3 mmol/l for both sevelamer carbonate and sevelamer hydrochloride). The second study demonstrated that sevelamer carbonate powder dosed three times per day was equivalent to sevelamer hydrochloride tablets dosed three times per day in 31 hyperphosphataemic (defined as serum phosphorus levels > 1.78 mmol/1) haemodialys is patients over two randomised ~~4 week~~4-week treatment periods (mean serum phosphorus time-weighted averages were 1.6 + 0.5 mmol/1 for sevelamer carbonate powder and 1.7 + 0.4 mmol/1 for sevelamer hydrochloride tablets).

In the clinical studies in haemodialysis patients, sevelamer alone did not have a consistent and clinically significant effect on serum intact parathyroid hormone (iPTH). In a ~~12 week~~12-week study involving peritoneal dialysis patients however, similar iPTH reductions were seen compared with patients receiving calcium acetate. In patients with secondary hyperparathyroidism Renvela should be used within the context of a multiple therapeutic approach, which could include calcium as supplements, 1,25 - dihydroxy Vitamin D3 or one of its analogues to lower the intact parathyroid hormone (iPTH) levels.

Sevelamer has been shown to bind bile acids in vitro and in vivo in experimental animal models. Bile acid binding by ion exchange resins is a well-established method of lowering blood cholesterol. In clinical trials of sevelamer, both the mean total-cholesterol and LDL-cholesterol declined by 15-39%. The decrease in cholesterol has been observed after 2 weeks of treatment and is maintained with long-term treatment.
Triglycerides, HDL-cholesterol and albumin levels did not change following sevelamer treatment.
Because sevelamer binds bile acids, it may interfere with the absorption of ~~fat soluble~~fat-soluble vitamins such as A, D, E and K.

Sevelamer does not contain calcium and decreases the incidence of hypercalcaemic episodes as compared to patients using ~~calcium based~~calcium-based phosphate binders alone. The effects of sevelamer on phosphorus and calcium were proven to be maintained throughout a study with one year follow-up. This information was obtained from studies in which sevelamer hydrochloride was used.

Pharmacokinetic properties
Pharmacokinetic studies have not been carried out with sevelamer carbonate, Sevelamer hydrochloride, which contains the same active moiety as sevelamer carbonate, is not absorbed from the gastrointestinal tract, as confirmed by an absorption study in healthy volunteers.

Preclinical safety data
Non-clinical data with sevelamer reveal no special hazard for humans based on conventional studies of safety pharmacology. repeated dose toxicity or genotoxicity.

Carcinogenicity studies with oral sevelamer hydrochloride were conducted in mice (doses of up to 9 g/kg/day) and rats (0.3, 1, or 3 g/kg/day). There was an increased incidence of urinary bladder transitional cell papilloma in male rats of the high dose group (human equivalent dose twice the maximum clinical trial dose of 14.4 g). There was no increased incidence of tumors observed in mice (human equivalent dose 3 times the maximum clinical trial dose).

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In an in vitro mammalian cytogenetic test with metabolic activation, sevelamer hydrochloride caused a statistically significant increase in the number of structural chromosome aberrations. Sevelamer hydrochloride was not mutagenic in the Ames bacterial mutation assay.

In rats and dogs, sevelamer reduced absorption of ~~fat soluble~~fat-soluble vitamins D, E and K (coagulation factors), and folic acid.

Deficits in skeletal ossification were observed in several locations in foetuses of female rats dosed with sevelamer at intermediate and high doses (human equivalent dose less than the maximum clinical trial dose of 14.4 g). The effects may be secondary to vitamin D depletion.

In pregnant rabbits given oral doses of sevelamer hydrochloride by gavage during organogenesis, an increase of early resorptions occurred in the high-dose group (human equivalent dose twice the maximum clinical trial dose).

Sevelamer hydrochloride did not impair the fertility of male or female rats in a dietary administration study in which the females were treated from 14 days prior to mating through gestation and the males were treated for 28 days prior to mating. The highest dose in this study was 4.5 g/kg/day (human equivalent dose 2 times the maximum clinical trial dose of 13 g/day, based on a comparison of relative body surface area).

PHARMACEUTICAL PARTICULARS

List of excipients

~~Renvela Film-coated tablet:~~

Tablet core: microcrystalline cellulose, sodium chloride, zinc stearate, purified water.
Film-coating: coating solution consist of: hypromellose, diacetylated monoglycerides

Incompatibilities

Not applicable.

Shelf life

~~The shelf-life for Renvela Film-coated tablet is~~ 3 years~~.~~

Special precautions for storage

~~Renvela Film-coated tablet:~~

Do not store above 30°C.
Keep out of the sight and reach of children.
Keep the bottle tightly closed in order to protect from moisture.

Nature and contents of container

~~Renvela Film-coated tablet:~~

HDPE bottles with a propylene cap and a foil induction seal.
Each bottle contains 30 tablets.

Special precautions for disposal and other handling

~~Renvela Film-coated tablet:~~

No special requirements for disposal.

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Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

HARUS DENGAN RESEP DOKTER
ON MEDICAL PRESCRIPTION ONLY

~~RENVELA Film-coated tablet :~~
Reg. No. DKI2477404417A1

Manufactured by:
Sanofi Winthrop Industrie,
CARBON BLANC - France

Registered by:
PT Kalventis Sinergi Farma,
Jakarta - Indonesia

~~Date of text revision:~~
~~As on approval date~~
Approval date:
Based on approval BPOM dated xxx - Standar Informasi Obat (SIO)

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LEAFLET KEMASAN: INFORMASI BAGI PENGGUNA

Renvela®
sevelamer carbonate

sanofi

genzyme
A SANOFI COMPANY

Kkomposisi

~~RENVELA Tablet salut selaput:~~ Setiap tablet mengandung 800 mg sevelamer carbonate.

Bacalah seluruh bagian lembaran ini dengan teliti sebelum Anda mulai mengkonsumsi obat ini karena di dalamnya terdapat informasi penting untuk Anda.

- Simpan lembaran ini. Suatu saat Anda mungkin memerlukannya.
- Jika Anda mempunyai pertanyaan lebih jauh, tanyakan kepada dokter atau apoteker yang biasa membantu Anda.
- Obat ini diresepkan hanya untuk Anda. Jangan diberikan kepada siapapun karena dapat mengganggu kesehatannya, sekalipun gejala yang mereka alami mirip dengan pengalaman Anda.
- Jika Anda mengalami efek samping. periksakan ke dokter. Demikian halnya jika efek samping yang muncul tidak tercantum dalam lembaran ini.

Apa saja informasi dalam lembaran ini

1. Apakah RENVELA itu dan apa khasiatnya

RENVELA mengandung zat aktif sevelamer carbonate. yang mengikat fosfat dari makanan dalam saluran pencernaan sehingga mengurangi kadar serum fosfor dalam darah.

Renvela digunakan untuk mengontrol hiperfosfatemia (kadar fosfat tinggi dalam darah) pada:

- Pasien dewasa yang melakukan dialisis (suatu teknik untuk pembersihan darah/cuci darah). Obat ini dapat digunakan pada pasien yang melakukan hemodialisis (menggunakan mesin penyaring darah) ataupun dialisis peritoneal (dimana cairan dipompakan ke perut dan suatu membran dalam tubuh akan menyaring darah)
- Pasien dengan penyakit ginjal kronis yang tidak melakukan dialysis dan memiliki kadar fosfor dalam darah sama atau lebih tinggi dari 1.78 mmol/l.

Renvela harus digunakan bersama pengobatan lainnya seperti supplemen kalsium dan vitamin D untuk mencegah berkembangnya penyakit tulang.

Pasien yang ginjalnya tidak berfungsi dengan baik tidak mampu mengendalikan kadar serum fosfor dalam darah. Jumlah fosfat kemudian meningkat (hyperphosphataemia). Peningkatan kadar serum fosfor dapat menyebabkan pengkristalan dalam tubuh yang disebut kalsifikasi. Pengkristalan itu

dapat mengakibatkan pembuluh darah menjadi kaku dan menghambat peredaran darah ke seluruh tubuh.

Serum fosfor yang meningkat juga dapat mengakibatkan gatal pada kulit, mata memerah, nyeri tulang dan patah tulang.

2. Apa yang perlu Anda ketahui sebelum mengonsumsi RENVELA

Jangan mengkonsumsi RENVELA jika:

- Kadar fosfat dalam darah Anda rendah (dokter perlu memeriksa hal ini)
- Anda mengalami penyumbatan usus
- Anda alergi terhadap zat aktif obat ini atau unsur-unsur lainnya (tertera pada bagian “Isi kemasan dan informasi lainnya”).

Peringatan dan Tindakan Pencegahan

- Konsultasikan dengan dokter sebelum mengkonsumsi RENVELA jika Anda mengalami sebagian dari
- gejala di bawah ini:
- Kesulitan menelan
- Hambatan dalam saluran makanan
- Sering merasa sakit
- Peradangan usus
- Pernah menjalani operasi besar pada bagian lambung atau usus.

Keamanan dan manfaatnya pada anak-anak (di bawah 18 tahun) belum ditetapkan. Oleh karena itu, RENVELA tidak dianjurkan untuk dikonsumsi oleh anak-anak.

Perawatan tambahan:

Karena faktor kondisi ginjal atau perawatan dialisis yang Anda jalani, Anda mungkin:

- Mengalami kekurangan atau kelebihan kalsium dalam darah. Karena RENVELA tidak mengandung kalsium, dokter mungkin akan menambahkan tablet kalsium dalam resep dokter.
- Mengalami kekurangan vitamin D dalam darah. Karenanya, dokter mungkin akan memonitor kandungan vitamin D dalam darah Anda dan menambahkan vitamin D sesuai kebutuhan dalam resep dokter. Jika Anda tidak mengkonsumsi suplemen multivitamin, Anda mungkin mengalami kekurangan vitamin A. E. K dan asam folat dalam darah dan karenanya dokter mungkin akan memonitor kadar-kadar tersebut serta menambahkan suplemen vitamin sesuai kebutuhan Anda.

Catatan khusus untuk pasien yang menjalani peritoneal dialysis:

Anda mungkin menderita peritonitis (infeksi cairan abdominal) sehubungan dengan peritoneal dialysis yang Anda jalani. Resiko ini dapat diperkecil dengan menerapkan secara ketat teknik steril saat pergantian kantung. Anda perlu segera memberitahu dokter jika Anda merasakan munculnya tanda atau gejala masalah perut, pembengkakan perut, sakit perut, nyeri perut. atau kekakuan perut, sembelit, demam, menggigil, mual atau muntah. Anda mungkin akan dimonitor lebih teliti lagi untuk mencermati masalah yang terkait dengan rendahnya kadar vitamin A, D, E, K dan asam folat.

Obat-obatan lain dan RENVELA

Katakan kepada dokter jika Anda sedang mengkonsumsi obat-obatan lain, atau belum lama berselang telah mengkonsumsinya, atau akan mengkonsumsi obat-obatan lain.

- RENVELA tidak boleh dikonsumsi bersamaan sebagai ciprofloxacin (antibiotik).
- Jika Anda mengkonsumsi obat-obatan untuk masalah detak jantung atau epilepsi Anda harus berkonsultasi dengan dokter ketika menjalani pengobatan dengan RENVELA.
- Efek dari obat-obatan seperti ciclosporin, mycophenolate mofetil dan tacrolimus (obat-obatan yang berfungsi menekan sistem kekebalan tubuh) akan melemah jika mengkonsumsi RENVELA. Dokter akan memberikan penjelasan jika Anda sedang mengkonsumsi obat-obatan tersebut.
- Kekurangan hormon Thyroid mungkin jarang ditemui pada orang-orang tertentu yang mengkonsumsi levothyroxine (digunakan untuk penderita kekurangan hormon thyroid) dan RENVELA. Oleh sebab itu, dokter mungkin akan memonitor dengan cermat tingkat thyroid yang merangsang pertumbuhan hormon dalam darah Anda.
- Jika Anda mengkonsumsi obat untuk mengatasi rasa terbakar di dada, *gastroesophageal reflux disease (GERD)* atau luka lambung. seperti omeprazole, pantoprazole, atau lansoprazole, Anda harus berkonsultasi dengan dokter ketika menjalani pengobatan dengan RENVELA.

Dokter akan memeriksa secara berkala apakah ada interaksi antara RENVELA dengan obat obatan lainnya.

RENVELA saat makan dan minum

RENVELA harus diminum saat makan.

Kehamilan, menyusui dan kesuburan

Jika Anda sedang mengandung atau menyusui, baru menduga sedang mengandung atau berencana untuk memiliki anak, mintakan saran kepada dokter sebelum mengkonsumsi obat ini. Tidak diketahui apakah RENVELA mengakibatkan dampak terhadap bayi yang masih dalam kandungan.

Katakan kepada dokter jika Anda akan menyusui bayi Anda. Tidak diketahui apakah RENVELA dapat terbawa melalui ASI dan berdampak pada bayi Anda.

Konsultasikan kepada dokter atau apoteker sebelum mengkonsumsi obat apapun juga.

Mengemudi dan menggunakan mesin

Sevelamer tidak memiliki pengaruh atau dapat diabaikan pengaruhnya pada kemampuan berkendara dan menggunakan mesin. Jika Anda merasakan dampaknya, jangan mengemudi dan jangan menggunakan peralatan atau mesin apapun.

Konsultasikan kepada dokter ketika mengonsumsi RENVELA

- Jika Anda mengalami sakit perut yang parah, gangguan pencernaan, atau adanya darah pada tinja (pendarahan pada saluran cena). Gejala-gejala tersebut dapat disebabkan oleh penyakit radang usus yang disebabkan oleh penumpukan Kristal pada usus. Hubungi dokter anda untuk memutuskan kelanjutan pengobatan.

3. Aturan pakai RENVELA

Anda harus mematuhi aturan pakai RENVELA sesuai resep dokter. Dosisnya disesuaikan dengan tingkat serum fosfor Anda.

Dosis awal tablet RENVELA yang dianjurkan untuk orang dewasa dan usia lanjut (65 tahun) adalah satu hingga dua butir tablet yang 800 mg setiap kali makan, 3 kali sehari.

Tablet harus diminum sekaligus. Jangan dihancurkan, dikunyah atau dibelah menjadi beberapa bagian.

Dosis awal yang direkomendasikan untuk Renvela adalah 2.4 — 4,8 g untuk dewasa per hari terbagi dalam 3 kali waktu makan. Dosis awal dan regimen yang tepat akan ditentukan oleh dokter anda.

Dalam beberapa kasus tertentu di mana RENVELA harus diminum bersamaan harus diminum bersamaan dengan obat lainnya. Dokter mungkin akan menganjurkan Anda minum obat tersebut 1 jam sebelum atau 3 jam sesudah Anda minum obat RENVELA, atau mungkin dokter mempertimbangkan perlunya memonitor kadar darah dalam obat tersebut.

Dokter akan memeriksa kandungan fosfor dalam darah Anda secara berkala dan jika perlu dokter mungkin akan mengubah dosis RENVELA untuk mencapai kadar fosfor yang tepat.

Jika Anda minum obat RENVELA melebihi dosis yang seharusnya

Belum pernah ada laporan tentang pasien yang overdosis. Jika terjadi overdosis, segera hubungi dokter.

Jika Anda lupa meminum obat RENVELA

Jika Anda lupa meminum satu dosis obat, lanjutkan dosis selanjutnya sesuai jadwal biasa setelah makan. Jangan minum 2 dosis sekaligus sebagai pengganti dosis yang terlupakan itu.

4. Efek samping yang mungkin timbul

Sebagaimana halnya obat appaun lainnya, efek samping dapat terjadi setelah meminum obat ini, namun tidak semua orang mengalaminya.

Berikut ini adalah beberapa laporan tentang efek samping yang pernah dialami pasien yang meminum obat RENVELA:
Sangat lazim (dapat terjadi pada lebih dari 1 dari 10 orang): muntah, sembelit, nyeri perut bagian atas, mual
Lazim (dapat terjadi pada 1 dari 10 orang): diare, sakit perut, gangguan pencernaan, perut kembung, distensi abdomen.
Sangat jarang (dapat terjadi pada 1 dari 10000 orang): hipersensitivitas
Tidak diketahui (frekuensi tidak dapat diperkirakan dari data yang tersedia): pernah dilaporkan terjadinya gatal-gatal, ruam, lambatnya motilitas (Gerakan) usus/penyumbatan di usus, dan perforasi pada dinding usus.

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Karena sembelit dapat merupakan gejala awal penyumbatan usus, hubungi dokter atau apoteker.

Beberapa efek samping dapat menjadi serius. Segera hubungi dokter jika Anda mengalami gejala di bawah ini:
Peradangan serius pada usus besar (gejala meliputi: sakit perut yang parah, gangguan pencernaan, atau darah pada tinja.

~~Jika Anda mengalami efek samping, sekalipun itu jenis efek samping yang tidak tercantum dalam lembaran ini, hubungi dokter.~~

Jika Anda mengalami efek samping apapun, bicarakan dengan dokter atau apoteker. Efek samping ini termasuk efek samping apapun yang mungkin muncul yang tidak tercantum pada leaflet ini. Anda juga dapat melaporkan efek samping secara langsung ke Industri Farmasi dengan kontak berikut farmakovigilans@kalventis.com. Dengan melaporkan efek samping Anda dapat membantu memberikan informasi tentang keamanan obat ini.

5. Cara menyimpan RENVELA

~~RENVELA Tablet salut selaput:~~
Jauhkan obat ini dari penglihatan dan jangkauan anak-anak.
Jangan meminum obat ini setelah tanggal kedaluwarsa yang tertera pada botol dan kemasannya di belakang huruf “EXP”.
Tutup botol dengan erat agar tidak menjadi lembab.
Produk medis ini tidak memerlukan kondisi penyimpanan khusus.
Jangan membuang obat-obatan melalui air limbah atau limbah rumah tangga. Tanyakan kepada apoteker tentang cara membuang obat-obatan yang tidak terpakai lagi. Langkah ini merupakan perlindungan lingkungan.

6. Isi kemasan dan informasi lainnya

RENVELA Tablet salut selaput mengandung:

- Bahan aktif sevelamer carbonate. Tiap tablet Renvela bersalut selaput mengandung 800 mg sevelamer carbonate.
- Bahan-bahan lainnya adalah *microcrystalline cellulose, sodium chloride*, ~~*dan*~~ *zinc stearate* dan *purified water*.
  Selaput tablet: larutan selaput mengandung *Hypromellose* dan *diacetylated monoglycerides*.

Apa ciri-ciri RENVELA dan isi kemasan

RENVELA tablet salut selaput berwarna putih di mana terdapat tulisan RV800 pada salah satu sisinya. Seluruh tablet dikemas dalam botol polyethylene dengan kepadatan tinggi dan tutup botolnya terbuat dari polypropylene serta bersegel induksi.

Ukuran kemasan:

~~RENVELA Tablet salut selaput:~~ 1 x 30 tablet per botol

HARUS DENGAN RESEP DOKTER

~~RENVELA Film-coated tablet:~~ Reg. No. DKI24774044117A1

Diproduksi oleh:

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Sanofi Winthrop Industrie,

CARBON BLANC – France

Didaftarkan oleh:

PT Kalventis Sinergi Farma,

Jakarta – Indonesia

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