NEW ZEALAND DATA SHEET

1 FOSRENOL® 750 mg and 1000 mg oral powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

FOSRENOL oral powder is presented in sachets. Each sachet contains lanthanum carbonate hydrate corresponding to 750 mg or 1000 mg lanthanum.

Excipient(s) with known effect:
Each 750mg sachet contains 641.7 mg and 1000mg sachet contains 855.6 mg of dextrates, containing glucose.

For the full list of excipients, see Section 6.1 LIST OF EXCIPIENTS.

3 PHARMACEUTICAL FORM

Oral powder.

Appearance
White to off-white powder.

For details on appearance, please refer to section 6.5 NATURE AND CONTENTS OF CONTAINER.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

FOSRENOL is indicated in adult patients as a phosphate binding agent for use in the control of hyperphosphataemia in adults with chronic renal failure on haemodialysis or continuous ambulatory peritoneal dialysis (CAPD). FOSRENOL is also indicated in adult patients with chronic kidney disease not on dialysis with serum phosphate levels ≥1.78 mmol/L in whom a low phosphate diet alone is insufficient to control serum phosphate levels.

4.2 DOSE AND METHOD OF ADMINISTRATION

Patients should adhere to recommended diets in order to control phosphate and fluid intake.

FOSRENOL oral powder is intended to be mixed with a small quantity of soft food (e.g. applesauce or other similar food product) and consumed immediately (within 15 minutes). The sachet must not be opened until ready to use. Once mixed with food, FOSRENOL oral powder must not be stored for future use. FOSRENOL oral powder is insoluble and must not be dissolved in liquid for administration.

Adults, including elderly (>65 years)
FOSRENOL should be taken with or immediately after food, with the daily dose divided between meals. Patients should adhere to recommended diets in order to control phosphate and fluid intake. FOSRENOL is presented as an oral powder intended to be mixed with soft food, therefore avoiding the need to take additional fluid. Serum phosphate levels should be

monitored and the dose of FOSRENOL titrated every 2-3 weeks until an acceptable serum phosphate level is reached, with regular monitoring thereafter. Dose titration may be performed with the chewable tablet presentation as these are available in a number of strengths allowing for smaller increases in dose.

Control of serum phosphate level has been demonstrated at doses starting from 750 mg per day. The maximum dose studied in clinical trials, in a limited number of patients, is 3750 mg. Patients who respond to lanthanum therapy usually achieve acceptable serum phosphate levels at doses of 1500 –3000 mg lanthanum per day.

Hepatic impairment

The effect of hepatic impairment on FOSRENOL pharmacokinetics has not been formally assessed. Due to its mechanism of action and the lack of liver metabolism, doses in hepatic impairment should not be modified, but patients should be monitored carefully (see SPECIAL WARNINGS AND PRECAUTIONS FOR USE and PHARMACOKINETIC PROPERTIES).

Children

The safety and efficacy of FOSRENOL has not been established in patients below the age of 18 years. (see SPECIAL WARNINGS AND PRECAUTIONS FOR USE and PHARMACODYNAMIC PROPERTIES)

4.3 CONTRAINDICATIONS

- Hypersensitivity to lanthanum or any of the excipients in the product
- Bowel obstruction, ileus, and faecal impaction
- Hypophosphataemia.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Tissue deposition of lanthanum has been shown with FOSRENOL in animal studies. In 105 bone biopsies from patients treated with FOSRENOL, some for up to 4.5 years, rising levels of lanthanum were noted over time (see section 5.1). Cases of lanthanum deposition in gastrointestinal mucosa, mainly after long term use, have been reported. The clinical significance of this is yet unknown. No clinical data are available on deposition of lanthanum in other human tissues.

The use of FOSRENOL in clinical studies beyond 2 years is currently limited. However, treatment of subjects with FOSRENOL for up to 6 years has not demonstrated a change in the benefit/risk profile.

Gastrointestinal Disorders

There have been cases of gastrointestinal obstruction, ileus, subileus, and gastrointestinal perforation reported in association with lanthanum, some requiring surgery or hospitalisation (see section 4.8). Some of the cases are found to have lanthanum deposition or Product residue in the gastrointestinal tract. Lanthanum deposition in gastroduodenal mucosa is demonstrated endoscopically as whitish lesions of different sizes and shapes. Also, various pathological features were identified in gastroduodenal mucosa with lanthanum deposition, such as chronic or active inflammation, glandular atrophy, regenerative changes, foveolar hyperplasia, intestinal metaplasia, and neoplasia.

Exercise caution in all patients predisposed to gastrointestinal obstruction, ileus, subileus and perforation; for example those with altered gastrointestinal anatomy (e.g., diverticular

disease, peritonitis, history of gastrointestinal surgery, gastrointestinal cancer and gastrointestinal ulceration), hypomotility disorders (e.g., constipation, diabetic gastroparesis) and when used with medications known to potentiate these effects. Some cases were reported in patients with no history of gastrointestinal disease.

During treatment with lanthanum carbonate, physicians and patients should remain vigilant for signs and symptoms of gastrointestinal disorders, especially constipation and abdominal pain/distention which may indicate bowel obstruction, ileus or subileus.

Treatment with lanthanum carbonate should be re-evaluated in patients who develop severe constipation or other severe gastrointestinal signs and symptoms.

Patients with acute peptic ulcer, ulcerative colitis, Crohn's disease or bowel obstruction were not included in clinical studies with FOSRENOL.

Renal Impairment
Patients with renal insufficiency may develop hypocalcaemia. FOSRENOL does not contain calcium. Serum calcium levels should therefore be monitored at the regular time intervals for this patient population and appropriate supplements given.

Hepatic Impairment
Lanthanum is not metabolised by liver enzymes, but it is most likely excreted in the bile. Conditions resulting in a marked reduction of bile flow may be associated with incrementally slower elimination of lanthanum, which may result in higher plasma levels and increased tissue deposition of lanthanum (see PRECLINICAL SAFETY DATA and PHARMACOKINETIC PROPERTIES). Caution should therefore be exercised in patients with hepatic impairment or biliary obstruction and monitoring of liver function may be required.

FOSRENOL should be discontinued if hypophosphataemia develops.

Patients with rare glucose-galactose malabsorption should not take this medicine.

Abdominal x-rays
Abdominal x-rays of patients taking lanthanum carbonate may have a radio-opaque appearance typical of an imaging agent.

Paediatric population
Safety and efficacy of FOSRENOL have not been established in children and adolescents; use in children and adolescents is not recommended (see section 4.2).

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

The drug interactions profile of FOSRENOL is characterised by the potential of lanthanum to bind to drugs with anionic functions (e.g. carboxyl, carbonyl and hydroxyl groups).

Lanthanum carbonate hydrate is not a substrate for cytochrome P450 and does not significantly inhibit the activities of the major human cytochrome P450 isoenzymes, CYP1A2, CYP2D6, CYP3A4/5, CYP2C9/10 or CYP2C19 *in vitro*.

In a clinical study, it was demonstrated that FOSRENOL does not alter gastric pH. Therefore, FOSRENOL drug interactions based on altered gastric pH are not expected.

Effects of FOSRENOL on the Absorption of Other Products

Quinolone Antibiotics

Co-administration of FOSRENOL with quinolone antibiotics may reduce the extent of their absorption as a result of complex formation. The bioavailability of oral ciprofloxacin was decreased by approximately 50% when taken with FOSRENOL in a single dose study in healthy volunteers. It is recommended that oral quinolone antibiotics are taken at least 2 hours before or 4 hours after FOSRENOL.

Levothyroxine

Phosphate binders (including FOSRENOL) have been shown to reduce the absorption of levothyroxine. Consequently, thyroid hormone replacement therapy should not be taken within 2 hours of dosing with FOSRENOL and closer monitoring of TSH levels is recommended in patients receiving both medicinal products.

Drugs Binding to Antacids

There is potential for FOSRENOL to interact with other compounds subject to reduced absorption when co-administered with antacids (e.g. aluminium-, magnesium-, calcium-based). Therefore, such compounds should not be taken within 2 hours of dosing with FOSRENOL.

Human volunteer studies have shown that co-administration of FOSRENOL with digoxin, warfarin or metoprolol does not produce clinically relevant changes in the pharmacokinetic profiles of these drugs.

In simulated gastric juice, lanthanum carbonate hydrate did not form insoluble complexes with warfarin, digoxin, furosemide, phenytoin, metoprolol or enalapril, suggesting a low potential to affect the absorption of these drugs.

Fat-Soluble Vitamins

Serum levels of fat-soluble vitamins (A, D, E and K) or other nutrients, were not affected by FOSRENOL administration in clinical studies.

Interaction with drugs such as tetracycline and doxycycline are theoretically possible; and if these compounds are to be co-administered, it is recommended that they are not to be taken within 2 hours of dosing with FOSRENOL.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

There are no human data on the effects of lanthanum carbonate on fertility. In rat toxicology studies, lanthanum carbonate had no adverse effects on fertility.

Use in pregnancy

(Category B3)
There are no adequate data from the use of FOSRENOL in pregnant women.
One study in rats showed reproductive foetotoxicity (delayed eye opening and sexual maturation) and reduced pup weights at high doses (see section 5.3). The potential risk for humans is unknown. FOSRENOL is not recommended for use during pregnancy.

Use in lactation

It is unknown whether lanthanum is excreted in human breast milk. The excretion of lanthanum in milk has not been studied in animals. Caution should be used in taking a decision whether to continue/discontinue breast feeding or to continue/discontinue therapy with FOSRENOL, taking into account the potential benefit of breast feeding to the child and the potential benefit of FOSRENOL therapy to the nursing mother.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

FOSRENOL may induce dizziness, nausea, and vertigo, which may impair the ability to drive and use machinery.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

The safety of FOSRENOL for use in patients has been examined in a number of clinical studies. The most commonly reported adverse drug reactions, with the exception of headache and allergic skin reactions are gastrointestinal in nature; these are minimised by taking FOSRENOL with food and generally abated with time with continued dosing (see section 4.2).

Table 1 presents the frequency of adverse drug reactions. The following conventions are used: Very common (≥1/10), Common (≥1/100, <1/10), Uncommon (≥1/1,000 to <1/100) and Rare (≥ 1/10,000 to < 1/1,000)

Table 1. Adverse Drug Reactions Associated with FOSRENOL

Organ System	Very Common Reactions	Common Reactions	Uncommon Reactions	Rare	Not Known
Infections and Infestations			Gastroenteritis, laryngitis		
Blood and lymphatic system disorders			Eosinophilia		
Endocrine disorders			Hyperparathyroidism		
Metabolism and nutrition disorders		Hypocalcaemia	Hypercalcaemia, hyperglycaemia, hyperphosphataemia, hypophosphataemia, anorexia, appetite increased		Decreased appetite
Nervous system disorders	Headache		Dizziness, taste alteration		
Ear and Labyrinth disorders			Vertigo		
Gastrointestinal disorders**	Abdominal pain, diarrhoea, nausea, vomiting	Constipation, dyspepsia, flatulence	Eructation, indigestion, irritable bowel syndrome, dry mouth, oesophagitis, stomatitis, stools loose, gastro-intestinal disorder NOS*, ileus, subileus, intestinal obstruction	Intestinal perforation	Product residue present
Skin and subcutaneous tissue disorders			Alopecia, sweating increased		

General Disorders and Administrative Site Conditions			Asthenia, chest pain, fatigue, malaise, peripheral oedema, pain, thirst	Tooth injury	
Musculoskeletal and connective tissue disorders			Arthralgia, myalgia, osteoporosis		
Investigations			Elevated blood aluminium, increase in GGT, increases in hepatic transaminases, alkaline phosphatase increased, weight decrease		

* Not otherwise specified.
** In a clinical trial in healthy subjects, the incidence of gastrointestinal adverse events was higher after administration of the oral powder formulation of FOSRENOL (13 subjects, 18.3%) than after chewable tablets (4 subjects, 6.6%).

Post marketing experience

Table 2 presents all adverse drug reactions derived from post-marketing reports and based on all safety information available, sorted by MedDRA SOC and decreasing category of frequency.

Table 2. Adverse Drug Reactions Associated with FOSRENOL

System/Organ Class **Adverse Drug Reaction**	**Incidence Category***
Nervous System Disorders	
Headache	Very common
Dizziness	Not known
Gastrointestinal Disorders	
Abdominal pain, diarrhoea, nausea, vomiting	Very common
Constipation, dyspepsia	Common
Ileus, subileus, intestinal obstruction	Uncommon
Intestinal perforation	Rare
Flatulence	Not known
Infections and infestations	
Gastroenteritis	Not known
Injury, poisoning and procedural complications	
Tooth injury	Rare
Investigations	
Product residue present	Not known
Skin and Subcutaneous Tissue Disorders	
Allergic skin reactions (including skin rashes, urticaria, and pruritus)	Very common
General Disorders and Administration Site Conditions	
Chest pain	Not known
Oedema peripheral	Not known
Metabolism and Nutrition Disorders	
Hypocalcaemia	Common
Hypophosphatemia	Uncommon
Hypercalcaemia	Not known
Decreased appetite	Not known
* Incidence category: Very common (≥1/10); Common (≥1/100 to <1/10); Uncommon (≥1/1000 to <1/100); Rare (≥1/10,000 to <1/1000). Not known (cannot be estimated from the available data).	

Transient QT changes have been observed but these were not associated with any adverse events.

Paediatric population
Frequency, type, and severity of adverse reactions in children have not been fully established. In particular, uncertainty exists on the accumulation in bone and risk of growth retardation with treatment in children.

Reporting
Reporting suspected adverse reactions after registration 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 reactions at https://nzphvc.otago.ac.nz/reporting/

4.9 OVERDOSE

No case of overdose has been reported. The highest daily dose of lanthanum administered to healthy volunteers during Phase I studies was 4718 mg given for 3 days. The adverse events seen were mild to moderate and included nausea and headache.

For information on the management of overdose, contact National Poisons Centre on 0800 POISON (0800 764766) in New Zealand.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group:
Drugs for treatment of hyperkalaemia and hyperphosphataemia.

ATC code: V03A E03

Mechanism of action
FOSRENOL contains lanthanum carbonate hydrate. Lanthanum is non-calcium, non-resin based dietary phosphate binder that inhibits absorption of phosphate by forming insoluble lanthanum phosphate complexes that pass through the gastrointestinal tract unabsorbed. Both serum phosphate and calcium phosphate product are reduced as a consequence of the reduced dietary phosphate absorption.

Lanthanum carbonate hydrate dissociates in the acid environment of the upper GI tract to release lanthanum ions. The activity of lanthanum as a phosphate binder is a result of the high affinity of lanthanum ions for dietary phosphate released from food during digestion.

In healthy subjects administered FOSRENOL 3 times daily for 3 days as oral powder or chewable tablets, FOSRENOL oral powder was found to be pharmacodynamically equivalent to FOSRENOL chewable tablets based on urinary phosphate excretion.

Clinical trials
Information from studies using chewable tablets
A total of 1130 patients with chronic renal failure treated with maintenance haemodialysis or CAPD were studied in two Phase II and two Phase III studies (LAM-IV-202, 204, 301 and 302). Three studies were placebo controlled (1 fixed dose and 2 titrated dose designs) and one included calcium carbonate as an active comparator. During these studies, 1016 patients received lanthanum carbonate, 267 received calcium carbonate and 176 received placebo.

Two placebo-controlled, randomised studies enrolled patients on dialysis after a washout from previous phosphate binders. After titration of lanthanum carbonate to achieve a serum phosphate level between 1.3 and 1.8 mmol/L in one study (doses up to 2250 mg/day), or ≤1.8 mmol/L in a second study (doses up to 3000 mg/day), patients were randomised to lanthanum carbonate or placebo as maintenance treatment. After the 4-week randomised placebo-controlled phase, the serum phosphate concentration rose between 0.5 and 0.6 mmol/L in the placebo group, in both studies, relative to patients who remained on lanthanum carbonate therapy. There were 61% patients on lanthanum carbonate who maintained their response, compared to 23% on placebo.

The active comparator study demonstrated that serum phosphate levels were reduced to target levels of 1.8 mmol/L at the end of the 5-week titration period, in 51% of the lanthanum group compared with 57% of the calcium carbonate group. At week 25 the percentage of randomised patients showing controlled serum phosphate levels was similar in the two treatment groups, 29% on lanthanum and 30% on calcium carbonate (using a missing=failure approach). Mean serum phosphate levels were reduced by a similar amount in both treatment groups.

Further long-term extension studies have demonstrated maintenance of phosphate reduction for some patients following continued administration of at least 2 years of lanthanum carbonate.

Hypercalcaemia was reported in 0.4% of patients with FOSRENOL compared with 20.2% on calcium-based binders in comparative studies. Serum PTH concentrations may fluctuate depending on a patient's serum calcium, phosphate and vitamin D status. FOSRENOL has not been shown to have any direct effects on serum PTH concentrations.

In the long-term bone studies a trend towards increasing bone lanthanum concentrations with time in the control population was observed from the averaged data, the median rising 3-fold from a baseline of 53 μg/kg at 24 months. In patients treated with lanthanum carbonate, the bone lanthanum concentration increased during the first 12 months of lanthanum carbonate treatment up to a median of 1328 μg/kg (range 122-5513 μg/kg). Median and range concentrations at 18 and 24 months were similar to 12 months. The median at 54 months was 4246 μg/kg (range 1673-9792 μg/kg).

Paired bone biopsies (at baseline and at one or two years) in patients randomised to either FOSRENOL or calcium carbonate in one study and patients randomised to either FOSRENOL or alternative therapy in a second study, showed no differences in the development of mineralisation defects between the groups.

Hyperphosphataemia

Lanthanum has been demonstrated to be an effective binder of dietary phosphate for use in controlling the hyperphosphataemia of chronic renal failure. Multiple studies have shown that lanthanum can reliably be used to achieve serum phosphate reductions to target levels through dose titration and to effectively maintain control of serum phosphate levels with long-term use. Maintenance of target phosphate levels was shown to be similar between lanthanum and calcium treatments.

The lowest effective dose of lanthanum that is effective in the control of serum phosphate levels was established to be approximately 750 mg/day. Doses of up to 3000 mg lanthanum resulted in a reduction of serum phosphate to within target control levels in most patients.

No difference in level of control was observed between those patients on haemodialysis and those receiving CAPD. In addition, no difference in the effectiveness of lanthanum carbonate administration was noted between patients under or over 65 years of age.

Paediatric population

See sections 4.2 and 4.4 for information on paediatric use.

5.2 PHARMACOKINETIC PROPERTIES

As binding between lanthanum and dietary phosphorus occurs in the lumen of the stomach and upper small intestine, the therapeutic effectiveness of FOSRENOL is not dependent on levels of lanthanum in the plasma.

Lanthanum is present in the environment. Measurement of background levels in non-lanthanum treated chronic renal failure patients during Phase III clinical trials revealed concentrations of <0.05 to 0.90 ng/mL in plasma, and <0.006 to 1.0 μg/g in bone biopsy samples.

Absorption

In healthy subjects administered FOSRENOL 3 times daily for 3 days as oral powder or chewable tablets, the systemic exposure to lanthanum (based on AUC_{0-48} and C_{max}) was approximately 30% higher and more variable following administration of FOSRENOL oral powder than FOSRENOL chewable tablets. By comparison with data for the chewable tablet (see below), the systemic exposure arising from the oral powder is still consistent with an absolute bioavailability <0.002%.

Information from studies using chewable tablets

Lanthanum carbonate has low aqueous solubility (<0.01 mg/mL at pH 7.5) and is minimally absorbed following oral administration. Absolute oral bioavailability is estimated to be <0.002% in humans.

In healthy subjects, plasma AUC and C_{max} increased as a function of dose, but in a less than proportional manner, after single oral doses of 250 to 1000 mg lanthanum, consistent with dissolution-limited absorption. The apparent plasma elimination half-life in healthy subjects was 36 hours.

In renal dialysis patients dosed for 10 days with 1000 mg lanthanum 3 times daily, the mean (± sd) peak plasma concentration was 1.06 (± 1.04) ng/mL, and mean AUC_{last} was 31.1 (± 40.5) ng.h/mL. Regular blood level monitoring in 1707 renal dialysis patients taking lanthanum carbonate for up to 2 years showed no increase in plasma lanthanum concentrations over this time period.

Distribution

Lanthanum does not accumulate in plasma in patients or in animals after repeated oral administration of lanthanum carbonate hydrate. The small fraction of orally administered lanthanum absorbed is extensively bound to plasma proteins (>99.7%) and in animal studies, was widely distributed to systemic tissues, predominantly bone, liver and the gastrointestinal tract, including the mesenteric lymph nodes. In long-term animal studies, lanthanum concentrations in several tissues, including the gastrointestinal tract, bone and liver increased over time to levels several orders of magnitude above those in plasma. An apparent steady-state level of lanthanum was attained in some tissues, e.g. the liver whereas levels in

gastrointestinal tract increased with duration of treatment. Changes in tissue lanthanum levels after withdrawal of treatment varied between tissues. A relatively high proportion of lanthanum was retained in tissues for longer than 6 months after cessation of dosing (median % retained in bone ≤100% (rat) and ≤87% (dog), and in the liver ≤6% (rat) and ≤82 % (dog). No adverse effects were associated with the tissue deposition of lanthanum seen in long-term animal studies with high oral doses of lanthanum carbonate (see 5.3) (See section 5.1 for information regarding changes in lanthanum concentrations in bone biopsies taken from renal dialysis patients after one year of treatment with lanthanum containing versus calcium containing phosphate binders).

Metabolism

Lanthanum is not metabolised. Studies in chronic renal failure patients with hepatic impairment have not been conducted. In patients with co-existing hepatic disorders at the time of entry into Phase III clinical studies, there was no evidence of increased plasma exposure to lanthanum or worsening hepatic function after treatment with FOSRENOL for periods up to 2 years.

Elimination

Lanthanum is excreted mainly in the faeces (>90%) with only around 0.000031% of an oral dose excreted via the urine in healthy subjects (renal clearance approximately 1mL/min, representing <2% of total plasma clearance).

After intravenous administration to animals, lanthanum is excreted mainly in the faeces (74% of the dose), both via the bile and direct transfer across the gut wall. Renal excretion was a minor route.

5.3 PRECLINICAL SAFETY DATA

Preclinical data reveal no special hazards for humans based on conventional studies of safety pharmacology, repeated dose toxicity, fertility or genotoxicity.

Lanthanum carbonate hydrate reduced gastric acidity in the rat in a safety pharmacology study. In rats administered high doses of lanthanum carbonate hydrate from day 6 of gestation to day 20 post-partum there were no maternal effects, but reduced pup weight and delays in some developmental markers (eye and vaginal opening) were seen. In rabbits given high daily doses of lanthanum carbonate hydrate during gestation, maternal toxicity with reduced maternal food intake and body weight gain, increased pre- and post-implantation losses and decreased pup weight were seen.

Studies in animals have shown deposition of lanthanum in tissues, mainly the gastrointestinal tract, mesenteric lymph nodes; liver and bone (see section 5.2). However, life-time studies in healthy animals do not indicate a hazard for man from the use of FOSRENOL. Specific immunotoxicity studies have not been performed.

Carcinogenicity

Lanthanum carbonate hydrate was not carcinogenic in mice or rats. In mice, an increase in gastric glandular adenomas was seen in the high-dose group (1500 mg/kg/day). The neoplastic response in the mouse is considered to be related to an exacerbation of spontaneous pathological stomach changes and to be of little clinical significance.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

FOSRENOL oral powder also contains the excipients dextrates (hydrated), colloidal silicon dioxide and magnesium stearate.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

36 months from date of manufacture.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25˚C.

6.5 NATURE AND CONTENTS OF CONTAINER

Pack size: 90 sachets (Outer carton contains 9 cartons of 10 sachets).

FOSRENOL 750 mg oral powder: White to off-white 2.1g of powder in sachets formed from a polyethylene terephthalate/aluminium/ polyethylene laminate.

FOSRENOL 1000 mg oral powder: White to off-white 2.8g of powder in sachets formed from a polyethylene terephthalate/aluminium/ polyethylene laminate.

Not all pack sizes may be marketed.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In New Zealand, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

$La_2(CO_3)_3.x\ H_2O$ = 457.8 (anhydrous), on average x = 4.5 moles of water.

CAS number
54451-24-0

7 MEDICINE SCHEDULE (POISONS STANDARD)

Prescription Only Medicine

8 SPONSOR

Takeda New Zealand Limited
Level 10, 21 Queen Street
Auckland, 1010
New Zealand
Telephone: 0508 169 077
www.takeda.com/en-au

9 DATE OF FIRST APPROVAL

01 October 2020

10 DATE OF REVISION

16 November 2022

SUMMARY TABLE OF CHANGES

Section changed	Summary of changes
4.3	Additional contraindication statement added
4.4	New statements under Gastrointestinal Disorders
4.5	Additional clarifications added
4.7	Additional warning term ‘nausea’ added
4.8	New table added under ‘post-marketing experience’