When your patients with ESRD on dialysis present with uncontrolled serum phosphate levels,

THINK OF PrVELPHORO®

PrVELPHORO® (sucroferric oxyhydroxide) is indicated for the control of serum phosphorus levels in adult patients with end-stage renal disease (ESRD) on dialysis.[1]

VELPHORO is a phosphate binder that does not contain calcium.*

* Clinical significance has not been established.

Dosing information for PrVELPHORO®?

Breakfast Lunch Dinner

Starting dose: The recommended starting dose of VELPHORO is 3 tablets (1,500 mg iron) per day administered as 1 tablet (500 mg iron) 3 times daily with meals.

Maximum dose: The maximum recommended dose is 3,000 mg iron (6 tablets) per day.[1]

Every 2–4 weeks

Titration and maintenance: The dose of **VELPHORO** can be titrated up or down in increments of 500 mg iron (1 tablet) per day every 2–4 weeks until an acceptable serum phosphorus level is reached, with regular monitoring thereafter.[1]

* Tablet is not actual size.

What should patients do in case of a missed dose or overdosage with VELPHORO?

If 1 or more doses are missed, the normal dose of **VELPHORO** should be resumed with the next meal. There are no reports of overdosage with **VELPHORO** in patients.

Any instances of overdosage of **VELPHORO** (e.g., hypophosphatemia) should be treated using standard clinical practice.[1]

How should VELPHORO be administered?

CHEW

VELPHORO is a **chewable tablet. It must be chewed** and not swallowed whole.

BREAK or CRUSH

Tablet may be crushed or broken into small pieces to aid with chewing and swallowing.

VELPHORO tablets must be taken with meals. In order to maximize the adsorption of dietary phosphate, the total daily dose should be divided across the meals of the day, taking into consideration the size of the meals.[1]

Does PrVELPHORO® interact with other drugs?

When administering any oral medicinal product that is known to interact with iron, the medicinal product should be administered at least 1 hour before or 2 hours after **VELPHORO**.[1]

Interaction studies have not been performed in patients on dialysis. Drug-drug interaction studies have been conducted in healthy male and female subjects with losartan, furosemide, digoxin, warfarin, and omeprazole. Concomitant administration of **VELPHORO** did not affect the bioavailability of these medicinal products as measured by area under the curve.[1]

Data from clinical studies have shown that **VELPHORO** does not affect the lipid lowering effects of HMG-CoA reductase inhibitors (e.g., atorvastatin and simvastatin).[1]

For more complete dosage and administration information, please refer to the Product Monograph.

In vitro studies revealed relevant binding of **VELPHORO** with the following drugs:[1]*

- Alendronate. Take at least 1 hour before taking **VELPHORO**.
- Doxycycline. Take at least 1 hour before taking **VELPHORO** or at least 2 hours after taking **VELPHORO**.
- Levothyroxine. Take at least 1 hour before taking **VELPHORO**.

Although no relevant interaction was found *in vitro*, caution should be exercised when patients take **VELPHORO** concomitantly with acetylsalicylic acid, cephalexin, cinacalcet, ciprofloxacin, clopidogrel, enalapril, hydrochlorothiazide, metformin, metoprolol, nifedipine, pioglitazone, and quinidine.[1]

What were the majority of ADRs reported with VELPHORO?

VELPHORO has a well-established safety and tolerability profile.† The majority of the ADRs reported from trials were gastrointestinal disorders.[1]

- Patients with peritonitis, significant gastric disorders and patients who have had major gastrointestinal surgery were not included in clinical studies with **VELPHORO**. **VELPHORO** should only be used in these patients if the benefits outweigh the risks.

Diarrhea was very common; however, the majority of these events were mild and transient, occurring soon after initiation of treatment and resolving with continued treatment.[1]

- In the 55-week long-term study, diarrhea led to treatment discontinuation in 3.1% of patients.

As expected with oral preparations containing iron, discoloured feces was very common.[1]

For more complete adverse reactions information, please refer to the Product Monograph.

* *In vitro* interactions are theoretical.

† The safety profile of **VELPHORO** was investigated in 2 active-controlled pivotal clinical studies. A total of 778 patients on hemodialysis and 57 patients on peritoneal dialysis were treated for up to 55 weeks.[1]

TR-TEAEs with incidence >5% in combined data from 6-week and 55-week pivotal studies[1]

System Organ Class Preferred Term (MedDRA)	VELPHORO n=835 (%)	Sevelamer n=374 (%)
Gastrointestinal disorders	**47.9**	**41.7**
Diarrhea	20.8	11.5
Nausea	8.4	13.6
Vomiting	5.4	8.8
Constipation	4.8	7.8
Metabolism and nutrition disorders	**37.0**	**38.5**
Hyperkalemia	4.7	6.7
Hypocalcemia	4.0	5.9
Infections and infestations	**26.0**	**30.2**
Nasopharyngitis	3.7	5.3
General disorders and administration site conditions	**19.2**	**23.8**
Vascular disorders	**18.8**	**23.5**
Hypertension	10.1	11.2
Hypotension	5.0	9.1
Musculoskeletal and connective tissue disorders	**18.4**	**20.3**
Muscle spasms	6.7	7.2
Investigations	**15.6**	**20.3**
Nervous system disorders	**13.2**	**16.6**
Headache	5.4	5.3
Respiratory, thoracic, and mediastinal disorders	**12.7**	**16.0**
Skin and subcutaneous disorders	**9.6**	**11.5**
Endocrine disorders	**5.7**	**11.0**
Hyperparathyroidism secondary	3.6	8.3

PrVELPHORO® is publicly reimbursed for the following (criteria exist):

- **Ontario** via Exceptional Access Program[2]
- **Quebec** RAMQ* under Exceptional Medications **(Code VA109)**[3†]
- **Saskatchewan** Drug Plan as exception drug status[4]
- **Manitoba** Drug Plan as exception drug status[5]
- **New Brunswick** Drug Plans as special authorization[6]
- **New Foundland and Labrador** Prescription Drug Program as special authorization[7]
- **Nova Scotia** Pharmacare as exceptional status drugs[8]
- **Prince Edward Island** Pharmacare as special authorization[9]
- **Veterans Affairs Canada** (VAC) as Standard Benefit[10]
- **Non-Insured Health Benefits** (NIHB) program as limited use benefit[11]

* Official mark of the Régie de l'assurance maladie du Québec.
† Coverage criteria: as a phosphate binder in persons suffering from severe renal failure where a calcium salt is contraindicated, is not tolerated, or does not make it possible to optimally control the hyperphosphatemia. It must be noted that taking this medication concomitantly with sevelamer or lanthanum hydrate is not authorized.

Criteria exist and may vary in provincial formularies. For listing criteria, check with individual provincial programs. Coverage restrictions in addition to the indicated condition may apply.

For more information on VELPHORO, scan the QR code.

Every VELPHORO prescription comes with our ORIJIN® patient support
Direct your patients to visit the ORIJIN website **orijinsupport.ca** and enter their **DIN 02471574**

Important Safety Information

Clinical use:
- Efficacy and safety in pediatric population (<18 years of age) have not been evaluated.
- No ove rall differences in safety or efficacy were observed between subjects ≥65 and younger subjects.

Contraindications:
- Patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.
- Patients with haemochromatosis or any other iron accumulation disorders.

Relevant warnings and precautions:
- Diabetes, hereditary fructose intolerance, glucose-galactose malabsorption, and sucrase-isomaltase insufficiency
- Caution in patients with gastrointestinal issues
- VELPHORO may cause black stools which may mask gastrointestinal bleeding
- Patients with hepatic/biliary/pancreatic disorders/disease
- Monitoring and laboratory tests regarding serum phosphorus and iron
- Pregnant or nursing women

Less common clinical trial or post-market adverse reactions:
In the 6-week and 55-week clinical studies, tooth discolouration and product taste were some of the less common (<1%), treatment-related treatment emergent adverse events reported in more than one patient.

Eosinophilic peritonitis has been listed in post-market spontaneous reports.

For more information:
Please consult the Product Monograph at velphoromonograph.ca for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece. The Product Monograph is also available by calling us at 1-877-341-9245.

ADRs=adverse drug reactions; TR-TEAEs=treatment-related treatment-emergent adverse events.

References: 1. VELPHORO Product Monograph. Otsuka Canada Pharmaceutical Inc. **2.** Ontario Ministry of Health. Formulary: Exceptional Access Program (EAP). **3.** Régie de l'assurance maladie du Québec. List of Medications. **4.** Government of Saskatchewan. Saskatchewan Drug Plan (Search Formulary: Velphoro). **5.** Manitoba Health. Bulletin #108: Manitoba Drug Benefits and Interchangeability Formulary Amendments. **6.** Government of New Brunswick. New Brunswick Drug Plans Formulary. **7.** Newfoundland and Labrador Prescription Drug Program. Bulletin #138. **8.** Nova Scotia Pharmacare. Appendix III – Criteria for Coverage of Exception Status Drugs. **9.** PEI Pharmacare. PEI Pharmacare formulary. **10.** Government of Canada. Veterans Affairs Canada. Drug formulary search form. **11.** Non-Insured Health Benefits: Drug benefit list.

Otsuka

Orijin™ SUPPORT PROGRAM

MEMBER OF INNOVATIVE MEDICINES CANADA

REVIEWED BY PAAB

PrVELPHORO® sucroferric oxyhydroxide

OCPI-VPO-00213E