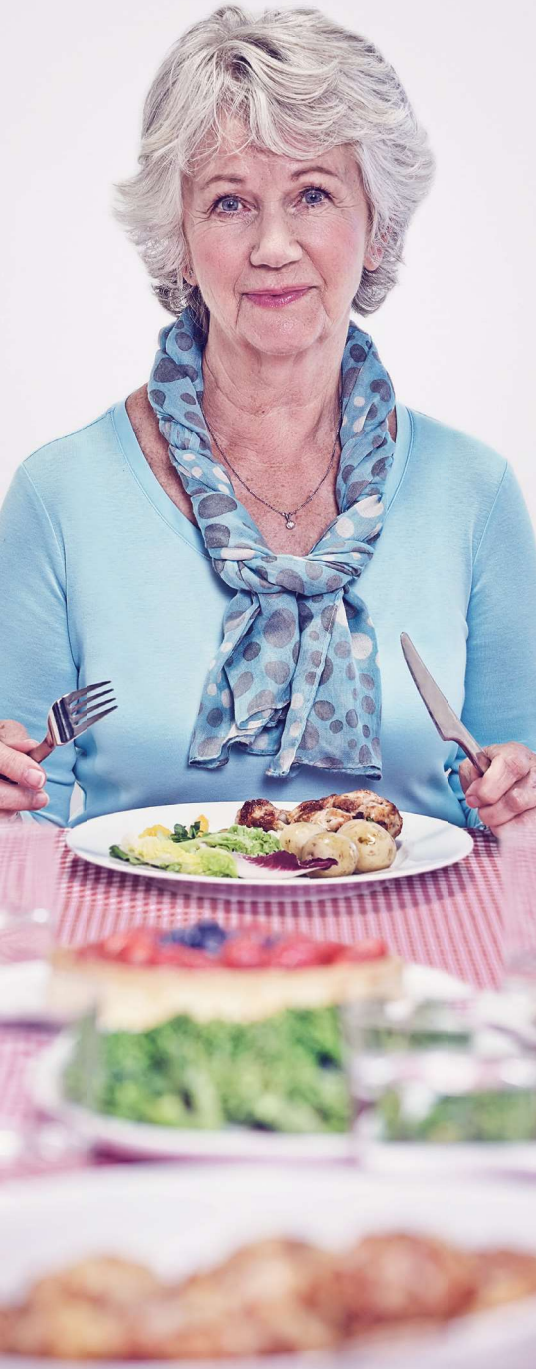
Pr VELPHORO®
sucroferric oxyhydroxide

Otsuka

Consider PrVELPHORO® for your patients

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



What is VELPHORO indicated for?

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

What is the recommended dose for VELPHORO?

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.[1]

Breakfast Lunch Dinner

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]

Every 2-4 weeks

‡ Tablet is not actual size.

What is the maximum daily dose of VELPHORO patients can take?

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

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

If one 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?

VELPHORO is a woodberry-flavoured **chewable tablet and must be taken with meals.**[1]

Tablets must be chewed and not swallowed whole. Tablets may be crushed.[1]

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 VELPHORO 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 one hour before or two 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]

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]

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

* Clinical significance has not been established.

† *In vitro* interactions are theoretical.

What is the safety profile for PrVELPHORO®?

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]

Does VELPHORO cause discoloured feces?

As expected with oral preparations containing iron, discolored feces were very common.[1]

- VELPHORO can cause discoloured (black) stool, which may visually mask gastrointestinal bleeding.

Is the iron in VELPHORO absorbed?

Changes in iron parameters during treatment with VELPHORO were consistent with a minimal level of iron absorption. No safety signals were detected with respect to clinical chemistry, hematological, or vitamin levels.[1]

Clinical significance is unknown.

Over 100,000 adult patients have been prescribed VELPHORO worldwide.[2]

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]

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

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

Important Safety Information

Clinical use:

- Efficacy and safety in pediatric population (<18 years of age) have not been evaluated.
- No overall 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

For more information:

Please consult the Product Monograph at http://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.

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

References: 1. VELPHORO Product Monograph. Otsuka Canada Pharmaceutical Inc. October 4, 2019. **2.** Data on File. Otsuka Canada Pharmaceutical Inc.

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REVIEWED BY PAAB

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