PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Velphoro

Chewable tablets

Each chewable tablet contains:
500 mg iron as sucroferric oxyhydroxide
For a list of inactive ingredients and allergens in the preparation, see section 2 – "Important information about some ingredients of the medicine", and section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Velphoro is intended for regulation of serum phosphorus levels in patients with chronic kidney disease (CKD) treated with hemodialysis (HD) or peritoneal dialysis (PD).

Therapeutic class: medicines for treatment of excess potassium (hyperkalemia) and excess phosphorus (hyperphosphatemia).

2. Before using the medicine:

X Do not use this medicine if:

- You are allergic (sensitive) to the active ingredient or to any of the medicine's ingredients (see section 6).
- You previously had an abnormal accumulation of iron in your organs (hemochromatosis).
- You are suffering from any other disorder associated with high levels of iron.

Special warnings regarding the use of the medicine

! Before treatment with Velphoro, inform the doctor if:

- You have suffered in the last three months from an inflammation of the peritoneum (the thin tissue that covers the interior wall of the abdomen).
- You are suffering from a significant problem in your stomach and/or liver.
- You underwent an extensive surgery in your stomach and/or intestines.

If you are unsure if the abovementioned applies to you, consult a doctor or a pharmacist before taking the medicine.

Velphoro may cause black stool. Black stool may visually mask any possible gastrointestinal bleedings. **If you have black stool as well as symptoms such as increased fatigue and shortness of breath, you should consult your doctor immediately (see section 4).**

! Children and adolescents

No information is available regarding safety and efficacy of using this preparation in children and adolescents. This medicine is not intended for children and adolescents under the age of 18.

! Drug-drug interactions

If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the physician or the pharmacist. Especially if you are taking:

- Alendronate (for treatment of bone diseases), doxycycline (an antibiotic), since these medicines are known to interact with iron.
- Levothyroxine (for treatment of thyroid impairment), since this medicine can potentially interact with Velphoro.

Be sure to take these medicines at least one hour before taking Velphoro or at least two hours after taking Velphoro.
Consult the doctor if you are uncertain.

! Use of the medicine and food

The tablet should be chewed with food (see section 3).

! Pregnancy and breastfeeding

No information is available regarding the effect of the medicine during pregnancy or breastfeeding.
If you are pregnant, think you might be pregnant, planning to become pregnant or breastfeeding, you should consult the doctor before starting the treatment.
The doctor will advise you whether to take the medicine during pregnancy, according to risk-benefit considerations during the pregnancy period.
If you are breastfeeding, your doctor will discuss with you whether to continue breastfeeding or to continue taking the medicine, while taking into account the benefit for you from continuing treatment with Velphoro and the benefit for your baby from breastfeeding.
It is unlikely that the medicine will pass into breastmilk.

! Driving and operating machinery

Velphoro should not have a significant effect on your ability to drive or operate tools or machinery.

! Important information about some ingredients of the medicine

The medicine contains starch and sucrose. If you have been told by your doctor that you have a sensitivity or an intolerance to some sugars, contact your doctor before using this medicine.
Velphoro may harm your teeth.
If you have diabetes, you should exercise caution and keep in mind that each Velphoro chewable tablet contains about 1.4 grams of carbohydrates.

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined by the doctor only.
The generally accepted dosage is: 3 chewable tablets per day (1,500 mg iron).
The maximal recommended daily dose is up to 6 chewable tablets per day (3,000 mg iron).
The doctor will adjust the dosage during the treatment according to your blood phosphorus level.

Do not exceed the recommended dose

The chewable tablet should be taken during a meal and be chewed. The chewable tablet may be crushed if needed, to make swallowing easier.
Do not swallow the chewable tablet whole.
You should divide the daily dose of chewable tablets according to the number of meals that you have per day.
While taking Velphoro, you should adhere to the treatments and the diet recommended for you per the doctor's orders, e.g., taking calcium supplements, vitamin D3 or calcimimetics.

If you took an overdose or by mistake a child swallowed this medicine, go immediately to the doctor or the emergency room of the hospital and take the package of the medicine with you. If you have taken by mistake too many Velphoro chewable tablets, stop the treatment and do not take any more chewable tablets. Contact the doctor immediately.

If you forgot to take this medicine at the required time, take the next dose with a meal at the regular

time. Do not take a double dose in order to compensate for the dose that you forgot to take.

If you stop taking the medicine, your phosphorus blood levels may rise.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.
Follow the treatment as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.
If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

As with any medicine, using Velphoro chewable tablets may cause side effects in some users.
Do not be alarmed when reading the list of side effects. You may not experience any of them.

The following side effects have been reported by patients that took Velphoro:

Very common side effects (occurring in more than one out of ten users):
Diarrhea (usually occurs in the beginning of treatment, and improves as treatment with Velphoro progresses), black stool.
If in addition to black stool you have symptoms such as increased fatigue and shortness of breath, the doctor should be contacted immediately (see section 2).

Common side effects (occurring in 1-10 out of 100 users):
Nausea, constipation, vomiting, indigestion, stomach or bowel pain, flatulence, discoloration of teeth, change in taste.

Uncommon side effects (occurring in 1-10 out of 1,000 users):
Bloating (abdominal distension), stomach inflammation, abdominal discomfort, swallowing difficulties, gastroesophageal reflux (acid going up from the stomach to the esophagus), tongue discoloration, high or low blood calcium level, fatigue, itching, rash, headache, shortness of breath.

If a side effect occurs, or if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il/

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
Store at temperature below 25°C. The medicine may be used for up to 90 days from opening the bottle.
Store in the original package.

6. Additional information:

In addition to the active ingredient, the medicine also contains:
Woodberry flavour, Magnesium stearate, Silica (Colloidal, Anhydrous), Neohesperidin-dihydrochalcone.

What does the medicine look like and what are the contents of the package?
A plastic bottle containing 30 or 90 chewable tablets. The chewable tablets are round and red-brown, with "PA500" printed on one side.
Not all package sizes may be marketed.

License holder and the address:
CTS Ltd., 4 Haharash St., Hod Hasharon.

Name and address of the manufacturer:
Vifor (International), Rechenstrasse 37
St. Gallen 9014, Switzerland

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by the Ministry of Health on 06/2016 and has been updated in accordance with the Ministry of Health instructions on 07/2020.

Registration number of the medicine in the national drug registry of the Ministry of Health:
156-48-34557-00