



SUMMER 2019 | VOL. 4.2

# AKF in Action

Fighting kidney disease and helping people live healthier lives.

**4** Beat the heat

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## Clinical trials: myths and facts



**D**id you know researchers are looking for people like you to receive treatment in their clinical trials? Clinical trials research and study the effectiveness of new treatments. They often provide world-class care and offer benefits to participants, such as free or low-cost treatments. Treatments being studied in clinical trials go through many rounds of testing before they are used on people. Those who participate in clinical trials help to advance treatment and improve the lives of future patients.

Test your knowledge with our clinical trials quiz. See if these statements are myths or facts on page 2.

Question	Myth	Fact
1. Clinical trials are scientific studies on volunteer human participants that help to discover better ways to prevent, detect, treat or cure diseases.	<input type="checkbox"/>	<input type="checkbox"/>
2. Participating in a clinical trial has the potential to improve your quality of life.	<input type="checkbox"/>	<input type="checkbox"/>
3. Clinical trials are required by law to have safeguards to protect participants' safety and privacy.	<input type="checkbox"/>	<input type="checkbox"/>
4. Unless my doctor tells me about a clinical trial, there is no other way I can find out about one or be able to join one.	<input type="checkbox"/>	<input type="checkbox"/>
5. You must live near a major hospital to participate in a clinical trial.	<input type="checkbox"/>	<input type="checkbox"/>
6. Once you sign up for a clinical trial, you will not be allowed to drop out.	<input type="checkbox"/>	<input type="checkbox"/>
7. In many cases you can bring a family member or loved one with you to a clinical trial for support.	<input type="checkbox"/>	<input type="checkbox"/>
8. The racial diversity of clinical trial participants does not affect clinical trial outcomes because medicine works the same for all people.	<input type="checkbox"/>	<input type="checkbox"/>
9. Clinical trial participants are never paid for their participation.	<input type="checkbox"/>	<input type="checkbox"/>
10. You can ask the researchers questions at any time when participating in a clinical trial.	<input type="checkbox"/>	<input type="checkbox"/>

continues on next page >



Let us know how you did on the quiz and what you learned! Tweet us at @KidneyFund and use #ClinicalTrials to tell us if you could see through the myths.

# Clinical trials: myths and facts

< continued from previous page

- 1. Clinical trials are scientific studies on volunteer human participants that help to discover better ways to prevent, detect, treat or cure diseases.**

**FACT!** The primary goals of clinical trials are to find new drugs, therapies or medical devices that improve or cure health conditions and to make sure they work well for patients.

- 2. Participating in a clinical trial has the potential to improve your quality of life.**

**FACT!** Participating in a clinical trial could possibly provide benefits that could improve your quality of life. For example, you may gain access to new and effective treatments available only to people participating in the trial, receive focused health care for your particular condition or learn more about your disease.

- 3. Clinical trials are required by law to have safeguards to protect participants' safety and privacy.**

**FACT!** Clinical trials must have safeguards to protect the people who choose to participate. These safeguards are meant to protect participants from possible harmful side effects of the treatments being tested and protect participants from being treated unfairly during the research study. All clinical trial participants are protected under a Clinical Trial Participant Bill of Rights.

- 4. Unless my doctor tells me about a clinical trial, there is no other way I can find out about one or be able to join one.**

**MYTH!** You do not need a recommendation from a doctor to participate in a clinical trial. You can search for clinical trials online, and it is your choice to request to join. You can always ask your doctor if they have recommendations for clinical trials you may qualify for, but this is not required.

- 5. You must live near a major hospital to participate in a clinical trial.**

**MYTH!** Clinical trials are held at universities, doctors' offices, community clinics and remotely through telemedicine. Ask your doctor about whether there are clinical trials near you, or search for nearby clinical trials yourself.

- 6. Once you sign up for a clinical trial, you will not be allowed to drop out.**

**MYTH!** Participating in a clinical trial is always voluntary. You have the right to leave the study at any time, for any reason, without any penalty.

- 7. In many cases you can bring a family member or loved one with you to a clinical trial for support.**

**FACT!** In many cases, you can bring someone with you for support unless otherwise mentioned. Many clinical trials will encourage you to bring someone to help you take notes or remember the information discussed about your treatment. If you are not sure whether you can bring someone, reach out to the clinical trial team to ask.

- 8. The racial diversity of clinical trial participants does not affect clinical trial outcomes because medicine works the same for all people.**

**MYTH!** Having a diverse group of participants—meaning people of different races/ethnicities, genders and ages—is important to the success of clinical trials. Due to genetics, certain diseases are more common among certain races and ethnicities. Plus, treatments can work differently among different populations.

- 9. Clinical trial participants are never paid for their participation.**

**MYTH!** Not all clinical trials offer money to participants, but some do. You might be given a stipend or reimbursement for certain aspects of your participation, like meals or travel costs. If you are considering participating in a trial, ask a member of the clinical trial research team whether you will be compensated for your participation, or what costs you might be responsible for if you participate.

- 10. You can ask the researchers questions at any time when participating in a clinical trial.**

**FACT!** Under the Clinical Trial Participant Bill of Rights, you are allowed to ask questions at any time throughout the entire clinical trial period. Do not hesitate to ask questions. Remember, you are not obligated or required to participate in a clinical trial if you change your mind.



**To learn more about clinical trials and to find a clinical trial match for you, visit [KidneyFund.org/clinical-trials](https://www.kidneyfund.org/clinical-trials).**



## Staff Spotlight

**Name:** Martin  
**Hometown:** Silver Spring, MD

### What do you do at the American Kidney Fund (AKF)?

I'm the Director of Community Engagement. I manage KidneyNation, our do-it-yourself fundraising program. I've been working for AKF's amazing mission for over four years now.

### Do you have a personal connection to kidney disease?

When I first joined AKF, I didn't really know much about kidney disease except the basics. Within my first few weeks at AKF, however, things got personal.

I learned two people very close to me had been diagnosed with CKD—a family member was in the earlier stages of the disease, while an old friend and amazing person would need to begin dialysis immediately. My work with our KidneyNation fundraising platform quickly gained a new level of meaning.

I'm happy to report my family member is doing well monitoring the disease's progression and my friend is also doing well—he's coming up on his 2-year transplant anniversary!

### Why are you passionate about fighting kidney disease?

I view kidney disease as a drastically underserved health issue. I've been so inspired by the patients I've met through clinics, events and KidneyNation. People affected by kidney disease understand the special circumstances a diagnosis creates, and I have been in awe watching people do everything they can to help others.

The fact that so many patients have expressed how much AKF's programs and services help them personally strengthens my resolve to raise as much money as possible, so our services can reach more patients and help bring back quality of life and hope to more people.

### What is the best part of your job?

The people, without a doubt. Meeting patients who have the drive and desire to help others facing similar challenges has helped me grow as a person. Meeting people who have memorialized loved ones lost to kidney failure with fundraisers has given me hope for greater patient outcomes. Working with colleagues whose tireless efforts on behalf of the patients we serve has inspired me to work harder every day.

### What are your favorite hobbies outside of work?

My wife and I love music. We try to see as much live music as we can, but a night on the couch watching TV together is always a wonderful thing, too. I enjoy bike riding and endurance sports, and have completed over 20 triathlons, half-marathons and century rides. Oh, and I love fundraising—I have raised more than \$25,000 through charity fundraisers in recent years!

## KidneyNation Spotlight

KidneyNation is AKF's do-it-yourself fundraising program through which people across the country—including you—can raise money for AKF's programs and services benefiting the kidney community. Learn more and get tips on how to start a successful fundraiser today at [KidneyNation.org](https://www.kidneyfund.org/kidneynation).

**Name:** Adrian  
**Location:** Vancouver, WA



### What is your connection to kidney disease?

I have kidney disease.

### Why do you care about fighting kidney disease?

I believe the voices of kidney patients are important because the more awareness there is about kidney disease, the more help there will be for the community. I've traveled around the country and seen people who are so sick with kidney disease, they cannot take care of themselves. It is my life's goal and passion to help those who cannot help themselves.

### Why are you passionate about raising money for AKF through KidneyNation?

AKF is a bunch of angels. They provide relief for those who have lost hope. I will always be involved in their efforts to create a better world for patients in need.

### What fundraiser are you working on now?

I am working on a spin-a-thon at the gym I work at—I work as a patient relations representative in a hospital and also at the gym. The community at the gym is really supportive of me and my journey with kidney disease. We're going to sell participation tickets and also have the option for people to give extra donations, of course.

I also did a similar fundraiser for AKF before, except last time it was a Zumba-thon!

### What advice do you have for other people who may want to start their own fundraiser?

Don't be afraid of the word "no!" You can't be afraid to ask for a donation because people's lives depend on the money raised. The very worst is that you may hear, "no," but that's nothing. If someone declines to give, just move on to the next person.

Be knowledgeable in case you get questions about kidney disease. Being in the public eye as a kidney disease advocate is helpful, too.



# BEAT THE HEAT!

## Stay hydrated without overdoing fluids

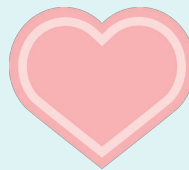
### FLUID INTAKE

When you are on dialysis, fluid (water) builds up in your blood between treatments. Here's some helpful info on fluid management. Ask your dietitian how much fluid you should have each day.

### Things to keep in mind . . .



Extra fluid in your body can make your dialysis treatments more difficult.



Too much fluid can cause swelling, high blood pressure, trouble breathing and heart failure.



Salty foods like chips and pretzels make you thirsty.

### CHILL

or freeze fruit for a refreshing snack.



### FREEZE

juice in an ice cube tray and eat it like a popsicle.



### CHOOSE

unsalted snacks.



### SUCK

on a lemon slice or sugar-free sour candy.



### REMEMBER!

Ice cream, Jell-o, soup and other liquid-based foods count as fluids, too--be careful to watch your intake of fluids.

### DROPS OF ADVICE





Photo ©Chelsea R.

sure in advance that the place where you are staying has elevators and is accessible. An Airbnb or similar rental situation could also work, but you should pick your place according to your needs—is there a reclining chair you could do your treatments in or a sofa where you can comfortably stretch out?

It is important for Chelsea to see a new place every year and not feel like she is stuck because she is on dialysis. Her favorite destination thus far has been Maui. While she has yet to travel outside of the United States since starting dialysis, she believes she would definitely be able to travel to her dream destination, Switzerland. She says it would take some extra planning and making sure to remember to bring certain things, such as a European plug adapter for her dialysis machine.

Are you an in-center dialysis patient? Chelsea says you should not feel tied down to your center! Reach out to centers in advance to let them know you will be in town and need to schedule treatments. She recommends scheduling early morning treatments if you can, so the rest of the day can be spent doing the fun activities you have planned for your trip. Your regular dialysis center may even be able to help connect you with a center where you are traveling.

Chelsea's biggest piece of advice for traveling is: just do it!

## Traveling as a dialysis patient

Summer is a great time to get away for a trip to the beach, a cooler climate or a long weekend in a place you have never been. Home hemodialysis patient, advocate and travel enthusiast Chelsea spoke to AKF about what it is like to travel as a dialysis patient. She wants every patient to know that you can—and should—travel while on dialysis.

Chelsea recommends starting to pack for your trip at least two weeks before leaving instead of rushing to throw everything in a suitcase at the last minute. Packing early allows you to double and triple check to make sure you have packed everything for your treatments, like gloves, gauze and masks. Though most of her dialysate and saline are shipped to her destination before she leaves home, Chelsea always packs extra to bring with her in case any of it breaks during shipment. She has a large suitcase everything fits into, and she found an inexpensive hand truck to help her transport her heavy dialysis machine. If you do not have a hand truck and are flying, an airport cart or airport staff may be able to assist you.

Though she usually travels with her husband, Chelsea has also been surprised by how easy solo business trips have been. Not having help from a travel partner means some things may take a little longer to set up, and you may need extra help carrying your equipment to your hotel room. Chelsea brings extra cash with her to tip those who help lift and lug her equipment.

Staying in hotels is preferable, according to Chelsea, and if you can get a suite, that is even better because you can designate separate rooms for dialysis and relaxing. When checking into your hotel, you may need to rearrange some of the furniture to set up for dialysis so you can have easy access to outlets. You will have a lot to carry, so make



Photo ©Chelsea R.



Photo ©Chelsea R.



## Real participant reviews of some of AKF's recent webinars:

"I learned more than I had expected. Easily followed. Thank you."

"The webinar I attended today was worthwhile and I enjoyed the nephrologist's presentation."

"The information was presented in a very easy to understand, non-technical format. It's confirmed my decision to become a kidney donor and I can't wait to get started!"

"As a registered dietitian, I gained useful, practical info to share with my renal dialysis patients."



## WATCH AND LEARN:

# AKF webinars available on demand

**A**KF hosts monthly webinars on many important topics relating to kidney disease. These webinars are all free and can be watched at your convenience at [KidneyFund.org/webinars](https://www.kidneyfund.org/webinars). Just look for these titles in our list of webinars to watch on-demand.

### Sexual Health, Sexuality, and Kidney Disease

Sexual health may not be discussed openly or frequently in the kidney disease community, however, it is an important topic to many.

**What you'll learn:** common sexual dysfunctions in the kidney disease community, factors that affect sexual function and treatment approaches that address sexual dysfunction in people with kidney disease.

### Healthy weight pre- and post-kidney transplant

Maintaining a healthy weight can be a big part of the kidney transplant process—both before transplant surgery and after.

**What you'll learn:** preparing for kidney transplant as it relates to healthy weight, strategies to maintain a healthy weight before and after transplant, post-transplant changes in metabolism, side effects of medicines and weight gain.

### Gout and kidney disease

The causes, treatments and seriousness of gout—a severe form of arthritis that commonly affects people with kidney disease—are often misunderstood.

**What you'll learn:** The causes, symptoms and risk factors for gout, the connection between gout and kidney disease, and the treatments for gout.



## Change of address?

Please make sure to notify AKF if your address has changed. Email [patientservice@KidneyFund.org](mailto:patientservice@KidneyFund.org).

# Kidney-friendly recipes

Drink this refreshing mixture of watermelon, lime and strawberry on a hot summer day, or serve it at a holiday BBQ. The bright colors and flavors will delight your taste buds!

Check out many more kidney-friendly recipes at [Kitchen.KidneyFund.org](http://Kitchen.KidneyFund.org). As always, please speak with your doctor and dietitian to come up with a food and fluid plan that is healthy for your unique needs.



## Ingredients

4 cups watermelon, cubed  
2 cups strawberries, chopped  
2 limes  
2 cups ice  
6 large basil leaves

## Method

1. Add cubed watermelon, chopped strawberries and juice from 2 limes into a blender.
2. Top with 2 cups of ice.
3. Blend until smooth, about 30 seconds to 1 minute.
4. Serve in individual glasses and top with strawberry slice and basil leaf.

**Tip:** Pour the drink mixture into popsicle molds to make a fun summer treat, but remember to include it in your fluid total for the day if you have been told to monitor fluid intake.

## Watermelon Lime Refresher

Makes 6 low-phosphorus, low-potassium, low-sodium, low-protein servings

Recipe contributed by  
Sara Pellegrino, MPH, RD, LDN

## Nutrition facts (1 serving = 1 cup)

Calories: 56	Cholesterol: 0g	Protein: 1g
Fat: 0g	Carbohydrates: 14g	Sodium: 2mg
Saturated Fat: 0g	Sugar: 10g	Calcium: 24mg
Trans Fat: 0g	Fiber: 2g	Phosphorus: 29mg
		Potassium: 226mg

American Kidney Fund®

Kidney Kitchen

## Kidney Kitchen is supported in part by:



## Gout and kidney disease: Did you know?

About 10% of kidney disease patients have gout, and 40-60% of people with gout have kidney disease. Having gout, and especially chronic gout, can lead to serious health problems over time if left uncontrolled. Visit [KidneyFund.org/gout](http://KidneyFund.org/gout) for more information on the connection between gout and kidney disease. AKF's gout education and the *Goutful* campaign are supported by an unrestricted grant from Horizon Therapeutics plc.

### Tophi



Tophi are clumps of urate crystals that form on joints and cartilage including fingers, hands, feet and ankles. Tophi may not cause pain, but damage to your joints, bones and cartilage may still occur.

### Kidney stones



If you have gout, the build-up of urate crystals in your urinary tract puts you at risk for kidney stones.

### Kidney disease



If left untreated, the urate crystals that make kidney stones can cause long-term damage to your kidneys.

### Joint damage



Chronic swelling and tophi caused by gout can lead to permanent joint damage and deformity. In the worst cases, you may need surgery to fix or replace damaged joints.

### Psychological and emotional challenges



The chronic pain caused by gout often leads to emotional stress or depression. Discuss how you are feeling with your doctor.



American Kidney Fund®  
FIGHTING ON ALL FRONTS

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[KidneyFund.org](http://KidneyFund.org)

People across the country are raising money to benefit AKF's lifesaving programs and services. Join them today at [KidneyNation.org](http://KidneyNation.org)!



#### WHAT'S INSIDE:

- Clinical trials: myths and facts
- The people who make our mission possible
- Beat the heat
- Traveling while on dialysis



When patients' phosphate binder therapy was not successful...

# SWITCHING TO VELPHORO MADE A WORLD OF DIFFERENCE



Double the percentage of  
patients achieved phosphorus  
goal with half the pill burden\*<sup>1</sup>

Visit [RealWorldVelphoro.com](http://RealWorldVelphoro.com)  
TO SEE THE DIFFERENCE A SWITCH CAN MAKE

## INDICATION

Velphoro® (sucroferric oxyhydroxide) is a phosphate binder indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis.

## IMPORTANT SAFETY INFORMATION

- Velphoro must be administered with meals. Velphoro tablets must be chewed and not swallowed whole. To aid with chewing and swallowing, the tablets may be crushed.
- Patients with peritonitis during peritoneal dialysis, significant gastric or hepatic disorders, following major gastrointestinal (GI) surgery, or with a history of hemochromatosis or other diseases with iron accumulation have not been included in clinical studies with Velphoro. Monitor effect and iron homeostasis in such patients.
- In a parallel design, fixed-dose study of 6 weeks duration, the most common adverse drug reactions to Velphoro chewable tablets in hemodialysis patients included discolored feces (12%) and diarrhea (6%).

- Velphoro can be administered concomitantly with oral calcitriol, ciprofloxacin, digoxin, enalapril, furosemide, HMG-CoA reductase inhibitors, hydrochlorothiazide, losartan, metoprolol, nifedipine, omeprazole, quinidine and warfarin. Take doxycycline at least 1 hour before Velphoro. Velphoro should not be prescribed with oral levothyroxine.

Please see Brief Summary on adjacent page or visit [www.Velphoro.com](http://www.Velphoro.com) for full Prescribing Information.

\*A retrospective analysis of pharmacy data assessed the real-world effectiveness of Velphoro in 1,029 adult in-center hemodialysis patients who were switched to Velphoro during routine care. The study compared the proportion of patients with phosphorus levels  $\leq 5.5$  mg/dL and the mean prescribed phosphate binder pills/day at baseline (3 months prior to Velphoro; binders included sevelamer carbonate, calcium acetate, and lanthanum carbonate) and during Velphoro follow-up (6 months after switch to Velphoro, n=424). This was a noninterventional analysis and did not impact prescriptions or prescribing patterns.<sup>1</sup>

Reference: 1. Coyne DW, Ficociello LH, Parameswaran V, et al. Real-world effectiveness of sucroferric oxyhydroxide in patients on chronic hemodialysis: A retrospective analysis of pharmacy data. *Clin Nephrol.* 2017;88(2):59-67.



Velphoro is a registered trademark of Vifor Fresenius Medical Care Renal Pharma Ltd.

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Waltham, MA 02451

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**VELPHORO®**  
(sucroferric oxyhydroxide)  
chewable tablets  
POTENCY MAKES IT POSSIBLE

**Brief Summary:**

Please see Full Prescribing Information for additional information

**INDICATIONS AND USAGE**

Velphoro (sucroferric oxyhydroxide) is a phosphate binder indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis.

**DOSAGE AND ADMINISTRATION**

Velphoro tablets must be chewed and not swallowed whole. To aid with chewing and swallowing, tablets may be crushed.

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

Adjust by 1 tablet per day as needed until an acceptable serum phosphorus level is reached, with regular monitoring afterwards. Titrate as often as weekly.

**DOSAGE FORMS AND STRENGTHS**

Velphoro (sucroferric oxyhydroxide) chewable tablet 500 mg.

**CONTRAINDICATIONS**

None.

**WARNINGS AND PRECAUTIONS**

Patients with peritonitis during peritoneal dialysis, significant gastric or hepatic disorders, following major gastrointestinal surgery, or with a history of hemochromatosis or other diseases with iron accumulation have not been included in clinical studies with Velphoro. Monitor effect and iron homeostasis in such patients.

**ADVERSE REACTIONS**

In a parallel design, fixed-dose study of 6 weeks duration, the most common adverse drug reactions to Velphoro chewable tablets in hemodialysis patients included discolored feces (12%) and diarrhea (6%).

The following adverse reactions were identified during post approval use of Velphoro, and were reported voluntarily from a population of uncertain size.

Gastrointestinal Disorders: tooth discoloration

Skin and Subcutaneous Tissue Disorder: rash

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Medical Care North America at 1-800-323-5188 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**DRUG INTERACTIONS**

Velphoro can be administered concomitantly with oral calcitriol, ciprofloxacin, digoxin, enalapril, furosemide, HMG-CoA reductase inhibitors, hydrochlorothiazide, losartan, metoprolol, nifedipine, omeprazole, quinidine and warfarin.

Take doxycycline at least 1 hour before Velphoro.

Velphoro should not be prescribed with oral levothyroxine.

**USE IN SPECIFIC POPULATIONS****Pregnancy**

Pregnancy Category B: Reproduction studies have been performed in rats and rabbits at doses up to 16 and 4 times, respectively, the human maximum recommended clinical dose on a body weight basis, and have not revealed evidence of impaired fertility or harm to the fetus due to Velphoro. However, Velphoro at a dose up to 16 times the maximum clinical dose was associated with an increase in post-implantation loss in pregnant rats. Animal reproduction studies are not always predictive of human response.

There are no adequate and well-controlled studies in pregnant women.

**Labor and Delivery**

No Velphoro treatment-related effects on labor and delivery were seen in animal studies with doses up to 16 times the maximum recommended clinical dose on a body weight basis. The effects of Velphoro on labor and delivery in humans are not known.

**Nursing Mothers**

Since the absorption of iron from Velphoro is minimal, excretion of Velphoro in breast milk is unlikely.

**Pediatric Use**

The safety and efficacy of Velphoro have not been established in pediatric patients.

**Geriatric Use**

Of the total number of subjects in two active-controlled clinical studies of Velphoro (N=835), 29.7% (n=248) were 65 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects.

**OVERDOSAGE**

There are no reports of overdosage with Velphoro in patients. Since the absorption of iron from Velphoro is low, the risk of systemic iron toxicity is low. Hypophosphatemia should be treated by standard clinical practice.

Velphoro has been studied in doses up to 3,000 mg per day.

**HOW SUPPLIED/STORAGE AND HANDLING**

Velphoro are chewable tablets supplied as brown, circular, bi-planar tablets, embossed with "PA 500" on 1 side. Each tablet of Velphoro contains 500 mg iron as sucroferric oxyhydroxide. Velphoro tablets are packaged as follows:

NDC 49230-645-51      Bottle of 90 chewable tablets

**Storage**

Store in the original package and keep the bottle tightly closed in order to protect from moisture.

Store at 25°C (77°F) with excursions permitted to 15 to 30°C (59 to 86°F).

**PATIENT COUNSELING INFORMATION**

Inform patients that Velphoro tablets must be chewed and not swallowed whole. To aid with chewing and swallowing, the tablets may be crushed [see *Dosage and Administration*].

Velphoro should be taken with meals.

Instruct patients on concomitant medications that should be dosed apart from Velphoro [see *Drug Interactions*].

Inform patients that Velphoro can cause discolored (black) stool.

Inform patients that Velphoro can stain teeth.

Inform patients to report any rash to their healthcare professional.

Distributed by:

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