Patient Information VOWST (pronounced Vowst) (fecal microbiota spores, live – brpk) capsules, for oral use

Before you take VOWST, read this information sheet and be sure you understand it. If you have questions or experience any side effects, talk to your healthcare provider. This information does not take the place of talking about VOWST with your healthcare provider. Keep this patient information so you can read it again.

What is VOWST?

VOWST is a prescription medicine used to prevent *Clostridioides difficile* (*C. difficile*) infection from coming back in people 18 years of age or older after antibiotic treatment for *C. difficile* infection has been completed.

VOWST is not intended for treatment of *C. difficile* infection.

How should I take VOWST?

- VOWST is taken over three consecutive days.
- Before you take VOWST:
 - 2 to 4 days before your first dose of VOWST, finish your antibiotic treatment for *C. difficile* infection.
 - On the day before and at least 8 hours prior to the <u>first</u> dose of VOWST, drink 10 oz (296 mL) of magnesium citrate laxative.
 - Do not eat or drink, except for small amount of water, for at least 8 hours prior to taking the first dose.
- The next day after taking the laxative, take 4 VOWST capsules by mouth on an empty stomach prior to the first meal of the day.
- Take 4 VOWST capsules by mouth once daily for two more days in a row. Take VOWST capsules on an empty stomach prior to the first meal of the day.

Swallow each capsule whole. DO NOT crush, chew, or break the capsules.

Do any medications interfere with VOWST?

VOWST contains live bacteria. Antibiotics can interfere with VOWST. VOWST should not be taken at the same time as antibiotics.

What should I tell my healthcare provider before taking VOWST?

Tell your healthcare provider if you:

- have kidney disease because you may not be able to take the magnesium citrate laxative.
- have any other medical conditions now or have had before.
- take any medicines, including prescription and over-the-counter medicines, vitamins, and supplements.

- are pregnant or planning to get pregnant.
- are breast-feeding.

What are the possible side effects of VOWST?

The most common side effects observed in patients taking VOWST were:

- bloated abdomen
- fatigue
- constipation
- chills
- diarrhea

These are not all the possible side effects of VOWST. Be sure to tell your healthcare provider about any side effect that bothers you or that does not go away. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to Aimmune Therapeutics, Inc. at 1-833-246-2566 or FDA at 1-800-FDA-1088 or report online to <u>www.fda.gov/medwatch</u>.

How should I store VOWST?

- Keep the bottle of VOWST capsules either in the refrigerator or at room temperature (36 to 77°F, 2 to 25°C). Do not store in the freezer.
- Do not use VOWST past the expiration date stamped on the carton and the bottle.

Keep VOWST out of the reach of children.

What if I have questions?

- Call your healthcare provider.
- Call Aimmune Therapeutics, Inc.at 1-833-AIM-2KNO (1-833-246-2566).
- Go to the website www.VOWST.com.

What are the ingredients in VOWST?

Active ingredient: live bacterial spores

Inactive ingredients: Glycerol, Saline

Manufactured by: Seres Therapeutics, Inc. 200 Sidney Street, Cambridge, MA 02139 U.S. license number: 2262

Distributed by: Aimmune Therapeutics, Inc. 1007 US Highway 202/206, Bridgewater, NJ 08807

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