VOWST®—the only FDA-approved microbiome treatment in oral capsules that helps prevent *C. diff* from coming back again





# INDICATION What is VOWST?

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

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

# IMPORTANT SAFETY INFORMATION

Do not take VOWST at the same time as antibiotics. VOWST contains live bacteria and antibiotics can interfere with VOWST.

Swallow each capsule whole. DO NOT crush, chew, or break the capsule. See Patient Information for complete information about how to take VOWST.

# THE RISK OF C. DIFF RECURRENCE

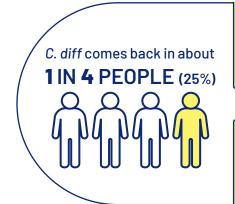
C. diff can come back, even after being treated with an antibiotic—this is called a **recurrence**.

C. diff can happen to anyone, but there are certain factors that can increase your risk of it coming back:

- Taking antibiotics
- Being 65 years of age or older
- Staying in a hospital or nursing home
- Having a weakened immune system
- Use of proton-pump inhibitor (PPI) therapy for acid reflux
- Being exposed to C. diff germs

While antibiotics can kill C. diff bacteria, they are a main risk factor for getting a recurrence





For those 1 in 4 people, once it comes back, your risk of recurrence increases up to



When *C. diff* comes back, you may recognize some common symptoms. Talk to your doctor if you are having\*:



Frequent, uniquely bad-smelling diarrhea



**Fever** 



Painful stomach cramps



Nausea and loss of appetite

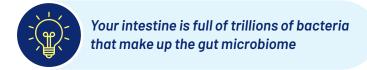
<sup>\*</sup>These are the most common recurrent *C. diff* symptoms, but not all possible symptoms.

# WHEN USED ALONE, ANTIBIOTICS DO NOT ADDRESS THE IMBALANCE THAT CAN CAUSE C. DIFF TO RETURN

#### The role of antibiotics in C. diff



Recurrent *C. diff* has historically been treated with antibiotics alone. Antibiotics are important because they kill *C. diff* bacteria that cause your infection, but they do not restore the balance of good and bad bacteria in your gut, which can lead to *C. diff* coming back.



# Why the balance of good and bad bacteria is important

good bacteria

bad bacteria



In a healthy gut microbiome, good and bad bacteria are balanced



But if your gut gets disrupted, your body's natural defense against *C. diff* is weakened



This causes some people to get *C. diff* again and again

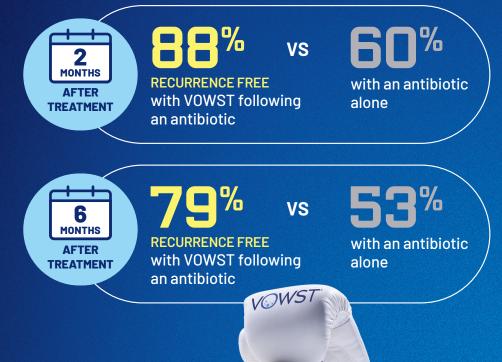


Taking a microbiome treatment that adds good bacteria to the gut may help prevent C. diff from returning

# VOWST® USED AFTER AN ANTIBIOTIC CAN HELP PREVENT ANOTHER C. DIFF RECURRENCE

In a 6-month clinical study, the majority of people given the 1-2 GUT PUNCH of VOWST following an antibiotic did not have *C. diff* come back

Percentage of people who were recurrence free after finishing treatment



#### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

Before taking VOWST, tell your doctor about all your medical conditions, including if you: have kidney disease because you may not be able to take the magnesium citrate laxative; or have any other medical conditions now or have had before, are pregnant or planning to get pregnant, or are breastfeeding.

**Tell your doctor about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and supplements.

# MOST COMMON SIDE EFFECTS OF VOWST

VOWST was generally well tolerated—the most common side effects were mild to moderate

In a clinical study, these side effects were seen in people taking VOWST after antibiotics and people taking antibiotics alone:

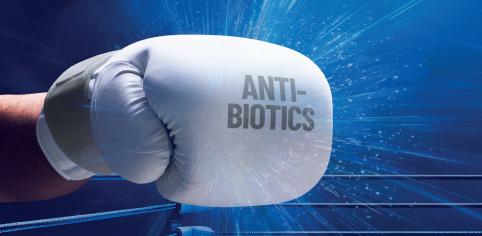
	People taking VOWST	People taking ANTIBIOTICS ALONE
Bloated abdomen	31%	29%
Fatigue	22%	22%
Constipation	14%	11%
Chills	11%	8%
Diarrhea	10%	4%

These are not all the possible side effects of VOWST—be sure to tell your doctor about any side effect that bothers you or does not go away



You may report side effects to Aimmune Therapeutics, Inc. at 1-833-246-2566, or to the FDA at 1-800-FDA-1088 or at www.fda.gov/MedWatch.





# **HOW DOES VOWST® WORK?**

VOWST is believed to work in the following way to prevent recurrent *C. diff\** 

Adding VOWST as a second therapy after antibiotics may be needed to prevent recurrent C. diff

### **FIRST ANTIBIOTICS**



Kills *C. diff* bacteria that cause your infection

### **THEN VOWST**



Works differently than antibiotics to add back good bacteria to your gut

good bacteria



bad bacteria

This is thought to help restore the balance of good and bad bacteria in your gut microbiome



Which can help prevent C. diff from coming back again

VOWST is not a probiotic.

\*The mechanism of action of VOWST has not been established.

#### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

The most common side effects of VOWST are:

- bloated abdomen
- chills

fatigue

- diarrhea
- constipation

These are not all the possible side effects of VOWST. Call your doctor for medical advice on side effects. You are encouraged to report negative side effects to the FDA. Call 1-800-FDA-1088 or visit www.fda.gov/MedWatch.



## **HOW DO I TAKE VOWST®?**

VOWST is taken orally at home after antibiotics in a 2-step dosing routine



# **VOWST CONTAINS\*** THE SAME GOOD BACTERIA

Found naturally in people's healthy gut microbiomes



**STEP 1** Finish a full course of antibiotics.

Within 1 to 3 days of finishing the antibiotic, drink a one-dose 10 oz laxative (magnesium citrate) Tell your doctor if you have kidney disease because you may not be able to take the magnesium citrate laxative.

- This is much less volume of laxative than that used for a colonoscopy, which can be 128 oz
- Taking a laxative is important because it can rid your gut of any leftover antibiotics so that VOWST can work properly



# **STEP 2** Take 4 capsules of VOWST orally once a day for 3 days.

Do not eat or drink for at least 8 hours before your first dose of VOWST.

For example, you can take the laxative in the evening at least 8 hours prior to the first dose of VOWST and fast overnight

Take VOWST before your first meal, on an empty stomach.

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

Do not take VOWST at the same time as antibiotics or the laxative.

Visit vowst.com/how-do-i-take-vowst to learn more about how to take VOWST





#### **FDA APPROVED**

VOWST is an FDA-approved microbiome treatment in oral capsules composed of good bacteria isolated from the stool of qualified donors.



#### UNDERGOES STRICT QUALITY CONTROL

Qualified donors are carefully screened, and samples are routinely tested during the VOWST manufacturing and purification process.



**VOWST** is taken orally at home and is the only **FDA-approved oral** microbiome treatment

Capsules not actual size.

#### IMPORTANT SAFETY INFORMATION

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<sup>\*</sup>Inactive ingredients: glycerol, saline.

# THE VOWST VOYAGE™ SUPPORT PROGRAM HELPS YOU ON YOUR TREATMENT JOURNEY\*

# THE VOWST VOYAGE SUPPORT PROGRAM ALSO OFFERS FINANCIAL ASSISTANCE TO ELIGIBLE PATIENTS



#### **CASE MANAGER CALL**

VOWST° is only available through specialty pharmacy delivery. After your doctor helps enroll you in the VOWST Voyage Support Program, a case manager will verify whether VOWST is covered under your insurance plan and let you know which specialty pharmacy will ship your VOWST prescription.



#### **DELIVERY SCHEDULING**

Next, you will receive a scheduling call for your VOWST prescription—it is very important you answer the call to accept your VOWST shipment.



#### **WELCOME KIT SHIPMENT**

Finally, the case manager will contact you to answer any questions you may have about the program and coordinate the shipment of a welcome kit, which may contain your laxative, directly to your home.



#### **DOSING TEXT REMINDERS**

Once you get your shipment of VOWST, you'll get helpful text message reminders each time you should take a dose of VOWST (you will only receive text messages if you opt in to receive them).

\*You do not have to enroll in the VOWST Voyage Support Program to be prescribed VOWST.



#### **VOWST Co-Pay Savings Program**

The VOWST Co-Pay Savings Program may be used to reduce your out-of-pocket cost for VOWST to as little as \$0, with a maximum savings amount of \$9,100 per calendar year. Offer not valid for patients whose prescriptions are reimbursed by Medicare, Medicaid, or other state or federal healthcare program, or where prohibited by law.

To read the full Terms, Conditions and Eligibility requirements visit VOWSTcopay.com.

#### **VOWST Patient Assistance Program**

Uninsured or underinsured patients may be eligible to receive VOWST at no cost if you meet financial and other eligibility requirements.

If you have concerns about affording your VOWST prescription, please contact us at 888–356–5444 and we may be able to help

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