

**The Most Powerful Front Line Defense
Against
Antibiotic Associated Diarrhea (AAD) & C-diff**

Diff-Stat™



***3 clinically proven ingredients
that help combat the effects of antibiotics on intestinal microbiota.***



Medical Nutrition USA, Inc.
Translating Science Into Solutions



CWI Medical
Medical Supplies & Health Care Products

200 Allen Boulevard, Farmingdale, NY 11735
1-877-9-CWIMED www.cwimedical.com

Staggering Statistics!

AAD and *C-diff* represent a serious threat to the health & well-being of LTC residents with epidemic outbreaks, and newer hyper-virulent mutated strains.

Studies have estimated the national cost of *C-diff* treatment to be between \$1 billion and \$3.2 billion, conservatively.¹

Up to 33% of LTC residents treated with an antibiotic acquire *C-diff*, with a 45% rate of recurrence.

Patients with *C-diff* Associated Disease discharged from an acute care facility to a LTC facility increased 183% over a three year period.

Approximately 7,178 hospital patients – on any one given day are infected or colonized with *C-diff* (94% were infected).¹

***C-diff* colonization in LTC ranges up to 20% compared with <3% in healthy adults.**

¹<http://www.consumersunion.org/campaigns/CDAD%20Policy%20Brief%20final%2011-11-08.pdf>



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Diff-Stat™ – Making a *difference*

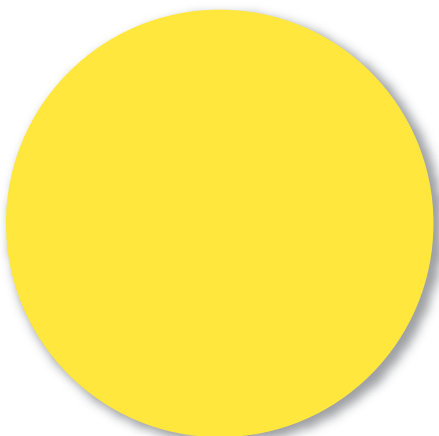
97% of Residents taking Diff-Stat™ while on Antibiotics did not develop AAD & 100% did not develop C-diff!

Incidence of AAD



- 97% had no AAD
- 3% developed AAD

Incidence of C-diff



- 100% had no C-diff
- 0% developed C-diff

ABSTRACT

Objective:

To assess the efficacy of a synbiotic chewable tablet (Diff-Stat) in preventing AAD & C-diff in residents on antibiotic therapy.

Design:

A multi-state, multi-center observational trial.
Setting: 17 LTC facilities.
Subjects: 93 residents (29 male and 64 female).
77% had no history of C-diff.

Methods:

Subjects on antibiotic therapy were given 1 chewable tablet bid within 3 days of starting antibiotics for the duration of antibiotic therapy and continued for 2 weeks post therapy. Clinicians completed a questionnaire evaluating the product.

Results:

A total of 93 subjects completed the trial.

Primary outcome:

97% (90/93) of residents did not develop AAD for up to 2 weeks post antibiotic therapy.

100% (93/93) of residents did not develop C-diff for up to 2 weeks post antibiotic therapy.

Secondary outcome:

99% (92/93) of clinicians indicated that Diff-Stat was easy to administer.

91% (85/93) of residents had "good" compliance to Diff-Stat.

0% (0/93) of residents had "poor" compliance to Diff-Stat.

99% (92/93) of residents indicated that the taste was acceptable.

Conclusion:

This survey provides support on the potential efficacy of Diff-Stat in helping to prevent AAD and C-diff in residents taking antibiotics, and demonstrates acceptance, tolerability, and ease of administration.



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The Diff-Stat™ difference

- **3 clinically proven ingredients**
working synergistically to defend against AAD & C-diff
- **Heat & Acid stable, Antibiotic resistant probiotics**
allowing for the delivery of a substantial amount of live cultures to the intestine
- **Great tasting chewable tablets**
providing for excellent compliance

Probiotic Saccharomyces boulardii
Non-pathogenic yeast that destroys toxins and toxin binding sites

Probiotic Lactobacillus Sporogenes (Bacillus coagulans)
Lactic Acid producing bacteria encapsulated in a spore increasing beneficial bacteria in the colon

Prebiotic Fructo-oligosaccharides (FOS)
Non-digestible carbohydrate that stimulates beneficial bacteria growth

Suggested Use:

Prevention of AAD & C-diff. Residents/patients who are ordered a broad spectrum antibiotic should take the recommended dose at the start of antibiotic therapy and continue taking at least 2 weeks after completing antibiotics. Residents/patients who are not currently on antibiotics but are at risk for AAD & C-diff should take the recommended dose for at least 30 days.

| Indications | Recommended dose per serving (1 tablet or 1 powder pak) |
|----------------------------------|------------------------------------------------------------|
| AAD & C-diff prophylaxis | 1 time daily |
| AAD | 2 times daily |
| C-diff | 2 times daily |
| Multiple C-diff relapses | 3 times daily |
| Maintain intestinal tract health | 1 time daily |

Caution: Diff-Stat™ should be taken 1 hour before or 2 hours after antifungal medications. Do not use if you have a yeast allergy.

Keep bottle tightly closed. Store in a cool, dry place. Do not expose to excessive heat. No refrigeration required.

Room temperature stable. 2 year shelf life.

Manufactured in an NSF® GMP registered facility.

Directions for Diff-Stat Powder Pak for residents/patients with a CVC:

1. Open Diff-Stat pak in another room from residents/patients with a central venous catheter (CVC).*
2. Mix Diff-Stat powder with 30 ml of sterile water and place in a syringe.**
3. Change gloves.
4. Administer orally or through naso-gastric/stomach tube.
5. Flush tube with 30 ml of sterile water.

*Saccharomyces boulardii spores could be aerosolized or inadvertently introduced into a CVC line when the pak is open. These spores can float in the air and potentially contaminate the CVC line, therefore it is important to open and mix in another room.

**Diff-Stat is only viable for 30 minutes in solution.



| Size | Item | Flavor | Case Pack | NDC # |
|----------------------------|---------|------------------|--------------|---------------|
| Jars (30 chewable tablets) | 80001 | Pineapple/Orange | 6/30 tablets | 26974-0410-80 |
| Unit Dose (2 g) | 80001-u | Unflavored | 96/2 g | 26974-0410-81 |

Supplement Facts

Serving Size: 1 chewable tablet
Servings per Container: 30

| Amount Per Serving | | % Daily Value* |
|-----------------------------------------------|-----------------|----------------|
| Calories | 12 | |
| Calories from Fat | 0 | |
| Total Carbohydrate | 3 g | 1% |
| Total Sugar | 3 g | |
| Protein | 0 g | |
| Saccharomyces boulardii | 7.5 billion CFU | ** |
| Lactobacillus Sporogenes (Bacillus coagulans) | 1 billion CFU | ** |
| Fructo-oligosaccharides (FOS) | 500 mg | ** |

*Percent Daily Values are based on a 2,000-calorie diet.

** Daily Value not established.

Other Ingredients: Dextrose, Sucrose, Stearic Acid, Microcrystalline Cellulose, Natural and Artificial Flavors, Silica and Magnesium Stearate.

Directions: Dissolve in mouth or chew.

Supplement Facts

Serving Size: 1 powder pak (2 g)

| Amount Per Serving | | % Daily Value* |
|-----------------------------------------------|-----------------|----------------|
| Calories | 1 | |
| Calories from Fat | 0 | |
| Total Carbohydrate | 500 mg | <1% |
| Total Sugar | 0 g | |
| Protein | 0 g | |
| Saccharomyces boulardii | 7.5 billion CFU | ** |
| Lactobacillus Sporogenes (Bacillus coagulans) | 1 billion CFU | ** |
| Fructo-oligosaccharides (FOS) | 500 mg | ** |

*Percent Daily Values are based on a 2,000-calorie diet.

** Daily Value not established.

Other Ingredients: Low moisture Microcrystalline Cellulose, Maltrin and Silicon Dioxide.

Directions: For enteral tube administration, mix with 30 ml sterile water & follow with 30 ml flush. Mix just prior to administration. For oral consumption, dissolve with 30 ml juice and consume immediately.



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