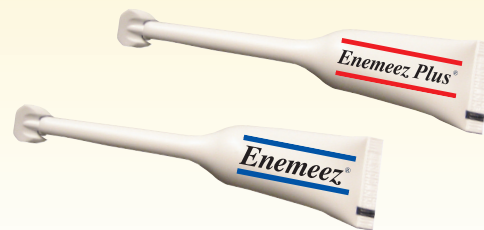


# Implementing a trial in your Facility

## Enemeez® & Enemeez® Plus



### Implementing Patient Orders

Suggested Order: *Enemeez*®, if no BM in 30 minutes  
*Enemeez*® x1, x2, or x3

### Pharmacy Ordering:

*Enemeez*® NDC #: 17433-9876-03

*Enemeez*® Plus NDC #: 17433-9877-03

### Preparation

With *Enemeez*® fast acting results, all bowel care products and equipment should be prepared prior to administering the *Enemeez*® mini-enema. Unlike other rectal stimulants, your staff may see results in under 15-20\* minutes. Nursing floor time schedules should be adjusted to allow for these quick results. Once the product is administered, most patients will have a stimulus within 2-5 minutes and a complete lower bowel evacuation within 15 minutes or less.

### Dosage

One unit rectally as needed or as directed by a doctor. Adults and children 12 years of age and older (with adult supervision), one to three units daily. Children under 12 years of age, consult a doctor prior to use. Due to severe constipation associated with a new spinal cord injury and/or patients that are experiencing a bowel program that has failed them, additional oral medications and/or administration of a second *Enemeez*® may be needed initially. This process can be repeated safely up to 3 times during a bowel care session or per day.

### Positioning:

- For best results, lay on left side with knees bent.
- Alternate position: Administer while seated on the toilet or kneel, then lower head and chest forward until side of face is resting on the surface.

### Administration

*Enemeez*® is to be used as an enema. This is not a suppository. Do not take orally.

#### Administering the mini enema:

1. Clear stool from the rectal opening, as you do not want to insert directly into stool.
2. Twist off and remove tip.
3. Place a few drops of the product or lubricant on the shaft of the tube to lubricate prior to insertion.
4. It is also recommended that one of these lubricants be

applied to the anus before inserting the tube.

5. With steady pressure, gently insert the tube into the rectum with care to prevent damage to the rectal wall.
6. Squeeze to empty the contents.
7. Keep the tube squeezed until it is removed from the rectum.
8. After the contents have been emptied, remove the disposable tube and discard. A small amount of liquid may remain in the unit after use.
9. Most patients will have a stimulus within 2-5 minutes.
10. Wait up to 15 minutes for evacuation.
11. After evacuation, perform digital stimulation to ensure the program is complete.

*If no evacuation occurs after the 15 minute period, perform digital stimulation to assist in bringing the stool down. If there are still no results, repeat steps 2-11.*

### Precautions

Individuals with sensitivity to Benzocaine should not use *Enemeez*® Plus. If rectal irritation or a rash around the anus appears, the enemas should be discontinued. Prolonged administration together with mineral oil should be avoided.

### Trial Phase

**Purpose:** To compare the effectiveness of a patients new/current bowel care program using *Enemeez*® versus a bisacodyl/secondary product. Clinical trial provided is designed for new acute injury inpatients.

### Outcomes reviewed:

1. Time spent from insertion to completion.
2. Did patient experience Autonomic Dysreflexia?
3. Number of episodes of incontinent stools or accidents.
4. Number of episodes of mucosal discharge. Length of time discharge occurred.
5. Time spent doing digital stimulation.
6. Length of time spent on cleaning/changing from incontinence and/or discharge.
7. Number of times incontinence interrupted rehabilitation, physical therapy etc.
8. Additional pads, clothing that was required to be used due to incontinence episode.
9. Overall nursing staff satisfaction, ease of use and patient satisfaction.

\*Alliance Laboratories In-house research. Customer Survey Nov. 6, 2009

## Inpatient Trial

### New Injury Patients:

*Enemeez*<sup>®</sup> should be trialed on a patient prior to the use of a bisacodyl. Please keep in mind that bisacodyl is a stimulant laxative and irritates the rectal mucosa. Neutrophils can persist in the mucosa for up to 30 hours after insertion of the bisacodyl, thus leading to inflamed rectal mucosa producing a mucous discharge and/or episodes of incontinence that may occur up to three (3) days after discontinuing bisacodyl. Trial should reflect the healing time needed on the rectal mucosa from the use of the bisacodyl product in order to produce an accurate recording of the trialing of the *Enemeez*<sup>®</sup> product. With older post injury patients, please allow at least five (5) bowel sessions for the body to acclimate to a new product/*Enemeez*<sup>®</sup>.

### Patient Base:

New acute injury patients during a four week period.

### Suggested Patient Criteria:

1. Patient is at least 18 years of age.
2. Speaks English.
3. Has a spinal injury requiring a bowel care program.
4. Able to assist healthcare provider in providing accurate information regarding their bowel program over a period of approximately four weeks.
5. Inpatient from your facility.

### Once Patient Trial Begins:

1. Place all new acute injury patients on *Enemeez*<sup>®</sup> for a four (4) week period, maintain patient on product for four (4) weeks.
2. Place all new acute injury patients on bisacodyl or secondary trialing product the following four (4) weeks.

### Healthcare provider shall receive and complete:

1. Four weeks of *Enemeez*<sup>®</sup> samples. Healthcare provider to determine if patient needs *Enemeez*<sup>®</sup> or *Enemeez*<sup>®</sup> Plus
2. Written instructions and education on the *Enemeez*<sup>®</sup> product from leading trial facility coordinator.
3. Provided forms to record bowel results daily.
  - a. Healthcare provider to record information on provided bowel care record.
  - b. If patient is released during the four week trial, patient will agree to complete bowel care form and come in during regular outpatient visits to discuss results with leading trial facility coordinator.

## Outpatient Trial

### Out Patients/Post Injury:

If patient has been using a bisacodyl product, please keep in mind that bisacodyl is a stimulant laxative and irritates the rectal mucosa. Neutrophils can persist in the mucosa for up to 30 hours after insertion of the bisacodyl, thus leading to inflamed rectal mucosa producing a mucous discharge and / or episodes of incontinence that may occur up to three (3) days after discontinuing bisacodyl. Trial should reflect the healing time needed on the rectal mucosa from the use of the bisacodyl product in order to produce an accurate recording of the trialing of the *Enemeez*<sup>®</sup> product. With older post injury patients, please allow at least five (5) bowel sessions for the body to acclimate to a new product/*Enemeez*<sup>®</sup>.

### Patient base:

20 post injury outpatients

### Suggested Patient Criteria:

1. Patient is at least 18 years of age.
2. Speaks English.
3. Has a spinal injury requiring a bowel care program
4. Able to assist healthcare provider in providing accurate information regarding their bowel program over a period of approximately four weeks.
5. Inpatient from your facility.

### Once patient has signed up for the trial:

Patient and/or healthcare provider shall receive:

1. Provided forms to record bowel results.
2. Four weeks of *Enemeez*<sup>®</sup> samples. Healthcare provider to determine if patient needs *Enemeez*<sup>®</sup> or *Enemeez*<sup>®</sup> Plus.
3. Written instructions and education on the *Enemeez*<sup>®</sup> product from leading trial facility coordinator.
  - a. Patient shall use *Enemeez*<sup>®</sup> for four weeks. Then use the secondary product after completing the *Enemeez*<sup>®</sup> trial.
  - b. Healthcare/Caregiver or patient to record information on provided bowel care record.
  - c. Patient agrees to come in during regular outpatient visit to discuss results with leading trial facility coordinator.

# Sample Bowel Care Record

Every time you do bowel care, write down:

- **Date.**
- **Start time.** The hour and minute you started stimulation or try to start a bowel movement.
- **Position.** Left side lying, right side lying, sitting, kneeling.
- **Autonomic Dysreflexia episodes.** Did you experience symptoms of autonomic dysreflexia during your bowel care program? If so, what types of symptoms ie: chills, sweats, raise in blood pressure, headache.
- **Stimulation method.** Stimulant medication, digital rectal stimulation, or other technique you use to start a bowel movement.
- **Times of results.** The time when the first stool begins to come out of the anus and the time when the last stool comes out.
- **Stool amount, consistency, and color.** Amount: if stool were formed into a ball--golf ball, tennis ball, softball. Consistency: hard, firm, soft, liquid. Color: especially anything unusual for you.
- **Incontinence episodes.** Time spent cleaning up after episode.
- **Therapy missed.** Missed minutes in therapy due to incontinence episodes.
- **Comments.** Problems such as any unplanned bowel movements, abdominal cramps, pain, muscle spasms, pressure ulcers, hemorrhoids, or bleeding.

Date	Start Time	Position	AD Symptoms	Stimulation method	Times of results First/Last	Stool Amount, Consistency, Color	Incontinence Episodes	Therapy Missed - Total Time	Comments