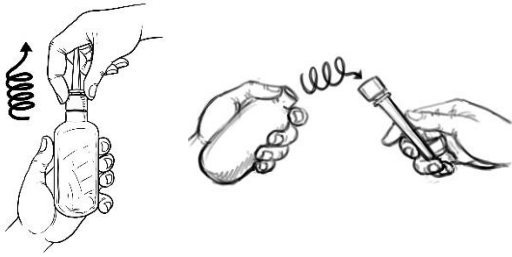


Product contents: • 4 empty douche bottles • 20 pre-lubricated douche tips with green caps

1



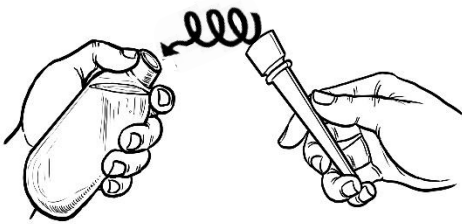
Wash your hands thoroughly with soap and water. Dry your hands. Remove the pre-lubricated tip with green cap from the empty douche bottle (leave the green cap in place on the douche tip).

2



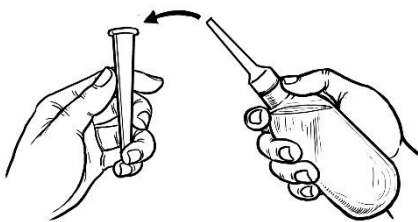
Fill the empty douche bottle with water (clean tap water or bottled water obtained from clinic staff), leaving just a small amount of room at the top. The bottle should be filled with approximately 120mL/4oz of water.

3



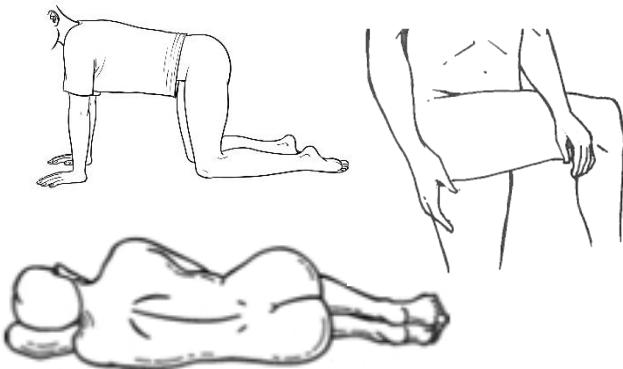
Place the pre-lubricated douche tip with green cap back on the bottle and turn until securely in place.

4



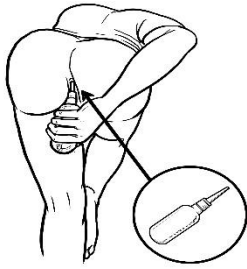
Remove the green cap from the douche tip.

5



Find the position that feels most comfortable. Many people already have a position they prefer (e.g. laying on their side, on bended knees, or standing with one leg raised).

6



Gently insert the pre-lubricated douche tip into the rectum, approximately [3-4 inches/8-9 cm], with the tip pointing toward the navel.

7



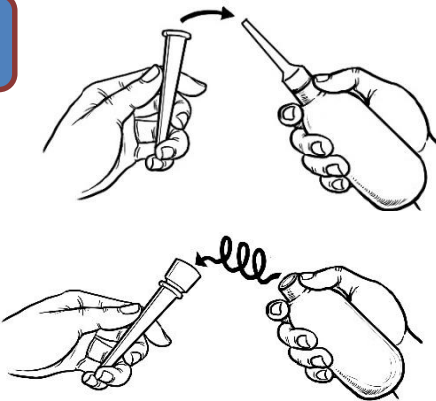
Slowly squeeze the douche bottle to allow the water to flow into the rectum until nearly all the liquid is gone.

8



Remove the tip from the rectum and maintain position until you feel a strong need to have a bowel movement, then release douche fluid in the toilet.

9



Place the green cap back on the douche tip.

Remove the covered douche tip from the bottle.

10



Dispose the used covered douche tip in the trash and discard any unused water remaining in the bottle.

MTN-035 Placebo Rectal Douche Instructions (page 3 of 3)

TIPS & IMPORTANT INFORMATION

Preparation

- ❖ If douche fluid is expelled prior to inserting the entire contents of the bottle, the remaining fluid should be administered, if possible, until bottle is emptied.

Administration

- ❖ It is recommended that you insert one dose of the study product between 30 minutes to 3 hours prior to engaging in receptive anal intercourse (RAI), and that you not insert more than one dose in a 24-hour period. If you forget to or cannot take a dose before RAI, skip the dose. If you do not engage in RAI in a given week, insert a dose of the product in the absence of RAI.
- ❖ Do not force the douche tip into the rectum, as this can cause injury. If you cannot get it in, do not continue trying. Contact the study clinic to discuss what to do next.

Side Effects

- ❖ You may experience some side effects during or after douche administration, such as feelings of fullness, cramping, gas or mild discomfort. It may be necessary to use the toilet several times before all fluid is expelled.
- ❖ Contact study staff if you have any problems during or after douche administration.

Storage and Transport

- ❖ Store the douche bottles and tips with green caps in a cool, dry place out of the reach of children.
- ❖ Return any unused douche bottles and douche tips with green caps to the clinic. Store them in the bag provided to you.
- ❖ During transport, keep the bag with you at all times to avoid loss.

Questions

Study staff are here to help and support you. Please contact us between visits with any questions or concerns, or if your product supply runs low.

[INSERT SITE SPECIFIC CONTACT INFO]