

MTN-035 Placebo Rectal Insert Instructions (Page 1 of 3)

Product contents: • one bottle of 20 placebo rectal inserts • Good Clean Love lubricant packets

1



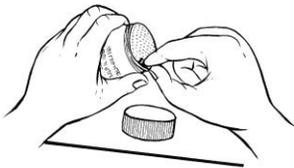
Wash and dry your hands thoroughly with soap and water.

2



Open the bottle by pushing the cap down while turning to the left.

3



The first time the bottle is opened, there will be a seal covering the bottle. Remove and discard this seal.

4



Inside the bottle, there will be cotton wool. Remove and discard this cotton wool.

5



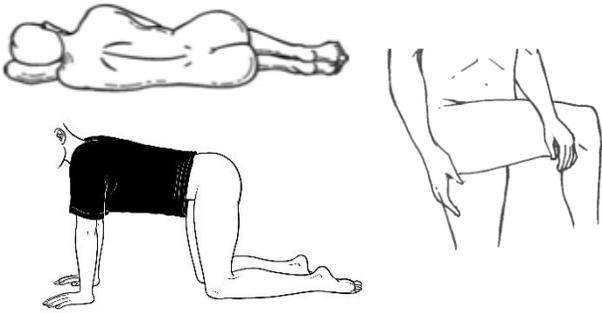
There is a sealed container inside the bottle that helps keep the inserts dry. Do not open this container, swallow it, or remove it from the bottle.

6



Remove one insert from the bottle when ready to insert. After removing the insert, close the bottle tightly by replacing the cap and turning it to the right.

7



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).

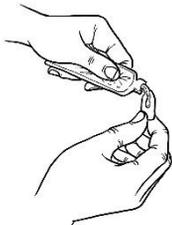
8



Relax your buttocks to make it easier to insert.

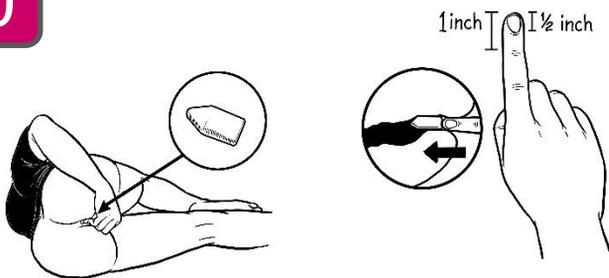
Gently spread your buttock open to expose the anus.

9



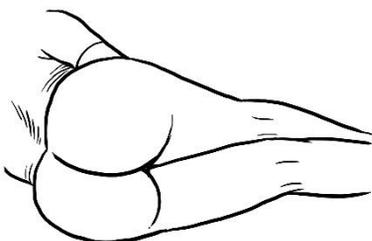
If desired, add a small amount of *Good Clean Love* lubricant to the insert tip.

10



Ease the insert, rounded end first, with your finger about [1 inch/2.5 cm] into your rectum.

11



Hold or clench buttocks together for a few seconds.

If possible, remain lying down or seated for about 30 minutes to allow it to dissolve.

Wash hands again with soap and water.

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TIPS & IMPORTANT INFORMATION

Preparation

- ❖ To reduce the discomfort associated with inserting the rectal insert, it is recommended that you empty your bowels before use.

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 insert into the rectum, as this may cause injury. If you cannot get it in, do not continue trying. Contact the study clinic to discuss what to do next.

After Insertion

- ❖ If the insert comes out after you insert it, you may not have pushed it far enough into the rectum. Be sure to push the insert past the sphincter, which is the muscular opening of the rectum.

Side Effects

- ❖ You may experience some side effects during or after administering the insert, such as abdominal pressure or pain, gas or rectal discomfort.
- ❖ Contact study staff if you experience any problems during or after insertion.

Storage and Transport

- ❖ Do not remove labels from the bottle. Keep the inserts in their original container and out of the reach of children.
- ❖ Store at room temperature and keep the container tightly closed.
- ❖ Return any unused inserts 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]