MTN-039 Rectal Insert Guide

What to expect before and during administration

The insert is small (about 1.5 cm). It contains two drugs, tenofovir alafenamide (TAF) and elvitegravir (EVG). For your first dose, staff will place 1 insert into your rectum; at a subsequent visit, 2 inserts will be placed into your rectum.

To prepare for the insert to be administered, staff will ask you to lie on your side, with legs bent towards your stomach.

Wearing gloves, the study clinician will spread your buttocks apart gently to expose your anus. This position and relaxing your buttocks, will help to ease insertion of the product.

Next, the clinician will use a gloved finger to apply lubricant to your anus (this is done to ease insertion). Then, the clinician will ease the insert through your anus, into your rectum (about 1 inch inside your rectum).

After placing the insert, the clinician will remove their finger, leaving the insert in place. Once in place, the insert is expected to dissolve rapidly.

You will then be asked to hold or slightly clench your buttocks together for a few seconds and remain lying down or seated. This will allow the insert to dissolve as much as possible. After the insert is placed, you will have rectal tissue and fluid collected, as well as vaginal fluid if applicable. Staff will tell you when these procedures will occur.

What to expect after administration

You may experience some side effects during or after administration of the insert. These can include abdominal pressure or pain, diarrhea, gas or rectal discomfort.

Tell or contact study staff if you experience any problems during or after administration. They are here to help and support you. Please speak to them or contact the site between visits with any questions or concerns you have.