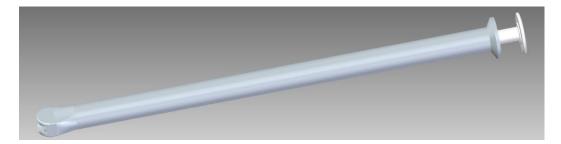


Instruction for use of multiple use vaginal-tablet-applicators (art. no. 1033xx)



Manufacturer of multiple use vaginal-tablet-applicators:

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Please note that following wording of the instruction for use is a suggestion. As Schägner as legal manufacturer of the applicator has no specific information about the medicine/medical device these applicators are packed with, it is up to the pharmaceutical company that encloses the vaginal applicator to the package that contains the vaginal tablet/s to adapt the instruction for use according to the specific requirements of the pharmaceutical company's vaginal tablet (see also "Demarcation of responsibilities" as stipulated by contract between Schägner and pharmaceutical company).

Suggestion for the instruction for use of vaginal-tablet-applicators:

"The plunger is pulled out from the applicator until it comes to a stop. Then the vaginal tablet is placed firmly into the holder of the applicator tube.

The applicator is then introduced into the vagina. This should be best carried out in dorsal position. The tablet is deposited into the vagina by slowly pressing the applicator plunger until it stops. Finally, the applicator is removed from the vagina.

After each use, prior to a subsequent use the applicator has to be cleaned according to following cleaning procedure:

The plunger is withdrawn from the applicator and both parts (tube and plunger) are cleaned with mild soap and rinsed with warm tap water for 5 seconds. The tubes inner and outer surface has to be rinsed. If necessary, larger amounts of remaining water are removed from both parts (tube and plunger) by short shaking-off the water. Both parts (tube and plunger) are air dried on a clean surface (e.g. clean paper fleece).

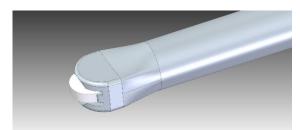
For the subsequent use of the applicator the plunger is introduced again in the applicator-tube.

The vaginal tablet applicator is intended for multiple use up to 24 times for one single patient. Thereafter the applicator should be disposed of as household waste after use.



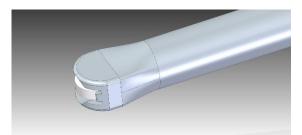
Note for prevention of misuse:

1. <u>Right placing ot tablet into applicator prior to application:</u> In order that the tablet does not accidentally fall out from the applicator prior to the application, the tablet has to be placed as follows in the applicator tube:



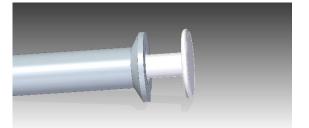
WRONG (insufficient) positioning of tablet in applicator. When tablet shows like this, it has to be pushed stronger with a clean finger into the

tube until it reaches the RIGHT positioning. The plunger will latch with a perceivable click into right lock-position.



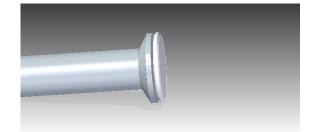
RIGHT placing of tablet in applicator tube.

2. <u>Right position of tablet plunger for proper tablet release from applicator:</u> For proper and safe release of the tablet the plunger has to reach the right end position as follows:



WRONG (insufficient) position of applicator plunger after the tablet should have been applied.

When plunger shows like this, the tablet is still in the applicator tube. The plunger has to be pushed stronger into the tube until it reaches the RIGHT position. Thus the tablet will be released from the applicator.



RIGHT stop-position of applicator plunger after the tablet should have been released from the applicator and applied properly.

Note on safety:

- Applicators that show obvious damages should not be used but returned to the pharmacy, pharmaceutical company or to the manufacturer."

Dr. Ute Linder Manfred Schägner GmbH Safety manager medical devices

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