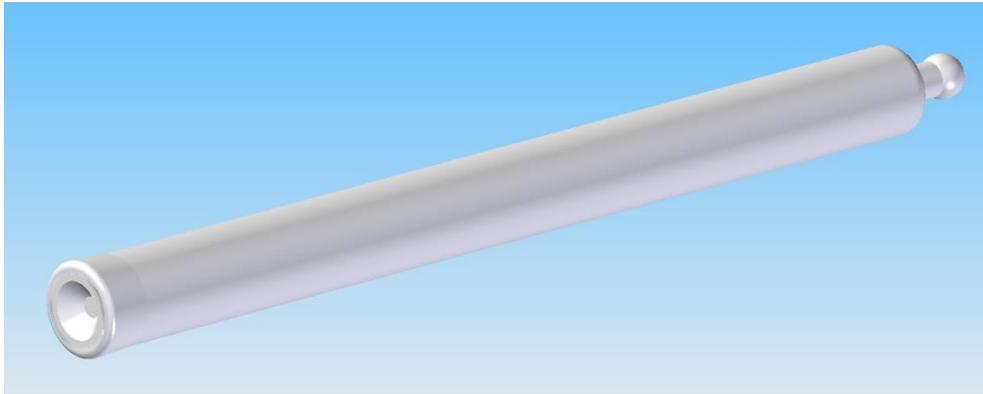


Instruction for use of vaginal-cream-applicators (art. no. 1001xx; 1017xx; 1019xx; 1027xx)



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Please note that following wording of the instruction for use is a suggestion. As Schägner as 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 cream/ointment/gel to adapt the instruction for use according to the specific requirements of the pharmaceutical company's vaginal cream/ointment/gel (see also "Demarcation of responsibilities" as stipulated by contract between Schägner and pharmaceutical company).

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

"The tube containing the medicinal product (cream/ointment/gel) is twisted into the applicator tube with thread respectively put into the applicator tube without thread.

By pressing the tube containing the cream/ointment/gel carefully until the applicator plunger comes to a stop the vaginal applicator is filled with the cream/ointment/gel.

Subsequently the applicator is removed from the tube containing the cream/ointment/gel - optionally by twisting.

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

The vaginal cream applicator is designed by the manufacturer for single use and should be disposed of as household waste after use.

Note on safety:

- **Prevention of incorrect applications:**
 - ***Cream should not be too soft. In case of temperature dependant viscosity of the cream/ointment/gel storage at < 25 °C might be recommended.***
 - ***Filling of applicator with cream/ointment/gel should be done carefully and slowly so that the cream is not squished between plunger and tube wall (behind the plunger).***
- ***Applicators that show obvious damages should not be used but returned to the pharmacy, pharmaceutical company or to the manufacturer"***

Optional reuse of the vaginal applicator:

- the reusability of the applicator depends on the consistency of the cream/ointment/gel and the patient's vaginal flora due to the underlying disease as well as domestic hygienic aspects.
- in case the pharmaceutical company designs the applicator to be reused a cleaning procedure as validated by the pharmaceutical company considering the consistency of the cream/ointment/gel, the patients vaginal flora as well as specific bioburden requirements (at least Eur.Pharm.5.1.4 or lower) and accordingly described in the IFU contained in the combination package of applicator and medicinal product has to be performed after each applicator use. The cleaning procedure has to comprise at least:
 - disassembling of the applicator by withdrawal of the plunger from the tube. Therefor the plunger has to be pushed strongly with the spherical plunger end on a hard surface.
 - washing of tube and plunger with lukewarm tap-water and mild soap, thorough rinsing of tube and plunger with tap-water, if necessary shaking-off larger amounts of water
 - air drying of the applicator parts on a dry and clean surface
 - reassembling of applicator by inserting the plunger into the tube
- Warning:
After approximately 5 reuses the diameter in the applicator tube that holds the plunger will be dilated, thus the plunger can be pushed through and the applicator will be disassembled easier during the application than an unused applicator. Such too easy disassembling of the applicator can lead to painful injury due to the sharp edge of the plunger when applying the reassembled applicator.

Therefor before each reuse the applicator has to be examined:

- for obvious damages especially at the tube end which is screwed on the (metal) tube containing the cream/ointment/gel. Applicators that show obvious damages should not be reused but disposed of as household waste.
- when the applicator is reassembled it should not be possible to push the plunger through the applicator tube by pressing the spherical end of the plunger and thus disassembling the applicator. Too easy disassembling by light pressure on the spherical end of the plunger should not be tolerated. Such applicators should be disposed of as household waste.

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