

Swabable Vial Adapter Device

Please refer to the device instructions for use (IFU) for complete set of directions for the device.

Intended Use/Indications for Use:

The Swabable Vial Adapter device is intended to allow multiple needleless accesses to an injection medication vial for the purpose of facilitating the withdrawal or addition of drugs/solutions from or to a vial.

Contraindications:

Currently no specific contraindications are known for the Swabable Vial Adapter.

Cautions/Precautions/Warnings:

- Do not use if the package is damaged. Do not use product, if fell out of package.
- Do not remove the vial adapter from vial after use.
- This device is intended to be used for one patient and one vial only.
- Contents are sterile and non-pyrogenic.
- After reconstitution store the drug in the conditions recommended by manufacturer.
- Before re-connecting a syringe to withdraw more reconstituted drug from the vial, disinfecting the Vial adapter valve with an alcohol pad is required.
- Reconnect syringe to a reconstituted vial within 24 hours from initial reconstitution.
- Manufacturer's approved package insert instructions for drug expiry following reconstitution.
- Re-sterilization may damage the device.
- Dispose of used device is accordance with applicable regulations.
- Single use only*

Registration Information

Information herein is for use only in countries with applicable health authority registrations. The Swabable Vial Adapter is 510(k) cleared by the United States Food and Drug Administration and carries the CE mark (0344). Products are shown for INFORMATION purposes only and may not be approved for marketing in specific regions. Please contact your West Pharmaceutical Services, inc. (West) representative for product availability.

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Date: 09-December-2021 **Number:** GN-REG-193

Title: Swabable Vial Adapter Device - Indications, Safety and Registration Zones

Revision: 1.0

^{*} Single use refers also as single occasion; the device is not intended to be reprocessed and/or used on another patient.