

SmartDose® 3.5 On-Body Delivery System (OBDS)

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

Intended Use/Indications for Use:

The SmartDose® 3.5 OBDS is intended for the administration of a fixed dose of drug product from a prefilled container assembly into subcutaneous (SC) tissue in a predetermined time.

Contraindications:

Currently no specific contraindications are known for the SmartDose 3.5 OBDS.

Cautions/Precautions/Warnings:

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- The operation of the device shall follow the Instruction for Use (IFU) provided with the device
- Training on this device should be conducted before giving an injection.
- This device is intended to be used for one patient and must only be used once.
- The device is intended to work with the supplied pre-filled cartridge only.
- The device shall not get wet and physical activity should be limited during the injection process
- Contents are sterile and non-pyrogenic.
- Do not re-sterilize the device
- Do not use if package or the device is dropped or damaged
- Do not use if the carton perforations are broken or if the white paper try is broken or missing.
- Dispose of used device in accordance with applicable regulations.
- In the event of any adverse events or if the device is not working properly, contact your doctor, pharmacist or nurse for assistance.

Registration Information

West's SmartDose® drug delivery platform is not independently cleared or approved by any Regulatory Body for general healthcare professional or patient use, nor is it available for general commercial purchase. Its distribution and use are subject to applicable regulatory requirements for clinical investigation, and for marketing authorization, as used in combination with a specific drug or biological product. Each component of a combination product is subject to the requirements established by the Regulatory Body for that component (drug, biologic or device). The regulatory process can be more complicated for combination products including an evaluation of the product characteristics, delivery system and its functionality, as well as the potential for undesirable interactions between the drug or biologic and the delivery system. As a result, we note that the SmartDose® drug delivery platform's compatibility with any particular drug or biologic must be confirmed, and its ability to achieve the desired patient benefits must also be confirmed, on a case-by-case basis in a manner sufficient to meet Regulatory Body requirements. Please contact your West Pharmaceutical Services, Inc.(West) representative for product availability. SmartDose® is a registered trademark of West Pharma. Services IL, Ltd., a subsidiary of West Pharmaceutical Services, Inc.