

ALADROP 12 KIT ^{*} Convenience Kit



Patent No.:
US 10,555,872 B1
US 10,800,556 B2
Other Patents Pending

Symbol Definitions

STERILE R	Sterile by Radiation	Single Use	Not Manufactured With Natural Rubber Latex
STERILE EO	Sterile by Ethylene Oxide	LOT Lot Number	Storage Temperature
Attention, See Instructions For Use	Quantity	Use By	DEHP Free
REF Reorder Number	Patent Information	Manufactured by	Manufactured for

ALADROP 12 EYE DROP INSTRUCTIONS FOR USE (IFU)

ALADROP 12 Convenience (ALADROP) Kit Contains:

1. An ALADROP insulated pouch
2. A Sterilizing, Filling and Capping Transport (Sterile) Kit providing a sealed, sterilized bag containing a stabilizing tray holding 12 each, 5 mL eye drop bottles, a plate holding 12 eye drop caps, and a sterilizing grade filter assembly comprising one 0.2 micron filter.

ALADROP 12 Tears Kit Description

The ALADROP 12 Kit is used for convenient sterile compounding and preparation of eye drops filled and provided in capped eye drop bottles. Contents of the ALADROP 12 Sterile Kit are presterilized and retained in a sterile state throughout eye drop bottle filling and capping by all fluid entering the ALADROP 12 bag being delivered through the sterilizing grade filter.

Warnings

1. Follow institutional protocols and Universal Precautions when handling all patient fluids, medications, devices, needles, syringes, and other transfer products, female/female adapters, alcohol, other cleaning agents, gloves, personal protective equipment (PPE) and other ancillary products that may be associated with use of this kit.
2. Inspect ALADROP 12 Sterile Kit bag before using. Do not use if damaged.
3. Fully instruct patients relative to storage and use of eye drop preparations.
4. For single use only.

Cautions

1. Do not use ALADROP 12 Sterile Kit bag near sharp objects.
2. Do not apply excessive force while injecting fluids through the syringe filter.
3. The filter can become clogged making syringe dispensing difficult, only use this kit with low viscosity liquids which are not deleteriously affected by filtering through a .2-micron filter.
4. If the sterile filter becomes clogged, bottle filling will be obstructed.
5. Air locks which can also obstruct bottle filling are best eliminated by priming.
6. Assure that bottle caps are securely affixed after threading caps to bottles.

7. Always follow institutional protocols relative to patient and caregiver safety.
8. Do not attempt to disconnect pre-assembled components unless so instructed.
9. Thoroughly mix all solutions before dispensing to assure concentration integrity.
10. Assure that eye drop preparations are appropriately stored, including refrigerated or frozen to maintain medicinal integrity prior to use.

Instructions for Use

1. Prepare selected solution following manufacturers protocols and dispense solution into a luer lock syringe.
2. Remove the ALADROP 12 Sterile Kit from the insulated pouch.
3. Center the tray directly under the 0.2 micron filter assembly and tent the bag above it.
4. Remove filter cap from the filter and attach the filled syringe thereto.
5. IMPORTANT: Prime filter assembly by pointing dispensing end upright and dispensing liquid from the attached syringe in the same manner a syringe is primed until liquid is seen entering the dispensing nozzle inside the bag.
6. Maximum volume of each vial is 5 mL. Deliver solution into each eye drop bottle being filled being careful to ensure the delivery nozzle is positioned within each bottle opening.
7. From the outside of the ALADROP Sterile Kit, grip the cap plate and place it on top of the bottles, aligning the caps with the bottles. (Note: The plate is easily displaced with proper technique.
8. Push caps downward onto the corresponding bottles, centering and aligning each cap.
9. Grip the filter assembly and push the nozzle into the top of the ratchet tool included inside the bag.
10. Using the ratchet, rotate each cap onto the corresponding bottle as shown in Figure 1.
11. After securely capping all bottles, perform bubble test to assure filter integrity.
12. Open the ALADROP 12 Sterile Kit package and remove the tray containing the closed eye drop bottles.
13. Turn each cap once more to assure each cap is tight.
14. Label bottles following institutional protocols.
15. Store bottles, not immediately used as specified by drug manufacturer.
16. If bottles are prepared for delivery to a patient, place a tray with filled bottles into the insulated pouch, seal and distribute to patient. Provide patient instructions relative to storage, use, warnings and cautions.

Figure 1

