



# **KSI-301 Syringe Preparation and Injection Procedures**

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# KSI-301 & Aflibercept - Handling Differences

## KSI-301

- **Injection volume:** 100  $\mu$ L
- **Dosing mark:** 0.1
- **Dosing needle:** 27G  $\frac{1}{2}$  inch needle
- **Injection may take 5 seconds**  
due to viscosity of drug

## Aflibercept

- **Injection volume:** 50  $\mu$ L
- **Dosing mark:** 0.05
- **Dosing needle:** 30G  $\frac{1}{2}$  inch needle


**Please note the injection volume difference between KSI-301 and aflibercept. Always ensure the correct volume is prepared and injected!**

# Pooled Drug Supply – Outside Carton Label

**Same study drug kits for BEACON, GLEAM, and GLIMMER!**

<b>Kit Number:</b> <Kit#>	<b>Protocol / EudraCT Number:</b>
<b>Lot Number:</b> <Blinded Lot#>	<input type="checkbox"/> <b>BEACON:</b> KS301P103 / 2020-001061-37
<b>Site Number:</b> _____	<input type="checkbox"/> <b>GLEAM:</b> KS301P104 / 2020-001062-11
<b>Subject Number:</b> _____	<input type="checkbox"/> <b>GLIMMER:</b> KS301P105 / 2020-001063-82
<b>Investigator Name:</b> _____	<b>Visit Date:</b> _____ <b>Visit Name:</b> _____

One vial of KSI-301 5 mg (50mg/ml) or Aflibercept 2 mg (40mg/ml) or one Sham vial.  
Solution for injection. For intravitreal use.  
Directions for use: Refer to Pharmacy Manual.  
To be opened by unmasked personnel only.  
Storage Conditions: Store between 2 to 8°C (36 to 46°F).  
Keep the vial in the outer carton to protect from light.  
Caution: New Drug - Limited by Federal (or United States) law to investigational use  
Sponsor: Kodiak Sciences Inc., 2631 Hanover Street, Palo Alto, CA 94304, USA  
Sponsor Tel: +1 650-281-0850 CRO: PPD



# KSI-301 Syringe Preparation

## Kit Contents:

- KSI-301 vial (red or blue cap)
- BD 1 mL Luer lock syringe
  - Use only a Kodiak supplied BD syringe
- BD 18-gauge x 1 ½ inch 5-micron filter needle
- TSK 27-gauge x ½ inch ultra-thin wall dosing needle
- Alcohol swab



**Use only the contents supplied in the kit**

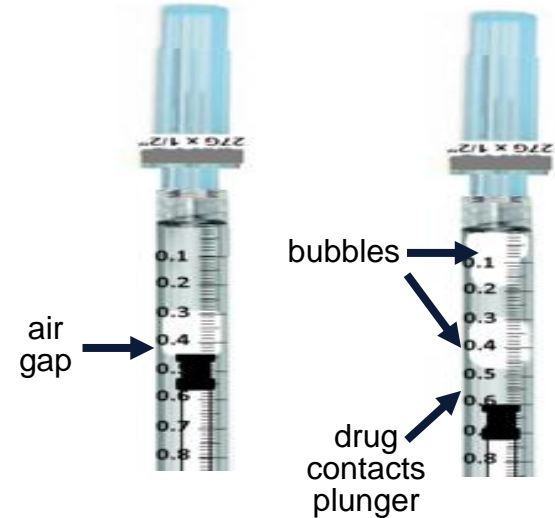
# KSI-301 Key Syringe Preparation tips

1. KSI-301 is stored at 2-8°C. Perform all steps at room temperature, it helps with the viscosity.
  - Vial may only be kept at room temperature for up to 8 hours prior to use.
2. Firmly attach the needles to the syringe and do not try to readjust. KSI-301 can act as a lubricant causing needle pop-off.
3. Always keep the vial upright.
4. Be patient! Might take 1 or 2 minutes to draw the medication
5. Fill at least 200 microliters (above the 0.2 mL mark)

# KSI-301 Syringe Preparation

## Working out the bubbles

- Hold the filled 1 mL syringe vertically upright. A noticeable air gap will appear directly above the rubber plunger.
- Remove air bubbles in two smooth down/up movements of the plunger:
  - First, **pull** the plunger down to 0.8 mL then **push it** back up to 0.5-0.6 mL until the plunger contacts the drug.
  - Second, repeat the above motion one more time to fully remove the air bubbles.



**6. Do not flick the syringe. It is not an effective way to remove air bubbles**

# KSI-301 Syringe Preparation

- Align the flat top edge of the rubber plunger to the 0.1 mL marking on the syringe barrel.
- The syringe is now ready for intravitreal injection.
- Use within 60 minutes of preparation



# KSI-301 Syringe Preparation Video





# KSI-301 Syringe Preparation Video



# KSI-301 Injection procedure



# Ocular Anesthesia

- Unmasked injecting investigator will choose method of anesthesia
- Method chosen must remain constant for duration of trial (including sham injections) to maintain masking

## Topical Proparacaine

- Instill 0.5% proparacaine drops to bulbar conjunctival
- Disinfect with 10% povidone iodine
- Apply sterile, cotton-tipped applicator soaked with 0.5% proparacaine to planned injection site for 10 seconds

## Subconjunctival Lidocaine

- Instill 0.5% proparacaine drops to bulbar conjunctiva
- Disinfect with 10% povidone iodine
- Draw up 0.2ml of lidocaine into 1-mL syringe using 18-gauge (g) needle.
- Remove 18g with 30g ½-inch needle
- Apply 1 drop 5% povidone iodine and wait 15 sec
- Inject lidocaine into subconjunctival space

**Anesthetic gels or viscous formulations are not allowed**

# Intravitreal Injection Aseptic Technique

- **Aseptic conditions using a sterile eyelid speculum and sterile gloves**
  - Either surgical masks should be used or minimize speaking during the preparation of the syringe and intravitreal injection
  - **If the patient is wearing a face mask, strong consideration should be given to creating a physical barrier between the top of the mask and the eye, to prevent oral flora from traveling out of the top of the mask and contaminating the sterile field.** This could be achieved by using a sterile, adhesive eye drape or taping the top of the mask to the skin.
  - **Kodiak will be providing 3M Steri-Drapes to all sites upon request!**



If you use Steri-Drapes don't forget to use them for both active *and* sham injections

# Post-Injection Assessments

To preserve masking, post Injection Assessments should be carried equally for all subjects (including sham injection procedure). **Post-injection Assessments may only be performed by unmasked site staff.**

- Within 5 minutes after the injection, check vision of the study eye for count fingers or hand motion.
- Tonometry (study eye) - between 30 and 50 minutes after injection. If the IOP is >30 mmHg or has increased by  $\geq 10$  mmHg from pre-injection, the IOP will be measured again at 60–80 minutes post-injection. If there are no safety concerns, the subject will be permitted to leave the clinic.
- IOP measurement (either Goldmann tonometry or Tonopen) must remain the same throughout the study for each participant.

# Conclusions

- **There are two key differences between KSI-301 and aflibercept**
  - KSI-301's injecting volume is 100 microliters compared to 50 microliters for aflibercept
  - KSI-301 is more viscous, so drawing the medication and the injection procedure take slightly more time than usual
- **Always ensure the correct volume is prepared and injected**
- **If the patient is wearing a facemask, please create a physical barrier between the top of the mask and the eye.**
  - Kodiak will be providing 3M Steri-Drapes to all sites upon request
  - Alternatively, tape the upper edges of the face masks with a medical adhesive tape the top part to the patient's skin