# INSTRUCTIONS FOR USE

# INVEGA SUSTENNA®

## PRODUCT NAME

INVEGA SUSTENNA® (25 mg paliperidone as 39 mg paliperidone palmitate) Prolonged-Release Suspension for Intramuscular Injection.

INVEGA SUSTENNA® (50 mg paliperidone as 78 mg paliperidone palmitate) Prolonged-Release Suspension for Intramuscular Injection.

INVEGA SUSTENNA® (75 mg paliperidone as 117 mg paliperidone palmitate) Prolonged-Release Suspension for Intramuscular Injection.

INVEGA SUSTENNA® (100 mg paliperidone as 156 mg paliperidone palmitate) Prolonged-Release Suspension for Intramuscular Injection.

INVEGA SUSTENNA® (150 mg paliperidone as 234 mg paliperidone palmitate) Prolonged-Release Suspension for Intramuscular Injection.

### International Non-Proprietary Name

Paliperidone palmitate

## DOSAGE FORMS AND STRENGTHS

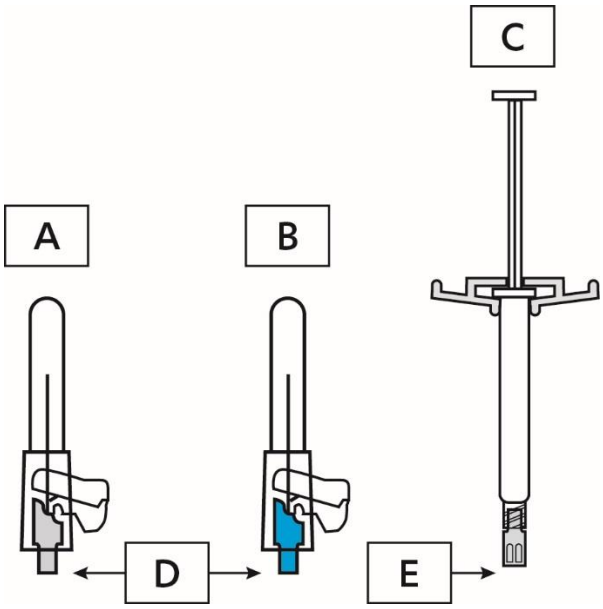
INVEGA SUSTENNA contains 25, 50, 75, 100, or 150 mg paliperidone (as 39, 78, 117, 156, or 234 mg of paliperidone palmitate, respectively).

The chemical name is (±)-3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-2-methyl-4-oxo-4*H*-pyrido[1,2-*a*]pyrimidin-9-yl hexadecanoate.

Prolonged-release suspension in prefilled syringes. The suspension is white to off-white.

## INSTRUCTIONS FOR USE AND HANDLING AND DISPOSAL

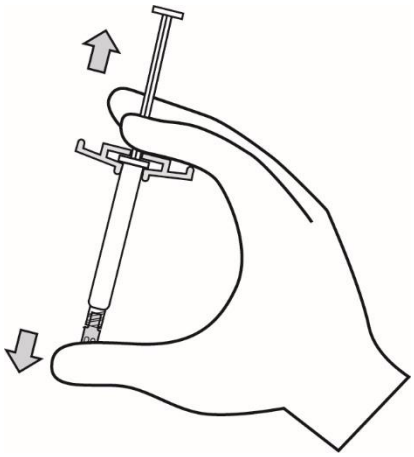
The kit contains a prefilled syringe and 2 safety needles (a 1½-inch 22 gauge needle and a 1-inch 23 gauge needle) for intramuscular injection.




**A-22Gx1½″ Gray hub; B-23Gx1″ Blue hub; C-Prefilled Syringe; D-Hub; E-Tip cap**

INVEGA SUSTENNA is for single use only.

1. Shake the syringe vigorously for a minimum of 10 seconds to ensure a homogeneous suspension.

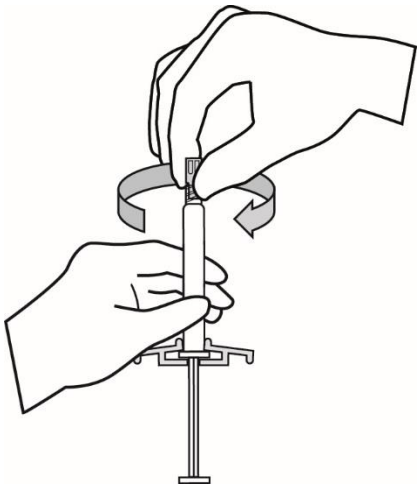


2. Select the appropriate needle.

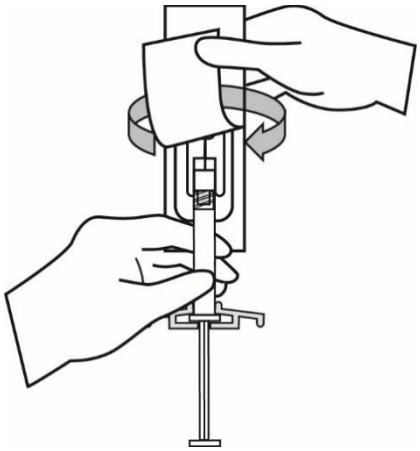
   For DELTOID injection, if the patient weighs < 200 lb (< 90 kg), use the 1-inch **23** gauge needle (needle with **blue** colored hub); if the patient weighs ≥ 200 lb (≥ 90 kg), use the 1½-inch **22** gauge needle (needle with **gray** colored hub).

   For GLUTEAL injection, use the 1½-inch **22** gauge needle (needle with **gray** colored hub).

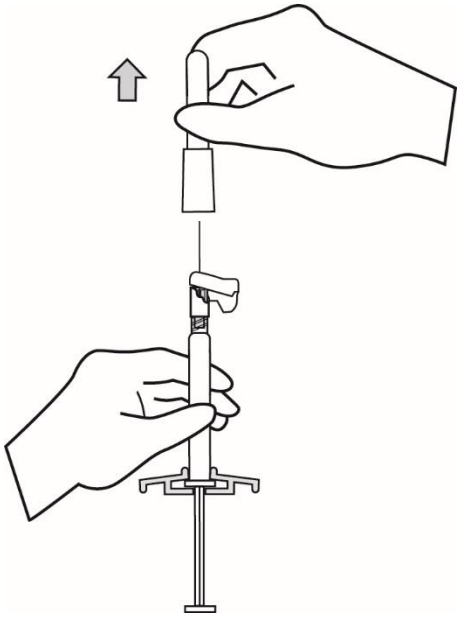
3. Hold the syringe with the tip cap pointing up, remove the rubber tip cap with a gentle twisting motion.



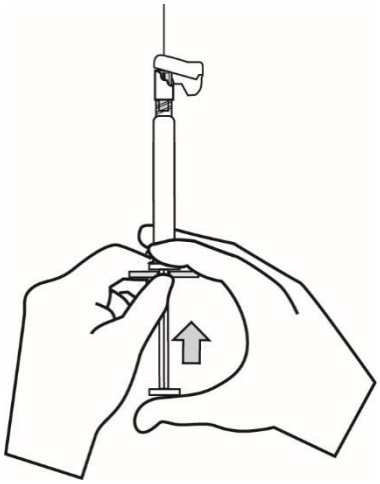
4. Peel the safety needle pouch half way open. Grasp the needle sheath using the plastic peel pouch. Hold the syringe pointing up. Attach the safety needle to the syringe using a gentle twisting motion to avoid needle hub cracks or damage. Always check for signs of damage or leaking prior to administration.



5. Pull the needle sheath away from the needle with a straight pull. Do not twist the sheath as the needle may be loosened from the syringe.



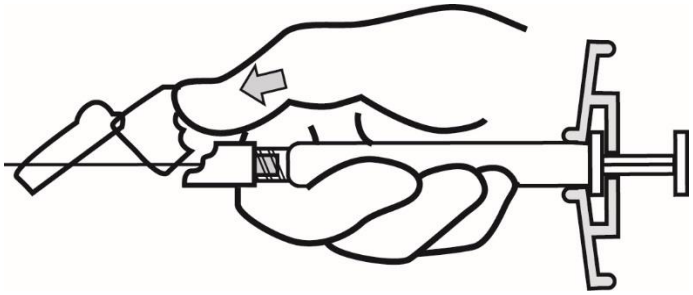
6. Bring the syringe with the attached needle in upright position to de-aerate. De-aerate the syringe by moving the plunger rod carefully forward.



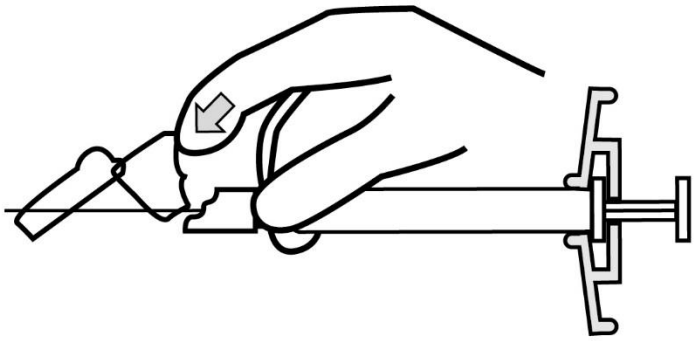
7. Inject the entire contents intramuscularly slowly, deep into the selected deltoid or gluteal muscle of the patient. **Do not administer intravascularly or subcutaneously.**

8. After the injection is complete, use either thumb or finger of one hand (8a, 8b) or a flat surface (8c) to activate the needle protection system. The needle protection system is fully activated when a 'click' is heard. Discard the syringe with needle appropriately.

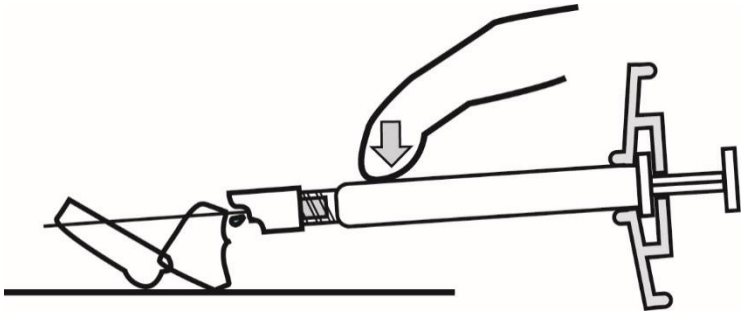
**8a**



**8b**



**8c**



# PHARMACEUTICAL INFORMATION

## List of Excipients

Inactive ingredients in INVEGA SUSTENNA are citric acid monohydrate, disodium hydrogen phosphate anhydrous, polyethylene glycol 4000, polysorbate 20, sodium dihydrogen phosphate monohydrate, sodium hydroxide, water for injection.

## Storage Conditions

Do not store above 30°C.

Keep out of the sight and reach of children.

## MANUFACTURED BY

Janssen Pharmaceutica N.V., Beerse, Kingdom of Belgium

## MARKETING AUTHORIZATION NUMBER

1C 21/54 (N)

## DATE OF AUTHORIZATION

7 June 2011

## DATE OF REVISION OF THE TEXT

CCDS v.05 Dec 2022

## IMPORTED BY

Janssen-Cilag Ltd., Bangkok, Thailand

To report Suspected Adverse Reactions, please contact us at aepqcjacth@its.jnj.com

For any product information, please contact us at medinfosea@its.jnj.com

Please see full prescribing information at
https://druglink.fda.moph.go.th/U1DR1C1062540002111C