Instructions for Use
DUPIXENT® (DU-pix-ent)
(dupilumab)
injection, for subcutaneous use
Single-Dose Pre-filled Pen (300 mg/2 mL)

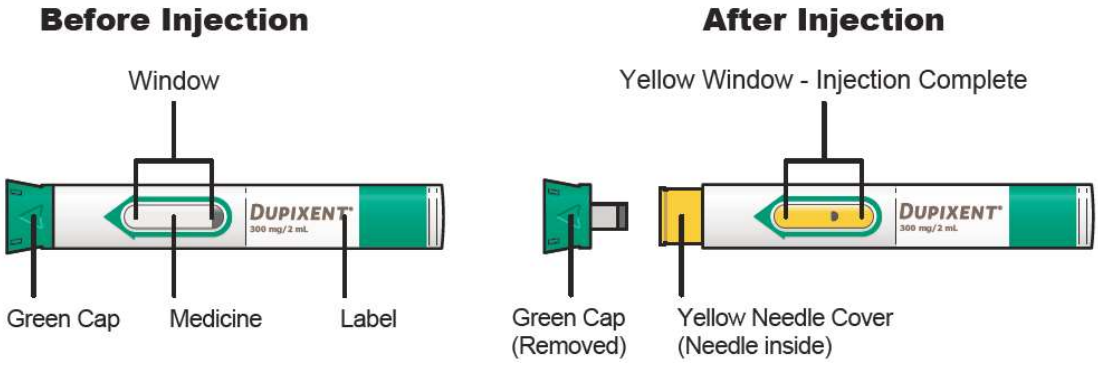
This Instructions for Use contains information on how to inject DUPIXENT.

Read this Instructions for Use before using the DUPIXENT Pre-filled Pen. **Do not inject yourself or someone else until you have been shown how to inject DUPIXENT.** Your healthcare provider can show you or your caregiver how to prepare and inject a dose of DUPIXENT before you try to do it yourself for the first time. Keep this Instructions for Use. Call your healthcare provider if you have any questions.

This DUPIXENT Pre-filled Pen is only for use in adults and children aged 2 years and older.

This DUPIXENT Pre-filled Pen is a single-dose device. It contains 300 mg of DUPIXENT for injection under the skin (subcutaneous injection).

The parts of the DUPIXENT Pre-filled Pen are shown below:

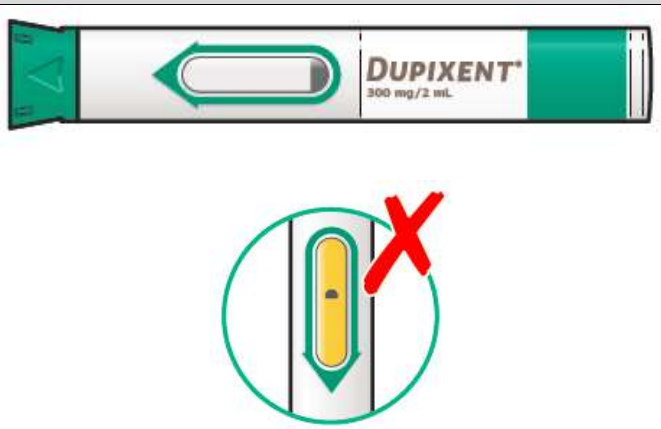
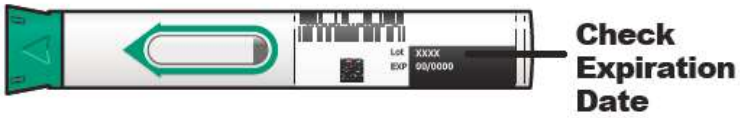


Important Information

- Read all of the instructions carefully before using the DUPIXENT Pre-filled Pen.
- Ask your healthcare provider how often you will need to inject the medicine.
- **In children 12 years of age and older,** it is recommended that DUPIXENT be administered by or under supervision of an adult.
- **In children 2 years to less than 12 years of age,** DUPIXENT should be given by a caregiver.
- Choose a different injection site for each injection.
- **Do not** press or touch the Yellow Needle Cover with your fingers.
- **Do not** inject through clothes.
- **Do not** remove the Green Cap until just before you give the injection.
- **Do not** try to put the Green Cap back on the DUPIXENT Pre-filled Pen.
- Throw away (dispose of) the used DUPIXENT Pre-filled Pen right away after use.
- **Do not** re-use a DUPIXENT Pre-filled Pen.

Storing DUPIXENT

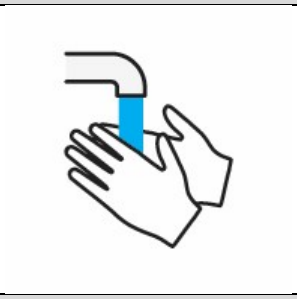
- Store unused DUPIXENT Pre-filled Pens in the refrigerator between 36ºF to 46ºF (2ºC to 8ºC).
- Store DUPIXENT Pre-filled Pens in the original carton to protect from light.
- If necessary, you may keep DUPIXENT Pre-filled Pens at room temperature up to 77ºF (25ºC) for up to **14 days**.
- **Do not** store DUPIXENT Pre-filled Pens at room temperature more than 77ºF (25ºC).
- After removing a DUPIXENT Pre-filled Pen from the refrigerator, it must be used within 14 days or thrown away (disposed of).
- **Do not** shake the DUPIXENT Pre-filled Pen at any time.
- **Do not** heat the DUPIXENT Pre-filled Pen.
- **Do not** freeze the DUPIXENT Pre-filled Pen.
- **Do not** put the DUPIXENT Pre-filled Pen into direct sunlight.
- **Keep DUPIXENT Pre-filled Pens and all medicines out of the reach of children.**

A. Get ready to inject	
A1. Gather supplies	
Find a clean, flat work surface. Make sure you have the following supplies:	
A2. Check the Pen	
• **Do not** use the DUPIXENT Pre-filled Pen if it has been damaged. • **Do not** use the DUPIXENT Pre-filled Pen if the Green Cap is missing or not securely attached. • **Do not** use the DUPIXENT Pre-filled Pen if the Window is yellow before use.	
A3. Look at the Label	
• Check to be sure that you have the correct Medicine and dose.	
• Check the expiration date. • ⚠ **Do not** use the DUPIXENT Pre-filled Pen if the expiration date has passed.	

A4. Check the Medicine	
• Look at the Medicine through the Window: it should be clear and colorless to pale yellow. • Note: You may see an air bubble, this is normal. • ⚠ **Do not** use the DUPIXENT Pre-filled Pen if the liquid is discolored or cloudy, or if it contains visible flakes or particles.	
A5. Wait 45 minutes	
• Lay the DUPIXENT Pre-filled Pen on a flat surface and let it warm up at room temperature less than 77ºF (25ºC) for at least **45** minutes. • ⚠ **Do not** heat the DUPIXENT Pre-filled Pen in a microwave, hot water or direct sunlight.	

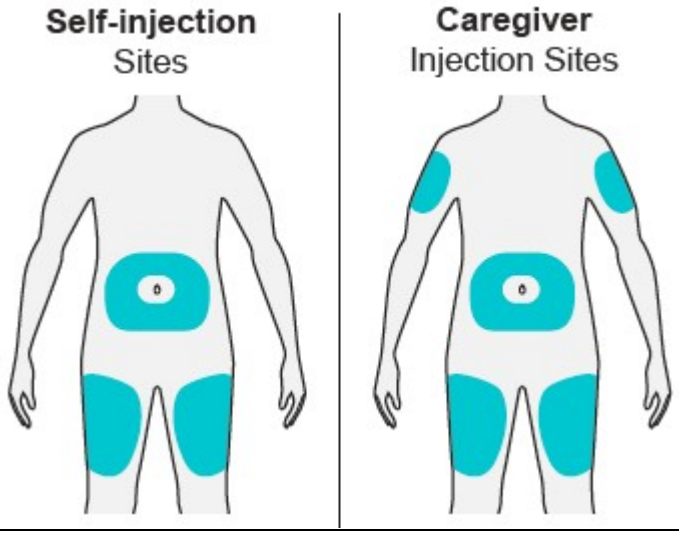
B. Choose and prepare your injection site

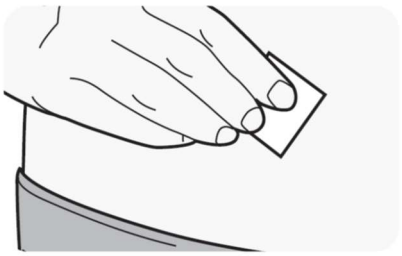
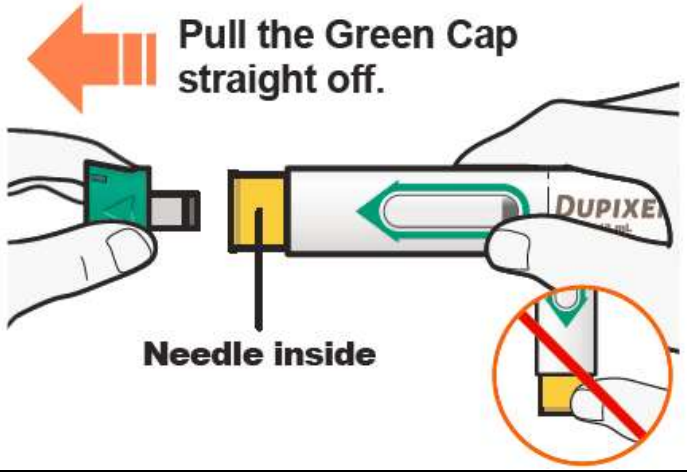
B1. Wash your hands well with soap and water



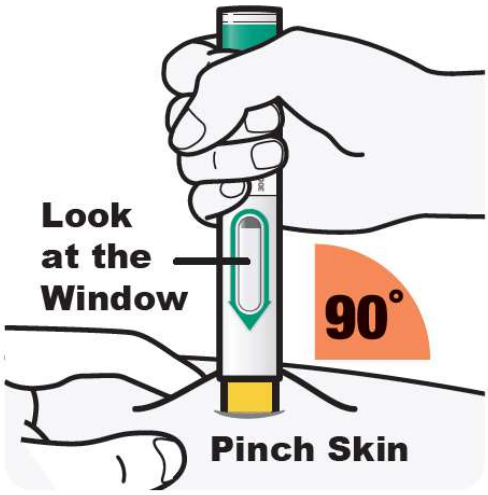
B2. Choose an injection site

- **Thigh**
- **Stomach** except for the 2 inches (5 cm) around your belly button (navel).
- A caregiver can also inject in the outer area of the **upper arm**.
- Choose a different site for each injection.
- ⚠ **Do not** inject into skin that is tender, damaged, has bruises or scars, or into areas with visible veins.
- ⚠ **Do not** inject through clothes.



B3. Prepare the injection site	
• Clean the injection site with an alcohol wipe. • Let the skin dry before injecting. • ⚠ **Do not** touch the injection site again or blow on it before the injection.	
C. Give the injection	
C1. Remove Green Cap	
• Remove the Green Cap by pulling it straight off, as shown. **Do not** twist the Green Cap off. • **Do not** remove the Green Cap until you are ready to inject. • **Do not** press or touch the Yellow Needle Cover with your fingers. The Needle is inside. • ⚠ **Do not** put the Green Cap back on the DUPIXENT Pre-filled Pen after you have removed it.	

C2. Pinch Skin and Place



Pinch the skin before and during the injection.

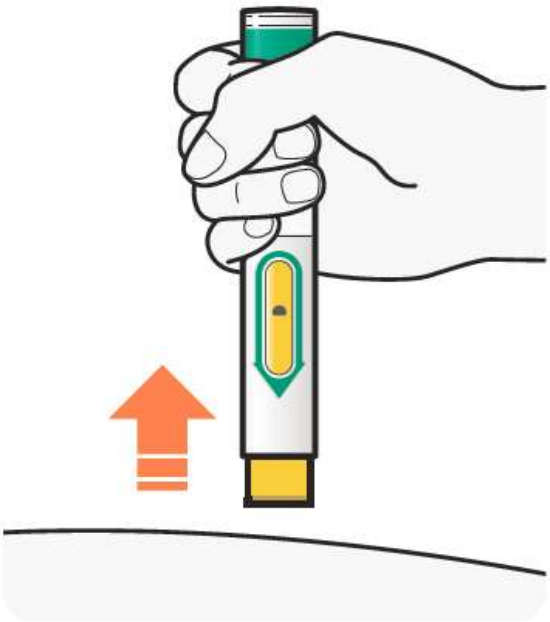
- Hold the DUPIXENT Pre-filled Pen as shown so that you can see the Window. Place the Yellow Needle Cover on the skin.
- Place the Yellow Needle Cover on the skin at approximately a 90-degree angle.
- Pinching is not needed for adults and children aged 12 years and older.

C3. Press down → Watch Window turn fully yellow → Then count to 5



Press and hold the DUPIXENT Pre-filled Pen firmly against the skin **until you cannot see the Yellow Needle Cover**. • There will be a "click" when the injection starts, **and** • The Window will start to turn yellow. • **Keep pressing** the DUPIXENT Pre-filled Pen against the skin.	Keep pressing the DUPIXENT Pre-filled Pen against the skin and watch the window: • The Window will turn completely yellow, **and** • You will hear a **2nd "click"**. • **Keep pressing** the DUPIXENT Pre-filled Pen against the skin.	Keep pressing the DUPIXENT Pre-filled Pen against the skin and **count to 5 to make sure you get your full dose.**

Pinching of the skin is not needed for adults and children aged 12 years and older.

C4. Remove	
• After you have completed the injection pull straight up to remove DUPIXENT Pre-filled Pen from the skin. The Yellow Needle Cover will cover the needle. • If you see any blood at the site, lightly dab a cotton ball or gauze pad. • ⚠ **Do not** rub the skin after the injection. • If the Window does not turn completely Yellow, or if it looks like medicine is still coming out of the pen, you may not have received a full dose. Dispose of (throw away) the pen and contact your healthcare provider right away. • ⚠ **Do not** give a second dose without speaking to your healthcare provider.	

D. Dispose of used DUPIXENT Pre-filled Pen

How to Dispose of (throw away) DUPIXENT Pre-filled Pen:

Put the used DUPIXENT Pre-filled Pens and Green Caps in a FDA-cleared sharps disposal container right away after use.

⚠ **Do not** dispose of (throw away) DUPIXENT Pre-filled Pens and Green Caps in your household trash.

If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:

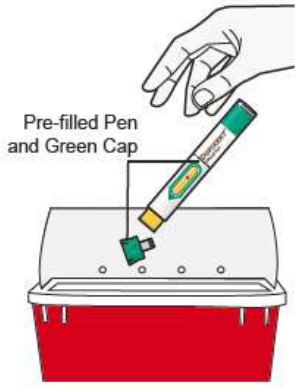
- made of a heavy-duty plastic,
- can be closed with a tightfitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used DUPIXENT Pre-filled Pens.

For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal

⚠ **Do not** dispose of your used sharps disposal container in your household trash unless your community guidelines permit this.

⚠ **Do not** recycle your used sharps disposal container.



Do not put the Green Cap back on.

Keep your sharps disposal container out of the reach of children.

REGENERON sanofi

Manufactured by:
Regeneron Pharmaceuticals, Inc.
Tarrytown, NY 10591
U.S. License No. 1760
Marketed by:
sanofi-aventis U.S. LLC (Bridgewater, NJ 08807) and
Regeneron Pharmaceuticals, Inc. (Tarrytown, NY 10591)
DUPIXENT® is a registered trademark of Sanofi Biotechnology

© 2022 Regeneron Pharmaceuticals, Inc. / sanofi-aventis U.S. LLC. All rights reserved.

This Instructions for Use has been approved by the U.S. Food and Drug Administration. Revised: November 2022