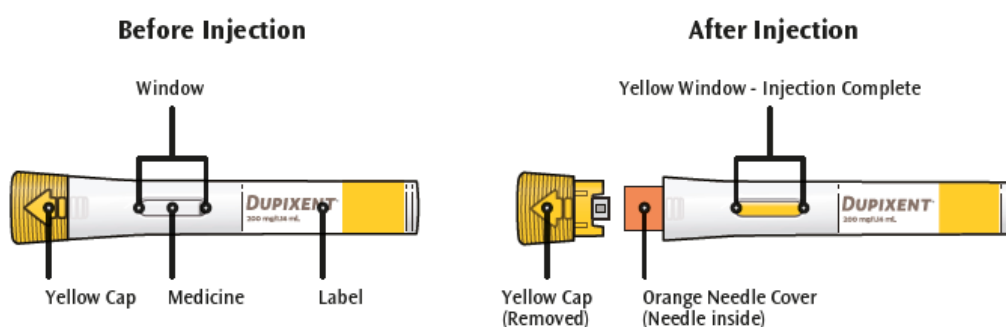


INSTRUCTIONS FOR USE

Dupilumab (200 mg) single-use solution for injection in a Pre-filled Pen

The parts of the Dupixent Pen are shown in this picture.



Important information

This device is a single-use Pre-filled Pen (called “pen” in these instructions). It contains 200 mg of Dupixent for injection under the skin (subcutaneous injection).

Read the 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.

In adolescents 12 years of age and older, it is recommended that Dupixent be administered by or under supervision of an adult. In children less than 12 years of age, Dupixent should be given by a caregiver. The Dupixent Pre-filled Pen is only for use in adults and children aged 2 years and older. Keep these instructions for use. Call your healthcare provider if you have any questions.

Do

- ✓ Keep these instructions for future use. Ask your healthcare provider or call sanofi at 1800 818 806 (Australia), if you have further questions.
- ✓ Read all of the instructions carefully before using the Pre-filled Pen

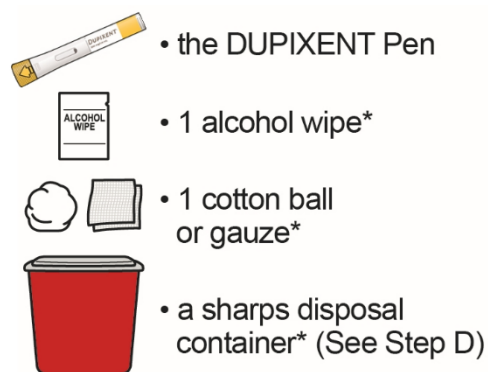
- ✓ Ask your healthcare provider how often you will need to inject the medicine.
- ✓ **In children 12 years and older**, it is recommended that Dupixent be administered by or under the supervision of an adult.
- ✓ **In children 2 years to less than 12 years of age**, Dupixent should be given by a caregiver.
- ✓ Rotate the injection site each time you inject.
- ✓ Ask your healthcare provider to show you the right way to use the pen before you inject for the first time.
- ✓ Keep the Pre-filled Pen(s) and all medicines out of the reach of children.
- ✓ Store Pre-filled Pens in the original carton to protect it from light
- ✓ Store unused Pre-filled Pens in the refrigerator between 2°C and 8°C.
- ✓ Remove the pen from the refrigerator at least 30 minutes before your injection so that it reaches room temperature.
- ✓ Throw away (dispose of) the Pre-filled Pen right away after use. See “Step 14: Dispose” below.

Do not

- ✗ Do not use the Pre-filled Pen if it has been dropped on a hard surface or damaged.
- ✗ Do not use the Pre-filled Pen if the Yellow Cap is missing or not securely attached.
- ✗ Do not press or touch the Orange Needle Cover with your fingers.
- ✗ Do not touch the Plunger Rod until you are ready to inject.
- ✗ Do not inject through clothes.
- ✗ Do not remove the Yellow Cap until just before you give the injection.
- ✗ Do not try to put the Yellow Cap back on the Pre-filled Pen.
- ✗ Do not re-use a Pre-filled Pen.
- ✗ Do not keep Pre-filled Pens at room temperature (less than 25°C) for more than 14 days. Throw away (dispose of) any Pre-filled Pens that have been left at room temperature for more than 14 days.
- ✗ Do not shake the Pre-filled Pen at any time.
- ✗ Do not heat the Pre-filled Pen.
- ✗ Do not freeze the Pre-filled Pen.
- ✗ Do not put the Pre-filled Pen into direct sunlight.

STEP 1: ENSURE YOU HAVE THE FOLLOWING:

- the Dupixent Pre-filled Pen
- 1 alcohol wipe*
- 1 cotton ball or gauze*
- a sharps (puncture resistant) disposal container* (See Step 14)



** Items not included in the carton.*

STEP 2: LOOK AT THE LABEL:

Confirm that you have the correct product and dose:



STEP 3: CHECK THE EXPIRATION DATE:

⚠ Do not use the Pre-filled Pen if the expiration date has passed.



STEP 4: CHECK THE MEDICINE:

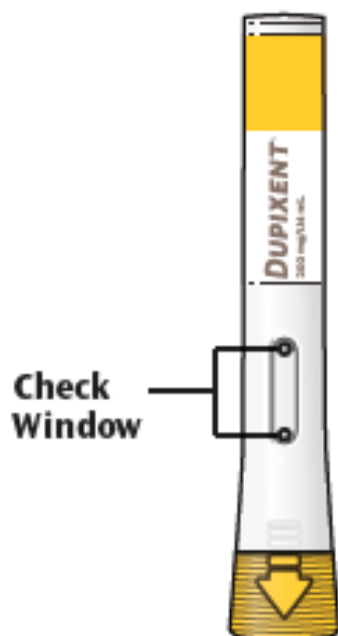
Look at the medicine through the Window on the Pre-filled Pen:

Check if the liquid is clear and colorless to pale yellow.

Note: You may see an air bubble; this is normal.

⚠ Do not use the Pre-filled Pen if the liquid is discolored or cloudy, or if it contains visible flakes or particles.

⚠ Do not use the Pre-filled Pen if the Window is Yellow.



STEP 5: WAIT 30 MINUTES:

Lay the Pre-filled Pen on a flat surface and let it naturally warm up at room temperature (less than 25°C) for at least 30 minutes.

 **Do not heat the Pre-filled Pen.**

 **Do not put the Pre-filled Pen into direct sunlight.**

 **Do not keep Dupixent at room temperature for more than 14 days. Dispose of (throw away) any Dupixent Pens that have been left at room temperature for longer than 14 days.**



STEP 6: CHOOSE YOUR INJECTION SITE:

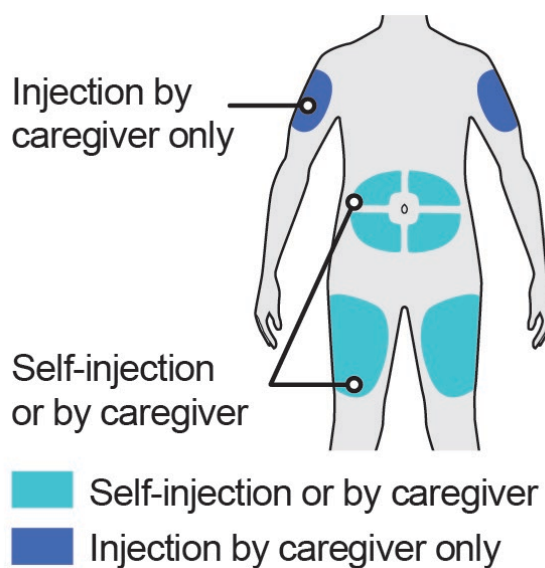
Recommended injection sites are:

- **Thigh**
- **Stomach** except for the 2 inches (5 cm) around your belly button (navel).
- **Upper Arm** If a caregiver gives your dose, they can also use the outer area of the upper arm.

Rotate the injection site each time you inject.

 **Do not inject through clothes.**

 **Do not inject into skin that is tender, damaged, bruised or scarred.**



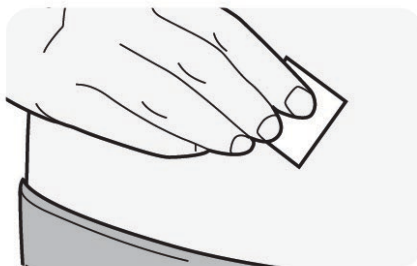
STEP 7: WASH YOUR HANDS:



STEP 8: PREPARE THE INJECTION SITE:

- Clean the injection site with an alcohol wipe.
- Let your skin dry before injecting.

⚠ Do not touch the injection site again or blow on it before the injection.



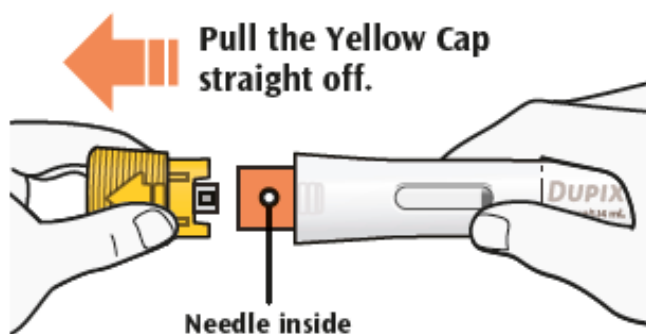
STEP 9: REMOVE YELLOW CAP:

Do not twist the Yellow Cap off.

Do not remove the Yellow Cap until you are ready to inject.

Do not press or touch the Orange Needle Cover with your fingers. The Needle is inside.

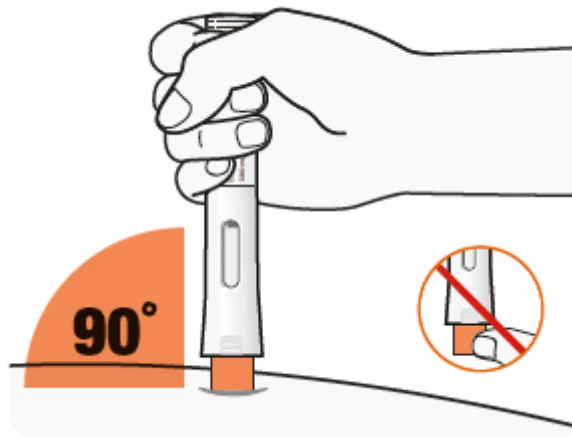
 **Do not put the Yellow Cap back on the Pre-filled Pen after you have removed it.**



STEP 10: PINCH SKIN AND PLACE:

- Pinch the skin before and during the injection.
- Pinching is not needed for adults and children aged 12 years and older.
- When placing the Orange Needle Cover on your skin, hold the Pre-filled Pen so that you can see the Window.
- Place the Orange Needle Cover on your skin at approximately a 90-degree angle.

 **Do not press or touch the Orange Needle Cover with your fingers. The Needle is inside.**



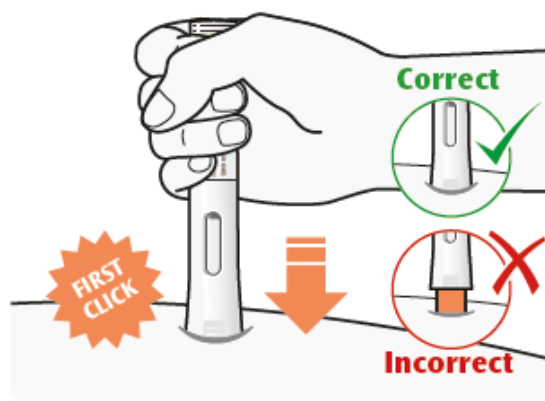
STEP 11: PRESS DOWN:

Press the Pre-filled Pen firmly against your skin until you cannot see the Orange Needle Cover, and hold.

- There will be a “click” when the injection starts.
- The window will start to turn Yellow.

The injection can take up to 15 seconds.

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



STEP 12: HOLD FIRMLY:

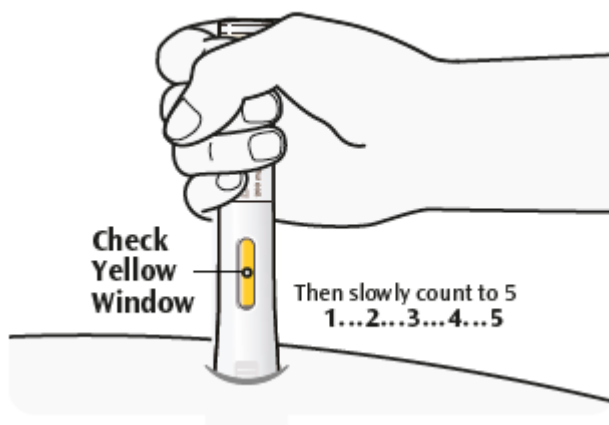
Keep holding the Pre-filled Pen firmly against your skin.

- You may hear a second click.
- Check that the entire Window has turned to Yellow.
- Then slowly count to 5.
- Then lift the pen up off the skin, your injection is complete.

If the Window does not turn completely Yellow, remove the pen and call your healthcare provider.

⚠ Do not repeat the injection without speaking to your healthcare provider.

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

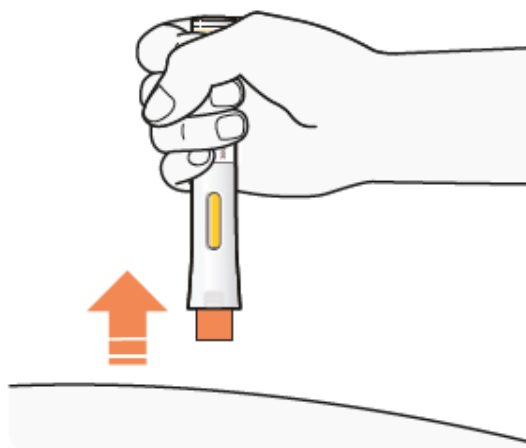


STEP 13: REMOVE:

After you have completed your injection pull straight up to remove Pre-filled Pen from the skin.

If you see any blood at the site, lightly dab a cotton ball or gauze pad.

⚠ Do not rub your skin after the injection.



STEP 14: DISPOSE:

Dispose of (throw away) your used Dupixent Pre-filled Pens, (Needle inside), and Yellow Caps in a puncture resistant (sharps disposal) container right away after use.

Do not dispose of (throw away) the used Pre-filled Pens (Needle inside), and Yellow Caps in your household rubbish.



Do not put the Yellow Cap back on.

