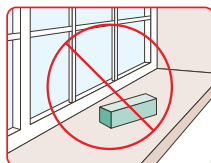


Instructions For Use DUPIXENT® 200/300 mg Solution for Injection in pre-filled Pen

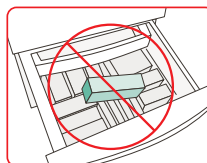
Supervised by Director, Igarashi Dermatology Higashigotanda **Dr. Atsuyuki Igarashi**

1 Storing DUPIXENT®

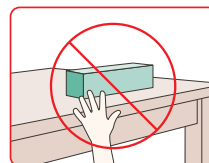
- ✓ Store the Pens **immediately put the whole carton in the refrigerator** at 2-8°C.
- ✓ Do not store the Pens near the cold air vents in the chilled compartment, vegetable compartment, or refrigerator compartment, because it may be frozen.



Do not put the Pens into high temperature or direct sunlight.



Do not put the Pens in the freezer.



Keep out of the reach of children.

⚠ Note • Do not shake, heat, or freeze the Pens.

2 Prepare for Injection

- ✓ Take the carton out of the refrigerator.
- ✓ Remove the Pen from the carton. Check the front side of the label to **make sure it is “DUPIXENT® 300 mg pre-filled Pen” or “DUPIXENT® 200 mg pre-filled Pen”**.
- ✓ Check the back side of the label to **make sure the expiration date has not passed**.
- ✓ Check **the liquid is colorless to pale yellow and clear** through the window.
- ✓ Lay the Pen on a flat surface and let it naturally warm to room temperature for **at least 30 minutes before use in the case of 200-mg Pen and at least 45 minutes before use in the case of 300-mg Pen**.

Front side of the label



Window

Check the label

Back side of the label



Window

Expiration date

* The illustration shows a 300-mg Pen. The 200-mg Pen is provided with a yellow-based design.

- ⚠ Note**
- Do not use the Pens if the expiration date has passed.
 - Do not use the Pens if it has been dropped on a hard surface or damaged, or if the needle cap is missing or not securely attached.
 - Do not use the Pens if the liquid looks different from its original color (colorless or pale yellow) or is cloudy, or if it contains like particles, through the window.
 - Do not leave the Pens for a long time after removing it from refrigerator.
 - Do not use the Pens if the window is yellow before use.
 - Do not remove the cap until you are ready to inject.

If you inject yourself, please refer to **3-8** on the right page, and if caregiver injects, please refer to **3-8** on the back side.

Steps for self-injection at home

3 Choose and clean your Injection Site

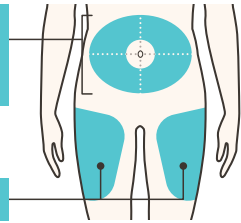
Choose the suitable sites for injection where are stomach except for around your belly button, or thigh (see the figure on the right).

- Wash your hands with soap, wipe hands with clean towels, and clean the injection site with alcohol wipe.
- Let the skin dry before injecting.
 - * Alcohol wipes are not included in the carton.

Stomach except for around your belly button (navel)

Avoid 5 cm around your belly button

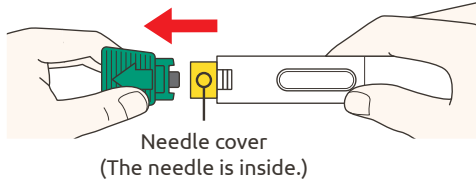
Thigh



- Note**
- Do not touch the injection site or blow on it after clean.
 - Do not inject through clothes.
 - Do not inject into skin that is tender, damaged, bruised, or scarred, and sites with severe symptoms of atopic dermatitis.
 - Choose a different site for each injection.
 - For stomach, choose a different site from the previous injection by dividing it into four areas; top, bottom, left, and right as shown in the figure above.

4 Remove the cap

Pull straight out without twisting



- Do not remove the cap until you are ready to inject.



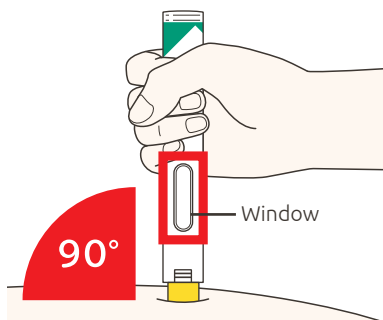
Do not touch the needle cover.

The needle is inside.

Note

- Do not put the cap back on once removed.

5 Place on Injection Site



Hold the Pen so that **you can see the window.**

Place the needle cover on the skin at **about a 90° angle.**

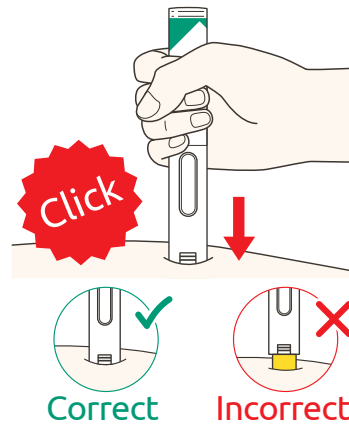
Note

- Do not press or touch the needle cover with your fingers.

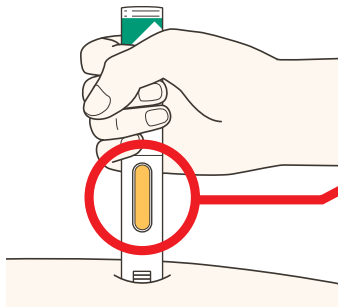
6 Press down

Press and **hold** the Pen firmly **until you cannot see the needle cover.**

- You will hear a “click” sound when the injection starts.
The window starts to turn yellow.
- The injection will take up to 15 seconds.



7 Keep the Pen pressed firmly



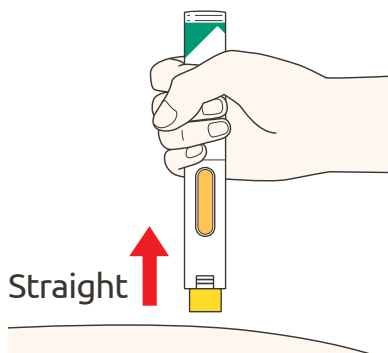
After the window **turns completely yellow**, keep it pressing down and **slowly count to 5**.

Note

- The liquid should be used up for one single injection. Do not re-use the Pen.

- You may hear a “click” sound again.
- If the entire window does not turn yellow, remove the Pen and contact your doctor or nurse. Do not give the second dose without your doctor's permission.

8 Remove the Pen from the Skin



- After you have completed the injection pull straight up to remove the Pen from the skin.
- Removing the Pen from skin too early will lead to leakage of the liquid.
- Lightly press an alcohol wipe on the injection site if you see any bleeding

Note

- Do not massage or rub the skin after the injection.

Steps for injection by caregiver at home

*Do not use a pen-type product but use a syringe-type product for administration to patients whose skin and subcutaneous tissue are thin (such as patients younger than 2 years). *The color of the needle cover of the 200-mg Pen is orange. *The illustration shows a 300-mg Pen.

3 Choose and clean Injection Site

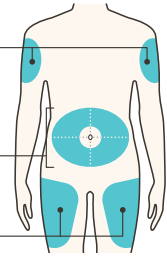
Suitable sites for injection are outer area of the upper arm, stomach except for around belly button, or thigh (see the figure on the right).

- Wash your hands with soap, wipe hands with clean towels, and clean the patient's injection site with alcohol wipe.
- Let the skin dry before injecting.
* Alcohol wipes are not included in the carton.

Outer area of the upper arm
If you are caregiver, you can also choose the outer area of the upper arm.

Stomach except for around belly button (navel)
Avoid 5 cm around belly button

Thigh

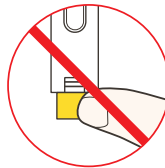
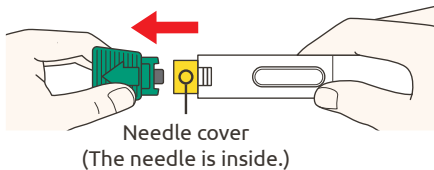


⚠ Note

- Do not touch the injection site or blow on it after clean.
- Do not inject through clothes.
- In children less than 12 years of age, DUPIXENT should be given by a caregiver.
- Do not inject into skin that is tender, damaged, bruised, or scarred, and sites with severe symptoms of atopic dermatitis.
- Choose a different site for each injection.
- For stomach, choose a different site from the previous injection by dividing it into four areas; top, bottom, left, and right as shown in the figure above.

4 Remove the cap

Pull straight out without twisting



Do not touch the needle cover.

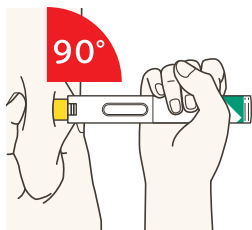
The needle is inside.

- Do not remove the cap until you are ready to inject.

⚠ Note

- Do not put the cap back on once removed.

5 Place on Injection Site



⚠ Note

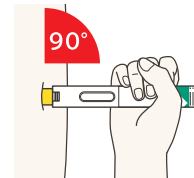
- Do not press or touch the needle cover with your fingers. The needle is inside.
- For use in children less than 12 years of age, pinch the skin before and during the injection.

< For use in children less than 12 years of age >

Pinch the skin before and during the injection.

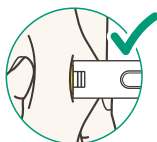
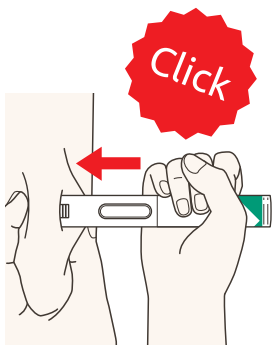
Hold the Pen so that **you can see the window.**

Place the needle cover on the skin **at about a 90° angle.**

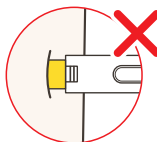


- Pinching is not needed for **children aged 12 years and older.**

6 Press down



Correct

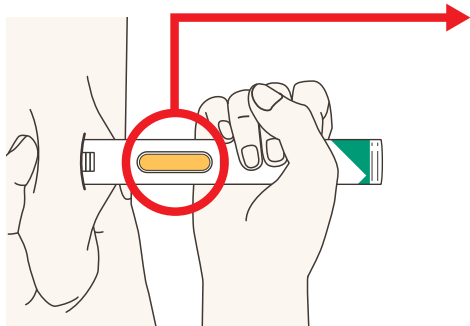


Incorrect

Press and **hold** the Pen firmly **until you cannot see the needle cover**.

- You will hear a “click” sound when the injection starts. The window starts to turn yellow.
- Do not release the pinched skin during the injection.
- The injection will take up to 15 seconds.

7 Keep the Pen pressed firmly



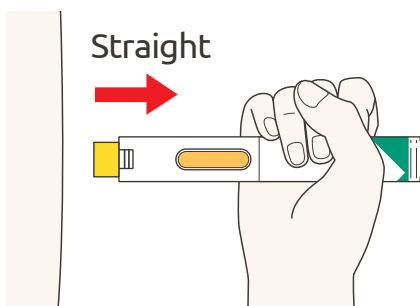
After the window **turns completely yellow**, keep it pressing down and **slowly count to 5**.

- You may hear a “click” sound again.
- If the entire window does not turn yellow, remove the Pen and contact your doctor or nurse. Do not give the second dose without your doctor's permission.

⚠ Note

- The liquid should be used up for one single injection. Do not re-use the Pen.

8 Remove the Pen from the Skin



- Confirm that the injection has completed, release the pinched skin.
- Pull straight up to remove the Pen from the skin.
- Removing the Pen from skin too early will lead to leakage of the liquid.
- Lightly press an alcohol wipe on the injection site if you see any bleeding.

⚠ Note

- Do not massage or rub the skin after the injection.

Disposal method of Pens

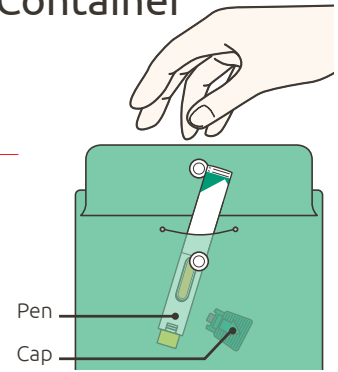
9 Put your Pens and Caps into Disposal Container

Do not put the cap back on.

Put your Pens and the caps separately in a disposal container.

Note

- Put your used Pens and the caps in a disposal container immediately to discard as medical waste following your doctor's instructions (if you do not have a disposal container, you can use any hard container such as a bottle with a lid or can instead).
- Throw away used alcohol wipes as household waste following your community rules.
- Keep the disposal container out of the reach of children.
- Do not recycle the disposal container.



? Frequently asked questions

<p>Q1 I forgot to have an injection on a scheduled day. What should I do?</p>	<p>A1 Please contact your doctor and follow his/her instructions.</p>
<p>Q2 I have injected more than the dose that I was instructed. What should I do?</p>	<p>A2 Please contact your doctor immediately and follow his/her instructions.</p>
<p>Q3 Other medications were also prescribed with DUPIXENT® 300 mg pre-filled Pens. Is it OK to use them?</p>	<p>A3 Use the prescribed ointments, oral medications, and inhalers as instructed. Do not discontinue them at your own discretion.</p>
<p>Q4 What time should I have an injection?</p>	<p>A4 There are no specific rules of the injection time. Inject DUPIXENT® 300 mg pre-filled Pens at a time convenient for you.</p>
<p>Q5 I don't feel well. Can I still have an injection as scheduled?</p>	<p>A5 Do not make your own judgment. Contact your doctor and follow his/her instructions.</p>
<p>Q6 I have a trip or business trip on the scheduled injection date. What should I do?</p>	<p>A6 When you know that you will be away overnights on injection scheduled day(s), please consult your doctor in advance.</p>
<p>Q7 Injections hurt. Is there any way to relieve the pain?</p>	<p>A7 When the liquid is too cold, you may feel more pain. Please allow the liquid to warm up to room temperature before injection. Remove the Pen from the refrigerator at least 30 minutes before injecting in the case of 200-mg Pen and at least 45 minutes before injecting in the case of 300-mg Pen. If the pain persists, please consult your doctor.</p>