

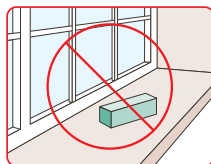
Instructions For Use

DUPIXENT[®] 200 mg/300 mg Solution for Injection in pre-filled Syringe

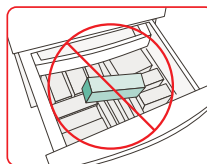
Supervised by Director, Igarashi Dermatology Higashigotanda **Dr. Atsuyuki Igarashi**

1 Storing DUPIXENT[®]

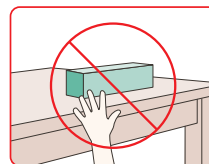
- ✓ Store the Syringes **immediately put the whole carton in the refrigerator** at 2-8°C.
- ✓ Do not store the Syringes near the cold air vents in the chilled compartment, vegetable compartment, or refrigerator compartment, because it may be frozen.



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



Do not put the Syringes in the freezer.



Keep out of the reach of children.

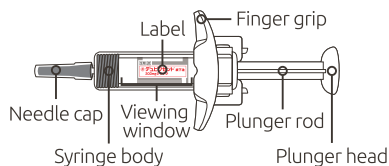
▲ Note • Do not shake, heat, or freeze the Syringes.

2 Prepare for Injection

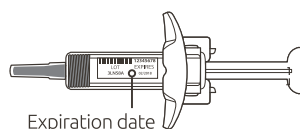
- ✓ Take the carton out of the refrigerator.
- ✓ Remove the Syringe from the carton by holding the Syringe body. Check the front side of the label to **make sure it is "DUPIXENT[®] 200 mg solution for Injection in pre-filled Syringe"** or **"DUPIXENT[®] 300 mg solution for Injection in pre-filled Syringe"**.
- ✓ 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 viewing window.
- ✓ Lay the Syringe on a flat surface and let it naturally warm to room temperature for **at least 30 minutes for 200 mg Syringe** or **at least 45 minutes for 300 mg Syringe** before use.



Front side of the label



Back side of the label



* The illustrations are the 300 mg pre-filled Syringe.

- ▲ Note**
- Do not use the Syringes if the expiration date has passed.
 - Do not use the Syringes 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 Syringes if the liquid looks different from its original color (colorless or pale yellow) or is cloudy, or if it contains like particles, through the viewing window.
 - Do not leave the Syringes for a long time after removing it from refrigerator.
 - Do not remove the needle cap or touch the plunger until you are ready to inject.

If you inject yourself, please refer to **3-9** on the right page, and if caregiver injects, please refer to **3-9** on the back side.

Steps for self-injection at home

3 Choose and clean your Injection Site

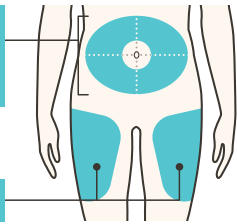
Choose the suitable sites for injection where are stomach except for around your belly button, or thigh (see the figure on the right).

- 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



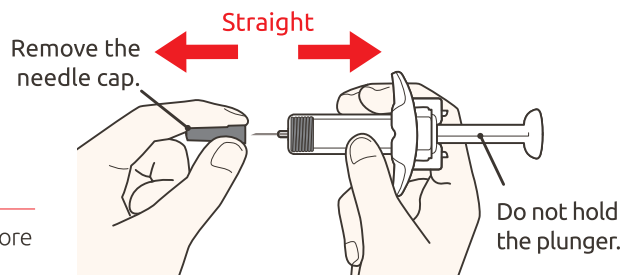
- Note**
- Do not touch the injection site or blow on it after clean.
 - Do not inject through clothes.
 - Do not inject into skin that is tender, damaged, bruised, or scarred, and sites with severe symptoms of atopic dermatitis.
 - Choose a different site for each injection.
 - For stomach, choose a 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 Needle Cap

- **Hold the Syringe in the middle of the Syringe body** and remove the needle cap.

Note

- Do not remove the needle cap until just before injection.
- Do not put the needle cap back on.
- Do not touch the needle.
- After removing the needle cap, avoid contacting the needle with other objects and inject right away.
- You may see an air bubble, which you do not need to remove. This is normal.
- Do not pull back on the plunger at any time.



5 Pinch a Fold of Skin

- **Pinch a fold of skin** at the injection site to insert the needle steadily.

Note

- Do not inject through clothes.



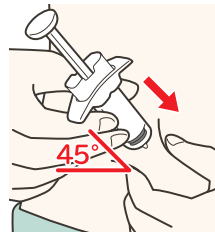
Stomach



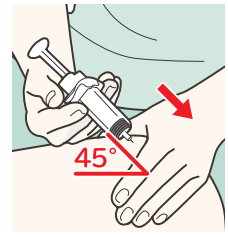
Thigh

6 Insert Needle at about 45° Angle

- Insert the needle completely into the fold of the skin at **about a 45° angle**.
- ☑ If you feel a tingling sensation **like pins-and-needles**, pull the needle tip a little.



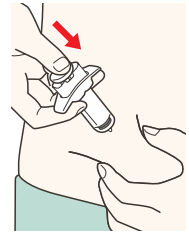
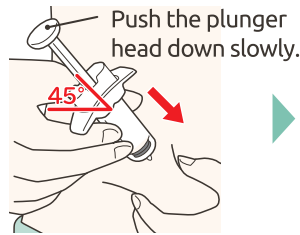
Stomach



Thigh

7 Inject Drug

- Once the needle is fully inserted, **relax the pinch**.
 - **Push the plunger head down slowly** and steadily as far as it will go until the Syringe is empty.
 - There is no problem if you feel some resistance during the injection, so push slowly.
- ☑ **Push the plunger head down completely.**

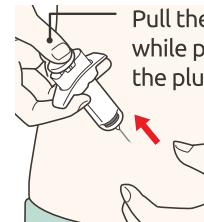
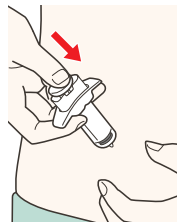


⚠ Note

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

8 Pull Needle out while pressing Plunger Head

- Release the pinched skin.
- Pull the needle out from the injection site at the **same angle (about 45° angle)** as you inserted it.



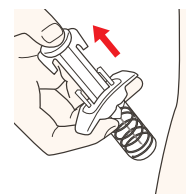
9 After Injection

- Lift your thumb slowly to release the plunger head after pulling the needle out.
- Lightly press an alcohol wipe on the injection site if you see any bleeding.

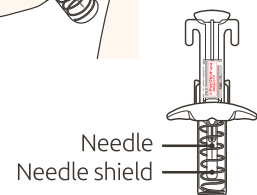
⚠ Note

- Do not put the needle cap back on after the injection is completed.
- Do not massage or rub the skin after the injection.
- Do not re-use the Syringe.

- ☑ The needle shield covers the needle.



After use



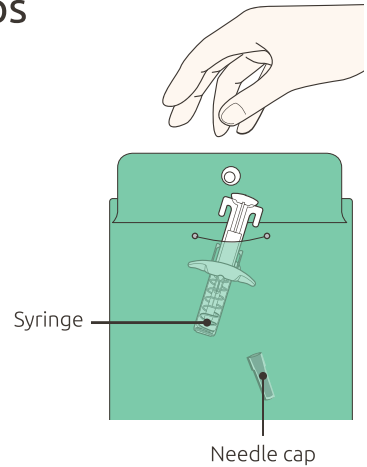
Disposal method of Syringes

10 Throw away Syringes and Needle Caps

- Put your used Syringes, and needle caps in a disposal container to throw away as medical waste following your doctor's instructions.
- **Do not put the needle cap back on.**

⚠ Note

- Put your used Syringes and needle caps in a disposal container right away after use (if you do not have a disposal container, use a 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® pre-filled Syringes. 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® pre-filled Syringes 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 Syringe from the refrigerator for at least 30 minutes before for 200 mg Syringe or at least 45 minutes before for 300 mg Syringe for injecting. If the pain persists, please consult your doctor.</p>

Steps for injection by caregiver at home

3 Choose and clean your Injection Site

Choose the suitable sites for injection where 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.

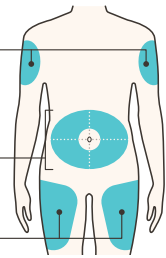
Outer area of the upper arm

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



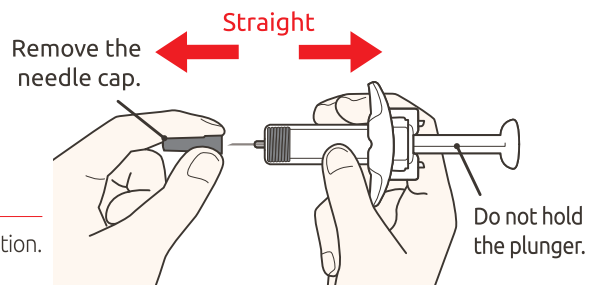
- Note**
- Do not touch the injection site or blow on it after clean.
 - Do not inject through clothes.
 - In children less than 12 years of age, DUPIXENT should be given by a caregiver.
 - Do not inject into skin that is tender, damaged, bruised, or scarred, and sites with severe symptoms of atopic 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 Needle Cap

- **Hold the Syringe in the middle** of the Syringe body and pull off the needle cap.

Note

- Do not remove the needle cap until just before injection.
- Do not put the needle cap back on.
- Do not touch the needle.
- After removing the needle cap, avoid contacting the needle with other objects and inject right away.
- You may see an air bubble, which you do not need to remove. This is normal.
- Do not pull back on the plunger at any time.



5 Pinch a Fold of Skin

- **Pinch a fold of skin** at the injection site to insert the needle steadily.

Note

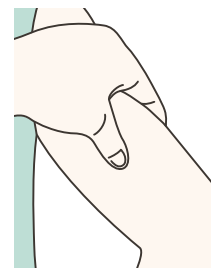
- Do not inject through clothes.



Stomach



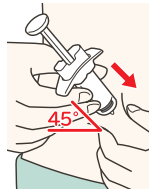
Thigh



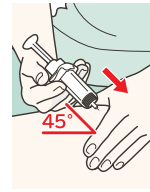
Upper arm

6 Insert Needle at about 45° Angle

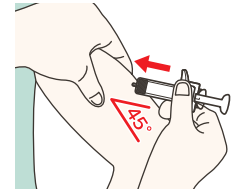
- Insert the needle completely into the fold of the skin at **about a 45° angle**.
- ☑ Ask the patient if he/she feels a tingling sensation **like pins-and-needles**. If the patient feels it, pull the needle tip a little.



Stomach



Thigh

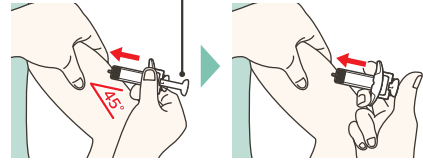


Upper arm

7 Inject Drug

- Once the needle is fully inserted, **relax the pinch**.
- **Push the plunger head down slowly** and steadily as far as it will go until the Syringe is empty.
- There is no problem if you feel some resistance during the injection, so push slowly.

Push the plunger head down slowly.



- ☑ **Push the plunger head down completely.**

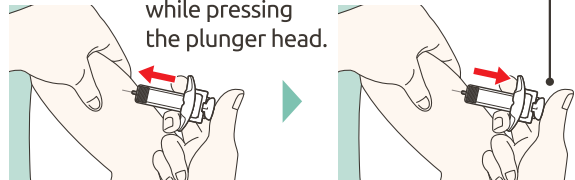
⚠ Note

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

8 Pull Needle out while pressing Plunger Head

- Release the pinched skin.
- Pull the needle out from the injection site at the **same angle (about 45° angle)** as you inserted it.

Pull the needle out while pressing the plunger head.

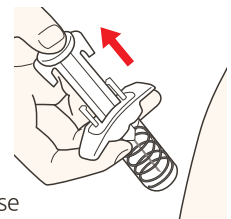


9 After Injection

- ☑ Lift your thumb slowly to release the plunger head after pulling the needle out.
- ☑ After use, the needle shield slides and covers the needle.
- ☑ Lightly press an alcohol wipe on the injection site if you see any bleeding.

⚠ Note

- Do not put the needle cap back on after the injection is completed.
- Do not massage or rub the skin after the injection.
- Do not re-use the Syringe.



After use

