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## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S4

**DUPIXENT® 200 mg solution for injection**

**DUPIXENT® 300 mg solution for injection**

**Dupilumab**

**DUPIXENT 200 mg** contains sugar (57 mg sucrose per 1,14 mL solution).

**DUPIXENT 300 mg** contains sugar (100 mg sucrose per 2 mL solution).

**Read all of this leaflet carefully before you start using DUXIXENT.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DUXIXENT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### **What is in this leaflet**

1. What DUXIXENT is and what it is used for
2. What you need to know before you use DUXIXENT
3. How to use DUXIXENT
4. Possible side effects
5. How to store DUXIXENT
6. Contents of the pack and other information.

#### **1. What DUXIXENT is and what it is used for**

DUXIXENT contains the active substance dupilumab.

Dupilumab is a monoclonal antibody (a type of specialised protein) that blocks the action of proteins called IL-4 and IL-13. Both play a major role in causing the signs and symptoms of atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP) and prurigo nodularis (PN).

DUPIXENT is used to treat adults, adolescents and children (6 months of age and older) with moderate-to-severe atopic dermatitis (also known as eczema, a type of inflammation of your skin resulting in itchy, red, swollen and cracked skin) whose disease is not adequately controlled with corticosteroid therapies applied as creams or ointments; or when those therapies are not advisable.

DUPIXENT can be used with or without other topical corticosteroid therapies (therapies applied as creams or ointments).

DUPIXENT is also used with other asthma medicines for the maintenance treatment of moderate-to-severe asthma in adults, adolescents and children (6 years of age and older).

DUPIXENT is also used with other medicines for the maintenance treatment of severe chronic rhinosinusitis with nasal polyposis (CRSwNP) in adults whose disease is not controlled with their current CRSwNP medicines. DUPIXENT can also reduce the need for surgery and the need for systemic corticosteroid use.

DUPIXENT is also used to treat adults with prurigo nodularis (PN) whose disease is not adequately controlled with prescription therapies applied as creams or ointments; or when those therapies are not advisable. DUPIXENT can be used with or without other topical corticosteroid therapies (therapies applied as creams or ointments).

## **2. What you need to know before you use DUPIXENT**

### **Do not use DUPIXENT**

- If you are allergic (hypersensitive) to dupilumab or any of the other ingredients of DUPIXENT (see section 6).

### **Warnings and precautions**

DUPIXENT is not a rescue medicine and should not be used to treat a sudden asthma attack.

Talk to your doctor or health care provider before you use DUPIXENT:

#### ***Allergic reactions***

- DUPIXENT can cause serious side effects, including allergic (hypersensitivity) reactions, anaphylactic reactions and angioedema. You must look out for signs of these conditions (i.e. breathing problems, swelling of the face, lips, mouth, throat or tongue, fainting, dizziness, feeling lightheaded [low blood pressure], fever, general ill feeling, swollen lymph nodes, hives, itching, joint pain, skin rash) while you are using DUPIXENT. Such signs are listed under “Serious side effects” in section 4.
- Stop using DUPIXENT and tell your doctor or get medical help immediately if you notice any signs of an allergic reaction.

#### ***Eosinophilic conditions***

- Patients taking an asthma medicine may develop inflammation of blood vessels or lungs due to an increase of certain white blood cells (eosinophilia).
- It is not known whether this is caused by DUPIXENT. This usually, but not always, happens in people who also take a steroid medicine which is being stopped or for which the dose is being lowered.
- Tell your doctor immediately if you develop a combination of symptoms such as a flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms and/or rash.

***Parasitic (intestinal parasites) infection***

- DUXIXENT may weaken your resistance to infections caused by parasites. If you already have a parasitic infection, it should be treated before you start treatment with DUXIXENT.
- Check with your doctor if you feel bloated, have diarrhoea, an upset stomach, greasy stools and dehydration, which could be a sign of a parasitic infection.
- If you live in a region where these infections are common or if you are travelling to such a region check with your doctor.

***Asthma***

If you have asthma and are taking asthma medicines, do not change or stop your asthma medicine without talking to your doctor. Talk to your doctor before you stop DUXIXENT or if your asthma remains uncontrolled or worsens during treatment with DUXIXENT.

***Eye problems***

Talk to your doctor if you have any new or worsening eye problems, including eye pain or changes in vision.

**Children and adolescents**

- In children 6 months to less than 12 years of age, DUXIXENT should be given by a caregiver.
- In children 12 years of age and older, it is recommended that DUXIXENT be administered by or under supervision of an adult.
- The safety and benefits of DUXIXENT are not yet known in children with atopic dermatitis below the age of 6 months.
- The safety and benefits of DUXIXENT are not yet known in children with asthma below the age of 6 years.
- CRSwNP does not normally occur in children. The safety and benefits of DUXIXENT are not yet known in children with CRSwNP below the age of 18 years.

- The safety and benefits of DUPIXENT are not known in children with PN below the age of 18 years.

**Other medicines and DUPIXENT**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Please consult your doctor, pharmacist or health care provider for advice if you need to take any other medicines.

Tell your doctor or health care provider if you have recently had or are due to have a vaccination.

***Other medicines for asthma***

Do not stop or reduce your asthma medicines, unless instructed by your doctor.

- These medicines (especially ones called corticosteroids) must be stopped gradually.
- This must be done under the direct supervision of your doctor and dependent on your response to DUPIXENT.

**Pregnancy and breastfeeding**

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you use DUPIXENT.

The effects of this medicine in pregnant women are not known; therefore, it is preferable to avoid the use of DUPIXENT in pregnancy.

Tell your doctor, pharmacist or health care provider if you become pregnant while using DUPIXENT.

Women receiving DUPIXENT are advised to not breastfeed their babies. You and your doctor should decide if you will breastfeed or use DUPIXENT. You should not do both.

If you are breastfeeding or are planning to breastfeed, talk to your doctor before you use

DUPIXENT.

### **Driving and using machines**

DUPIXENT is unlikely to influence your ability to drive and use machines.

### **DUPIXENT contains sodium**

DUPIXENT contains less than 1 mmol sodium (23 mg) per dose; it is essentially sodium free.

## **3. How to use DUXIXENT**

Always use DUXIXENT exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

Do not share medicines prescribed for you with any other person.

### **How DUXIXENT is given**

DUXIXENT is given by injection under the skin (subcutaneous injection).

### **How much DUXIXENT you will receive**

Your doctor will decide which dose of DUXIXENT is right for you.

## **ATOPIC DERMATITIS**

### ***Recommended dose in adults with atopic dermatitis***

The usual dose is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg (one single injection) given every other week, for adult patients. Your dosage may be increased to 300 mg (one single injection) per week.

### ***Recommended dose in children and adolescents (6 to 17 years of age) with atopic dermatitis***

The recommended dose of DUXIXENT for children and adolescents (6 to 17 years of age) with

atopic dermatitis is based on body weight:

| Body weight              | Initial dose                   | Subsequent doses        |
|--------------------------|--------------------------------|-------------------------|
| 15 kg to less than 30 kg | 600 mg (two 300 mg injections) | 300 mg every 4 weeks    |
| 30 kg to less than 60 kg | 400 mg (two 200 mg injections) | 200 mg every other week |
| 60 kg or more            | 600 mg (two 300 mg injections) | 300 mg every other week |

***Recommended dose in children (6 months to 5 years of age) with atopic dermatitis***

The recommended dose of DUPIXENT for children 6 months to 5 years of age with atopic dermatitis is based on body weight:

| Body weight              | Initial dose                  | Subsequent doses     |
|--------------------------|-------------------------------|----------------------|
| 5 kg to less than 15 kg  | 200 mg (one 200 mg injection) | 200 mg every 4 weeks |
| 15 kg to less than 30 kg | 300 mg (one 300 mg injection) | 300 mg every 4 weeks |

## ASTHMA

***Recommended dose in adults and adolescents (12 years of age and older) with asthma***

For adults and adolescents (12 years of age and older) with moderate-to-severe asthma, the recommended dose of DUPIXENT is:

- An initial dose of 400 mg (two 200 mg injections) followed by 200 mg given every other week administered as a subcutaneous injection.  
Your doctor may decide to increase the dose to 300 mg every other week based on your condition.
- For patients with oral corticosteroid-dependent asthma or with co-morbid moderate-to-severe atopic dermatitis or adults with co-morbid severe chronic rhinosinusitis with nasal polyposis, an initial dose of 600 mg (two 300 mg injections) followed by 300 mg administered every other week as a subcutaneous injection.

***Recommended dose in children (6 to 11 years of age) with asthma***

The recommended dose of DUPIXENT for children (6 to 11 years of age) with asthma is based on

body weight:

| <b>Body weight</b>       | <b>Initial and subsequent doses</b>                   |
|--------------------------|-------------------------------------------------------|
| 15 kg to less than 30 kg | 300 mg every 4 weeks                                  |
| 30 kg to less than 60 kg | 200 mg every other week<br>or<br>300 mg every 4 weeks |
| 60 kg or more            | 200 mg every other week                               |

For patients 6 to 11 years old with asthma and co-morbid moderate-to-severe atopic dermatitis, your doctor will decide which dose of DUPIXENT is right for you.

## **CHRONIC RHINOSINUSITIS WITH NASAL POLYPOSIS**

### ***Recommended dose in adults with chronic rhinosinusitis with nasal polyposis (CRSwNP)***

In CRSwNP, the recommended first dose of DUPIXENT is an initial dose of 300 mg, followed by 300 mg given every two weeks by subcutaneous injection.

## **PRURIGO NODULARIS**

### ***Recommended dose in adults with prurigo nodularis (PN)***

For patients with prurigo nodularis, the recommended dose of DUPIXENT is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week by subcutaneous injection.

DUPIXENT is given as an injection under your skin (subcutaneous injection). You and your doctor or nurse should decide if you should inject DUPIXENT yourself. Before injecting DUPIXENT yourself you must have been properly trained by your doctor or nurse. Your DUPIXENT injection may also be given by a caregiver after proper training by a doctor or nurse.

Each pre-filled syringe contains one dose of DUPIXENT 200 mg or DUPIXENT 300 mg. Do not



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shake the pre-filled syringe.

Read the INSTRUCTIONS FOR USE for the DUPIXENT 200 mg or DUPIXENT 300 mg pre-filled syringes before using.

The DUPIXENT 200 mg pre-filled syringe with a needle shield should be allowed to reach room temperature by waiting for 30 minutes before injecting.

The DUPIXENT 300 mg pre-filled syringe with a needle shield should be allowed to reach room temperature by waiting for 45 minutes before injecting.

DUPIXENT can be injected into the thigh or abdomen, except for the 5 cm around the navel. If somebody else administers the injection, the upper arm can also be used. It is recommended to rotate the injection site with each injection. DUPIXENT should not be injected into skin that is tender, damaged or has bruises or scars.

Always check the label of your syringe before each injection to make sure you have the correct medicine.

### **If you use more DUPIXENT than you should**

Contact your doctor if you inject more DUPIXENT than you should, or the dose has been given too early.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

### **If you missed a dose of DUPIXENT**

If your dose schedule is **every week** and you miss a dose of DUPIXENT:

- Wait until the next scheduled dose to give your DUPIXENT injection.

If your dose schedule is **every other week** and you miss a dose of DUPIXENT:

- Give the DUPIXENT injection within 7 days from the missed dose, then continue with your original schedule.
- If the missed dose is not given within 7 days, wait until the next scheduled dose to give your DUPIXENT injection.

If your dose schedule is **every 4 weeks** and you miss a dose of DUPIXENT:

- Give the DUPIXENT injection within 7 days from the missed dose, then continue with your original schedule.
- If the missed dose is not given within 7 days, start a new **every-4-week** dose schedule from the time you remember to take your DUPIXENT injection.

### Effects when treatment with DUPIXENT is stopped

It is important that you do not stop using DUPIXENT without talking to your doctor or pharmacist first.

### 4. Possible side effects

DUPIXENT can have side effects.

Not all side effects reported for DUPIXENT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while you are receiving DUPIXENT, please consult your doctor, pharmacist or other healthcare provider for advice.

DUPIXENT can cause serious side effects, including generalised allergic (hypersensitivity) reactions. If any of the following happens, stop using DUPIXENT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching

- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DUPIXENT. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

*Frequent side effects:*

- injection site reactions (redness, swelling, itching)
- eye infection
- eye redness and itching
- eyelid itching, redness and swelling
- eye dryness
- cold sores (e.g. on lips and skin)
- pinworms (enterobiasis) (in children 6 to 11 years old with asthma).

*Frequency of side effect not known:*

- swelling of the face, lips, mouth, throat or tongue (angioedema)
- inflammation of the eye surface, sometimes with blurred vision (keratitis)
- ulcers on the outer clear layer of the eye, sometimes with blurred vision (ulcerative keratitis)
- joint pain (arthralgia)
- facial rash or redness.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to:

- The Pharmacovigilance Unit at Sanofi: [za.drugsafety@sanofi.com](mailto:za.drugsafety@sanofi.com) (email),  
<https://ae.reporting.sanofi/> (web portal) or +27 11 256 3700 (tel), or
- SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA's

publications: <https://www.sahpra.org.za/Publications/Index/8>

By reporting side effects, you can help provide more information on the safety of DUPIXENT.

## **5. How to store DUPIXENT**

### **Store all medicines out of reach of children.**

Store refrigerated at 2 °C to 8 °C in the original carton to protect from light.

If necessary, pre-filled syringes may be kept at room temperature up to 25 °C for a maximum of 14 days. Do not store above 25 °C. After removal from the refrigerator, the product must be used within 14 days or discarded.

If you need to permanently remove the carton from the refrigerator, write down the date of removal in the space provided on the outer carton, and use DUPIXENT within 14 days.

Do not freeze.

Do not expose to heat.

Do not shake.

Do not use after the expiry date stated on the label and carton.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Any waste material should be disposed of in accordance with local requirements.

## **6. Contents of the pack and other information**

### **What DUPIXENT contains**

The active substance is dupilumab.

Each DUPIXENT 200 mg pre-filled syringe with needle shield contains 200 mg of dupilumab in 1,14 mL solution for injection.

Each DUPIXENT 300 mg pre-filled syringe with needle shield contains 300 mg of dupilumab in 2 mL solution for injection.

The other ingredients are:

DUPIXENT 200 mg: L-arginine hydrochloride (50 mM), L-histidine (20 mM), polysorbate 80 (0,2 % *m/v*), sodium acetate (12,5 mM), sucrose (5 % *m/v*) and water for injection, adjusted to pH 5,9 with acetic acid.

DUPIXENT 300 mg: L-arginine hydrochloride (25 mM), L-histidine (20 mM), polysorbate 80 (0,2 % *m/v*), sodium acetate (12,5 mM), sucrose (5 % *m/v*) and water for injection, adjusted to pH 5,9 with acetic acid.

### **What DUPIXENT looks like and contents of the pack**

DUPIXENT is a sterile, preservative-free, clear to slightly opalescent, colourless to pale yellow solution for subcutaneous injection, with no visible particulate matter.

**DUPIXENT 200 mg pre-filled syringe with needle shield:** DUPIXENT 200 mg is provided as a single dose in a 1,14 mL siliconised clear Type I glass pre-filled syringe with a fixed 27-gauge 1,27 cm, thin wall stainless steel staked needle.

The pre-filled syringe is provided with a white polypropylene plunger rod, a white polycarbonate finger flange, and a safety system consisting of a polycarbonate needle guard with a stainless-steel spring. The needle cap is not made with natural rubber latex.

Each cardboard box contains 1 or 2 pre-filled syringe/s.

Not all pack sizes may be marketed.

**DUPIXENT 300 mg pre-filled syringe with needle shield:** DUPIXENT 300 mg is provided as a single dose in a 2,25 mL siliconised clear Type I glass pre-filled syringe with a fixed 27-gauge 1,27 cm, thin wall stainless steel staked needle.

The pre-filled syringe is provided with a white polycarbonate plunger rod, a white polycarbonate finger flange, and a safety system consisting of a polycarbonate needle guard with a galvanised steel spring. The needle cap is not made with natural rubber latex.

Each cardboard box contains 1 or 2 pre-filled syringe/s.

Not all pack sizes are marketed.

**Holder of the certificate of registration**

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**Registration numbers**

**DUPIXENT 200 mg:** 56/13.12/0056

**DUPIXENT 300 mg:** 51/13.12/0879

## INSTRUCTIONS FOR USE

### INSTRUCTIONS FOR USE

#### DUPIXENT 200 mg pre-filled syringe with needle shield

Read the INSTRUCTIONS FOR USE before using the DUPIXENT 200 mg pre-filled syringe.

This device is a single-dose pre-filled syringe (called “syringe” in these instructions). It contains 200 mg of DUPIXENT for injection under the skin (subcutaneous injection).

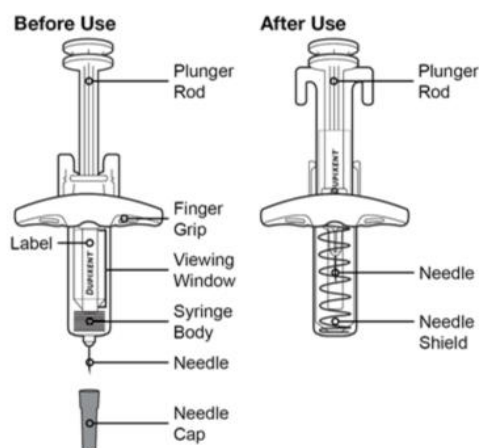
Do not inject yourself or someone else until you have been shown how to inject DUPIXENT 200 mg. Your health care provider can show you or your caregiver how to prepare and inject a dose of DUPIXENT 200 mg before you try to do it yourself for the first time.

In adolescents 12 years of age and older, it is recommended that DUPIXENT 200 mg be administered by or under supervision of an adult.

In children less than 12 years of age, DUPIXENT 200 mg should be given by a caregiver.

Keep these instructions for future use.

The parts of the DUPIXENT 200 mg syringe are shown in this picture.



### IMPORTANT INFORMATION

It is important that you do not try to give yourself or someone else the injection unless you have received training from your doctor or health care professional:

- Read all the instructions carefully before using the syringe.
- Ask your doctor or health care professional how often you will need to inject the medicine.
- Ask your doctor or health care professional to show you the right way to use the syringe

before you inject for the first time.

- Rotate the injection site each time you inject.
- **Do not** use the syringe if it has been dropped on a hard surface or been damaged.
- **Do not** use the syringe if the needle cap is missing or not securely attached.
- **Do not** touch the plunger rod until you are ready to inject.
- **Do not** inject through clothes.
- **Do not** get rid of any air bubbles in the syringe.
- To reduce the risk of accidental needle sticks, each pre-filled syringe has a needle shield that is automatically activated to cover the needle after you have given your injection.
- **Do not** pull back on the plunger rod at any time.
- **Do not** re-use the syringe.

## HOW TO STORE DUPIXENT

- Keep the syringe(s) out of the reach of children.
- Keep unused syringes in the original carton and store in the refrigerator between 2 °C and 8 °C.
- Remove the syringe from the refrigerator at least 30 minutes before your injection so that it reaches room temperature.
- **Do not** keep DUPIXENT at room temperature for more than 14 days.
- **Do not** shake the syringe at any time.
- **Do not** heat the syringe.
- **Do not** freeze the syringe.
- **Do not** put the syringe into direct sunlight.

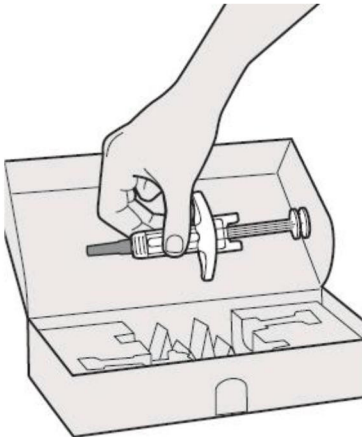
## STEP 1: REMOVE

Remove the syringe from the carton by holding the middle of the syringe body.

- **Do not** pull off the needle cap until you are ready to inject.



- **Do not** use the syringe if it has been dropped on a hard surface or damaged.



## STEP 2: PREPARE

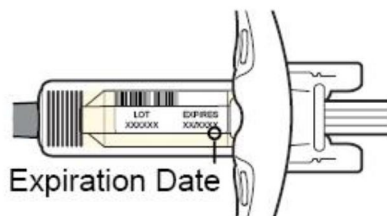
Ensure you have the following:

- The DUPIXENT 200 mg pre-filled syringe.
- 1 alcohol wipe\*.
- 1 cotton ball or gauze\*.
- A sharps disposal container\* (see STEP 12).

*\* Items not included in the carton.*

Look at the label:

- Check the expiration date. **Do not** use the syringe if the expiration date has passed.
- Check that you have the correct product and dose.



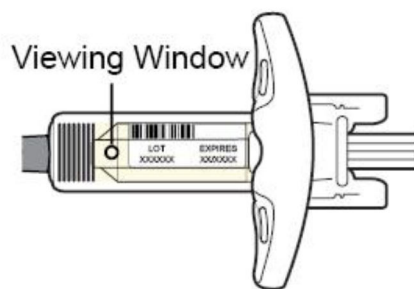
**STEP 3: INSPECT**

Look at the medicine through the viewing window on the syringe:

- Check if the liquid is clear and colourless to pale yellow.

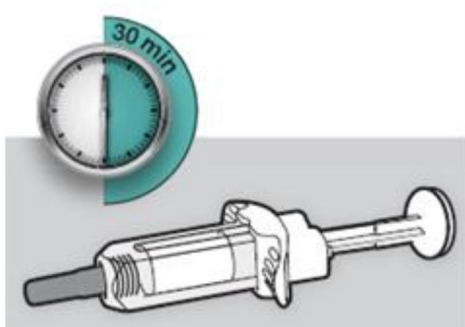
*Note: you may see an air bubble; this is normal.*

- **Do not** use the syringe if the liquid is discoloured or cloudy, or if it contains visible flakes or particles.

**STEP 4: WAIT 30 MINUTES**

Lay the syringe on a flat surface and let it naturally warm to room temperature for at least 30 minutes.

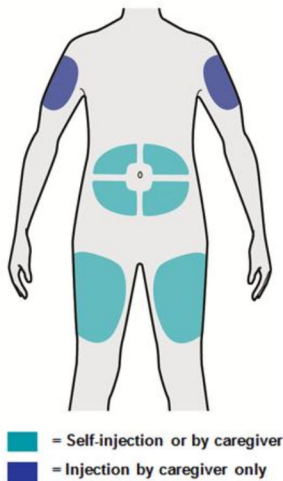
- **Do not** heat the syringe.
- **Do not** put the syringe in direct sunlight.
- **Do not** keep DUPIXENT at room temperature for more than 14 days.



**STEP 5: CHOOSE**

Select the injection site.

- You can inject into your thigh or stomach, except for the 5 cm around your navel.
- If somebody else gives you the injection, you can also use the upper arm.
- **Do not** inject into skin that is tender, damaged or has bruises or scars.

**STEP 6: CLEAN**

Wash your hands.

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.

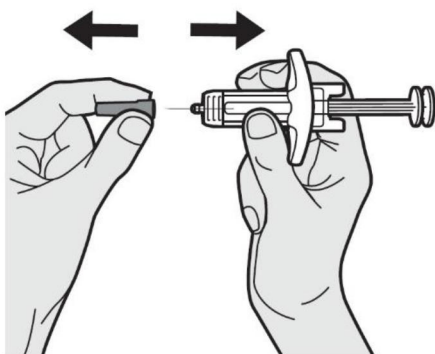


**STEP 7: PULL**

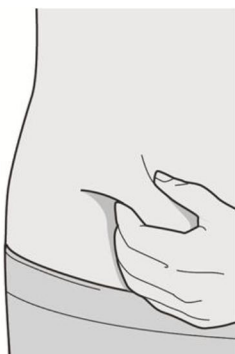
Hold the syringe in the middle of the syringe body with the needle pointing away from you and pull off the needle cap.

- **Do not** put the needle cap back on.
- **Do not** touch the needle.

Inject your medicine immediately after removing the needle cap.

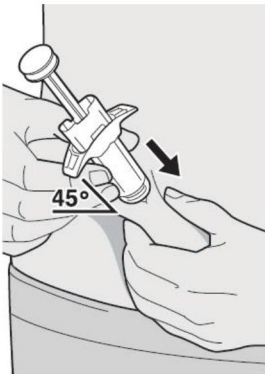
**STEP 8: PINCH**

Pinch a fold of skin at the injection site, as shown in the picture.



**STEP 9: INSERT**

Insert the needle completely into the fold of skin at roughly a 45-degree angle.

**STEP 10: PUSH**

Relax the pinch.

Push the plunger rod down slowly and steadily as far as it will go until the syringe is empty.

*Note: You will feel some resistance; this is normal.*

**STEP 11: RELEASE AND REMOVE**

Lift your thumb to release the plunger rod until the needle is covered by the needle shield and then remove the syringe from the injection site.

Lightly press a cotton ball or gauze on the injection site if you see any blood.

- **Do not** put the needle cap back on.
- **Do not** rub your skin after the injection.



## STEP 12: DISPOSE

Dispose of the syringe and the needle cap in a puncture-resistant container.

- **Do not** put the needle cap back on.
- Always keep the container out of the reach of children.



## INSTRUCTIONS FOR USE

### DUPIXENT 300 mg pre-filled syringe with needle shield

Read the INSTRUCTIONS FOR USE before using the DUPIXENT 300 mg pre-filled syringe.

This device is a single-dose pre-filled syringe (called “syringe” in these instructions). It contains 300 mg of DUPIXENT for injection under the skin (subcutaneous injection).

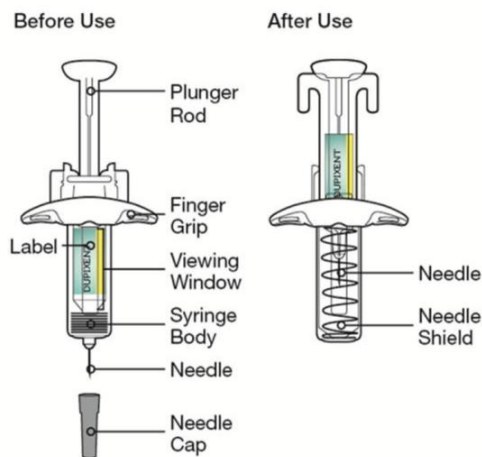
Do not inject yourself or someone else until you have been shown how to inject DUPIXENT 300 mg. Your health care provider can show you or your caregiver how to prepare and inject a dose of DUPIXENT 300 mg before you try to do it yourself for the first time.

In adolescents 12 years of age and older, it is recommended that DUPIXENT 300 mg be administered by or under supervision of an adult.

In children less than 12 years of age, DUPIXENT 300 mg should be given by a caregiver.

Keep these instructions for future use.

The parts of the DUPIXENT 300 mg syringe are shown in this picture.



## IMPORTANT INFORMATION

It is important that you do not try to give yourself or someone else the injection unless you have received training from your doctor or health care professional:

- Read all the instructions carefully before using the syringe.
- Ask your doctor or health care professional how often you will need to inject the medicine.
- Ask your doctor or health care professional to show you the right way to use the syringe

before you inject for the first time.

- Rotate the injection site each time you inject.
- **Do not** use the syringe if it has been dropped on a hard surface or damaged.
- **Do not** use the syringe if the needle cap is missing or not securely attached.
- **Do not** touch the plunger rod until you are ready to inject.
- **Do not** inject through clothes.
- **Do not** get rid of any air bubbles in the syringe.
- To reduce the risk of accidental needle sticks, each pre-filled syringe has a needle shield that is automatically activated to cover the needle after you have given your injection.
- **Do not** pull back on the plunger rod at any time.
- **Do not** re-use the syringe.

## HOW TO STORE DUPIXENT

- Keep the syringe(s) out of the reach of children.
- Keep unused syringes in the original carton and store in the refrigerator between 2 °C and 8 °C.
- Remove the syringe from the refrigerator at least 45 minutes before your injection so that it reaches room temperature.
- **Do not** keep DUPIXENT at room temperature for more than 14 days.
- **Do not** shake the syringe at any time.
- **Do not** heat the syringe.
- **Do not** freeze the syringe.
- **Do not** put the syringe in direct sunlight.



**STEP 1: REMOVE**

Remove the syringe from the carton by holding the middle of the syringe body.

- **Do not** pull off the needle cap until you are ready to inject.
- **Do not** use the syringe if it has been dropped on a hard surface or damaged.

**STEP 2: PREPARE**

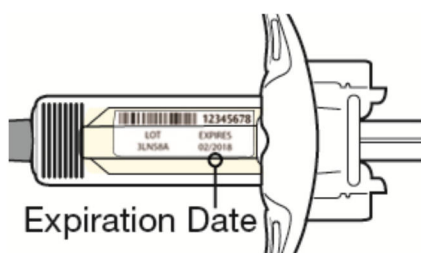
Ensure you have the following:

- The DUPIXENT 300 mg pre-filled syringe.
- 1 alcohol wipe\*.
- 1 cotton ball or gauze\*.
- A sharps disposal container\* (see STEP 12).

*\* Items not included in the carton.*

Look at the label:

- Check the expiration date. **Do not** use the syringe if the expiration date has passed.
- Check that you have the correct product and dose.



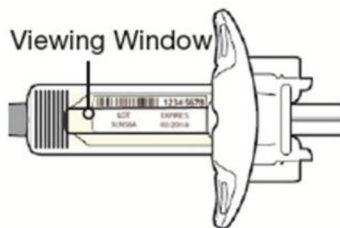
**STEP 3: INSPECT**

Look at the medicine through the viewing window on the syringe:

- Check if the liquid is clear and colourless to pale yellow.

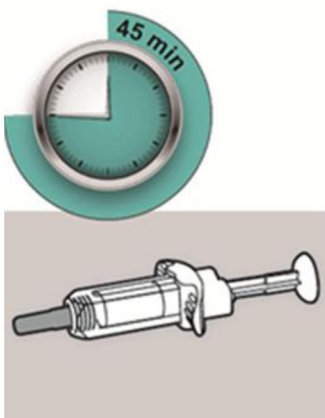
*Note: you may see an air bubble; this is normal.*

- **Do not** use the syringe if the liquid is discoloured or cloudy, or if it contains visible flakes or particles.

**STEP 4: WAIT 45 MINUTES**

Lay the syringe on a flat surface and let it naturally warm to room temperature for at least 45 minutes.

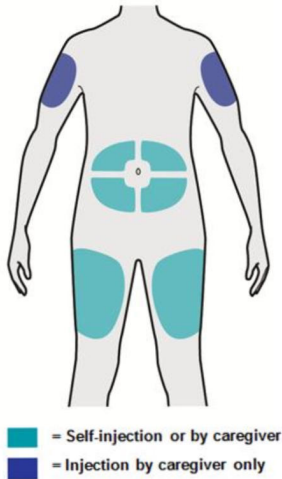
- **Do not** heat the syringe.
- **Do not** put the syringe in direct sunlight.
- **Do not** keep DUPIXENT at room temperature for more than 14 days.



**STEP 5: CHOOSE**

Select the injection site.

- You can inject into your thigh or stomach, except for the 5 cm around your navel.
- If somebody else gives you the injection, you can also use the upper arm.
- Do not inject into skin that is tender, damaged or has bruises or scars.

**STEP 6: CLEAN**

Wash your hands.

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.

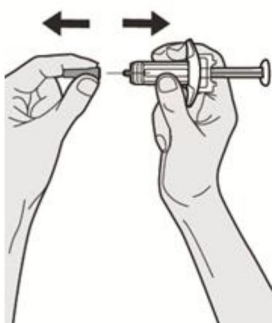


**STEP 7: PULL**

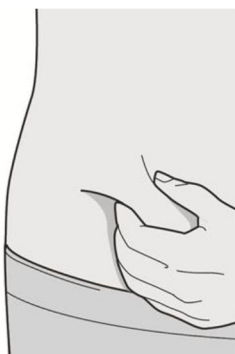
Hold the syringe in the middle of the syringe body with the needle pointing away from you and pull off the needle cap.

- **Do not** put the needle cap back on.
- **Do not** touch the needle.

Inject your medicine immediately after removing the needle cap.

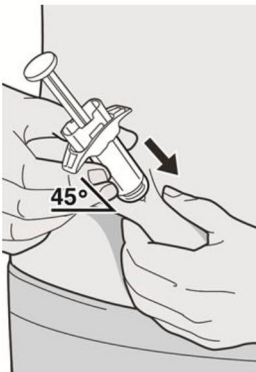
**STEP 8: PINCH**

Pinch a fold of skin at the injection site, as shown in the picture.



**STEP 9: INSERT**

Insert the needle completely into the fold of skin at roughly a 45-degree angle.

**STEP 10: PUSH**

Relax the pinch.

Push the plunger rod down slowly and steadily as far as it will go until the syringe is empty.

*Note: You will feel some resistance; this is normal.*

**STEP 11: RELEASE AND REMOVE**

Lift your thumb to release the plunger rod until the needle is covered by the needle shield and then remove the syringe from the injection site.

Lightly press a cotton ball or gauze on the injection site if you see any blood.

- **Do not** put the needle cap back on.
- **Do not** rub your skin after the injection.



## STEP 12: DISPOSE

Dispose of the syringe and the needle cap in a puncture-resistant container.

- **Do not** put the needle cap back on.
- Always keep the container out of the reach of children.

