

# Dupixent® (dupilumab injection) 300 mg Pre-filled Pen

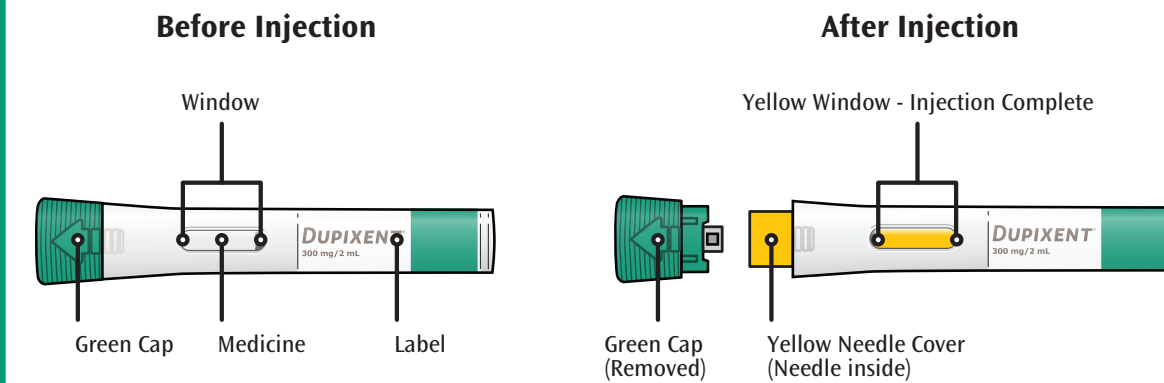
## Instructions for Use

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. The Dupixent Pre-filled Pen is only for use in adults, adolescents and pediatric patients aged 2 years and older. In children less than 12 years of age, Dupixent should be given by a caregiver. In adolescents 12 years of age and older, it is recommended that Dupixent be administered by or under supervision of an adult.

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

Keep these instructions for future use. If you have any further questions, you should ask your healthcare professional or call 1-800-265-7927.

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



### Important Information:

- 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 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** use the Pre-filled Pen if it has been damaged.
- **Do not** use the Pre-filled Pen if the Green Cap is missing or not securely attached.
- **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 Pre-filled Pen.
- Throw away (dispose of) the Pre-filled Pen right away after use. See "Step D: Dispose" below.
- **Do not** re-use a Pre-filled Pen.

### How should I store Dupixent?

- Keep the Pre-filled Pen(s) and all medicines out of the reach and sight of children.
- Store unused Pre-filled Pens in the refrigerator between 2°C and 8°C (36°F and 46°F).
- Store Pre-filled Pens in the original carton to protect it from light.
- **Do not** keep Pre-filled Pens at room temperature (less than 25°C (77°F)) for more than 14 days. Throw away (dispose) any Pre-filled Pens that have been left at room temperature for more than 14 days.
- **Do not** shake the Pre-filled Pen.
- **Do not** heat the Pre-filled Pen.
- **Do not** freeze the Pre-filled Pen.
- **Do not** put the Pre-filled Pen into direct sunlight.

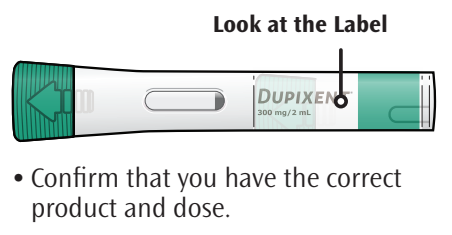
## A Prepare

### A1 Gather supplies

- 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 D)

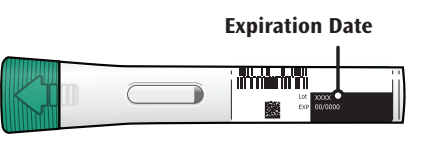
\* Items not included in the carton.

### A2 Look at the Label



- Confirm that you have the correct product and dose.

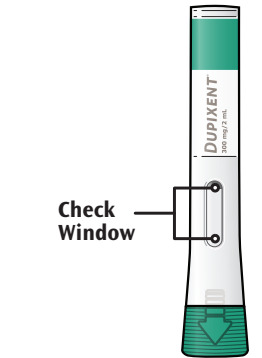
### A3 Check Expiration Date



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

### A4 Check the Medicine

Look at the medicine through the window on the Pre-filled Pen. Check to ensure 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.**

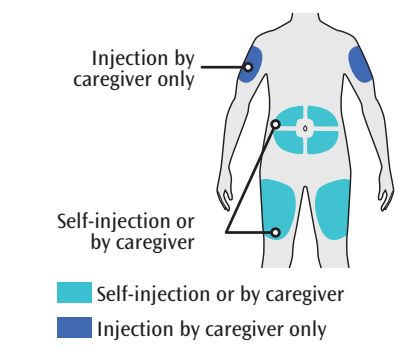
### A5 Wait 45 minutes

Place the Pre-filled Pen on a flat surface and allow it to warm to room temperature (less than 25°C (77°F)) for at least 45 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 (throw away) any Dupixent Pens that have been left at room temperature for longer than 14 days.**

## B Choose your injection site

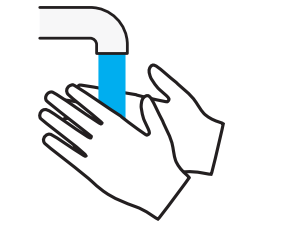
### B1 Recommended injection sites are:



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

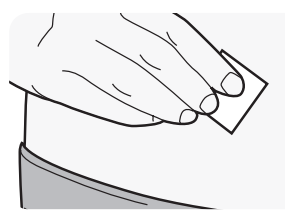
- Choose a different injection site for each Dupixent injection.
- **Do not inject through clothes.**
- **Do not inject into skin that is tender, damaged, bruised or scarred.**

### B2 Wash your hands



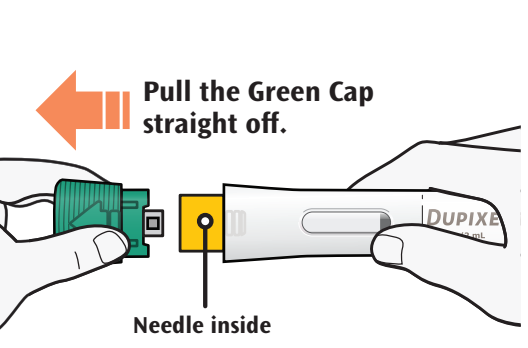
### B3 Prepare the injection site

- 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.**



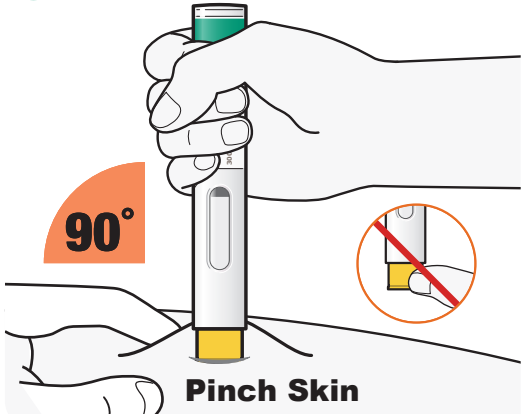
## C Give injection

### C1 Remove Green Cap



- Pull the Green Cap straight off.
- **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 Pre-filled Pen after you have removed it.**

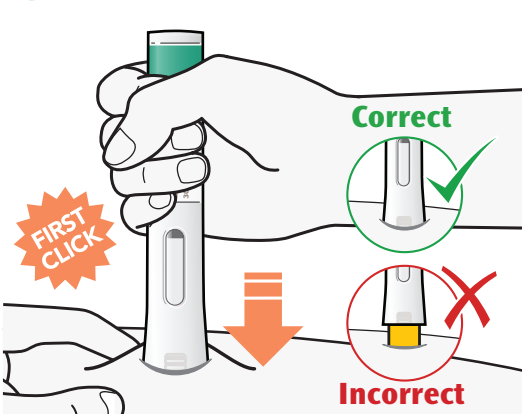
### C2 Pinch Skin and Place



- For pediatric patients 2 years of age to less than 12 years of age, pinch the skin before and during the injection.
- Pinching of the skin is not needed for adults and adolescent patients aged 12 years of age and older.
- When placing the Yellow Needle Cover on your skin, hold the Pre-filled Pen so that you can see the Window.

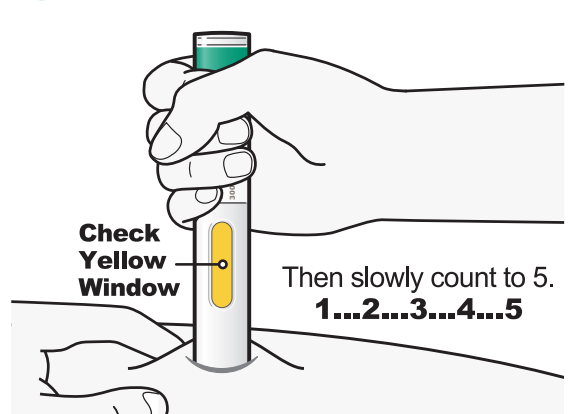
- Place the Yellow Needle Cover on your skin at approximately a 90-degree angle.
- **Do not press or touch the Yellow Needle Cover with your fingers; the Needle is inside.**

### C3 Press down



- Press the Pre-filled Pen firmly against your skin until you cannot see the Yellow 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 the skin is not needed for adults and children aged 12 years and older.

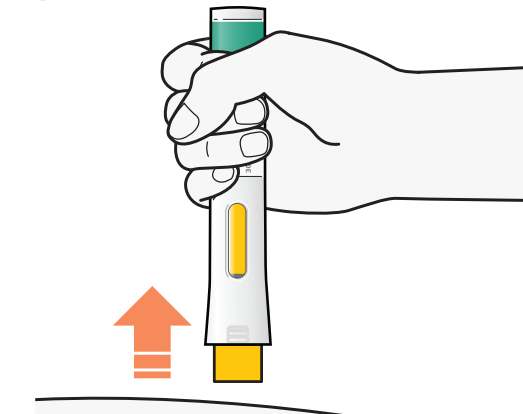
### C4 Hold firmly



- 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.

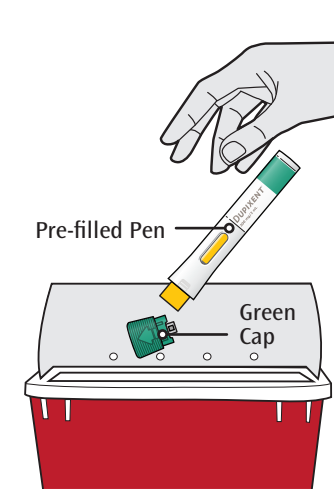
- If the window does not turn completely yellow, remove the pen and call your healthcare professional.
- **Do not give yourself a second dose unless instructed by your healthcare professional.**
- Pinching of the skin is not needed for adults and children aged 12 years and older.

### C5 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 the site with a clean cotton ball or gauze pad.
- **Do not rub your skin after the injection.**

## D Dispose



- Dispose of (throw away) your used Dupixent Pre-filled Pens, (Needle inside), and Green 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 Green Caps in your household trash.
- **Do not put the Green Cap back on.**

This leaflet was prepared by sanofi-aventis Canada Inc. Dupixent® is a registered trademark of Sanofi Biotechnology, SA. Last Revised: March 14, 2024. Manufactured by sanofi-aventis Canada Inc., Toronto, Ontario, Canada M2R 3T4. Questions: 1-800-265-7927



**PATIENT MEDICATION INFORMATION**  
**READ THIS FOR SAFE AND EFFECTIVE USE**  
**OF YOUR MEDICINE**

## PrDupixent®

Dupilumab injection

Solution for subcutaneous injection

**Dupixent 300 mg single-use syringe (300 mg / 2 mL) in pre-filled syringe with or without needle shield or pre-filled pen**

**Dupixent 200 mg single-use syringe (200 mg / 1.14 mL) in pre-filled syringe with needle shield or pre-filled pen**

## sanofi

Read this carefully before you start taking **Dupixent** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Dupixent**.

**What is Dupixent used for?**

Dupixent is an injectable prescription medicine used to:

**Atopic Dermatitis**

- To treat patients aged 6 months and older with moderate-to-severe atopic dermatitis, also known as atopic eczema. Dupixent can be used with or without topical corticosteroids.
- It is not known if Dupixent is safe and effective in children with atopic dermatitis below age of 6 months.

**Asthma**

- In addition to other asthma medicines for maintenance treatment of adults, adolescents and children (6 years and older) with severe asthma with a type 2/eosinophilic phenotype or oral corticosteroid-dependent asthma, whose asthma is not controlled with their current asthma medicines. Severe eosinophilic asthma is a type of asthma where patients have increased eosinophils in the blood or lungs. Eosinophils are a type of white blood cell that are associated with inflammation of the airways that can cause your asthma to get worse or can increase the number of asthma attacks.
- It is not known if Dupixent is safe and effective in children with asthma below age of 6 years.
- Dupixent is not used to treat sudden breathing problems.

**Chronic Rhinosinusitis with Nasal Polyposis**

- To treat adult patients with severe chronic rhinosinusitis with nasal polyposis (CRSwNP) in combination with intranasal corticosteroids, whose disease is not controlled with systemic corticosteroids or surgery.
- It is not known if Dupixent is safe and effective in children below age of 18 years.

**Eosinophilic Esophagitis**

- To treat adults and adolescent patients aged 12 years and older, who weigh at least 40 kg, with eosinophilic esophagitis (EoE).

**Prurigo Nodularis**

- Treat adult patients with moderate-to-severe prurigo nodularis (PN) whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids.
- It is not known if Dupixent is safe and effective in children below age of 18 years.

**How does Dupixent work?**

Dupixent contains the active substance dupilumab.

Dupilumab is a monoclonal antibody (a type of specialized protein) that blocks the action of inflammatory proteins called IL-4 and IL-13. IL-4 and IL-13 contribute to signs and symptoms of atopic dermatitis, asthma, CRSwNP, EoE and prurigo nodularis.

Using Dupixent for atopic dermatitis can improve the condition of your skin and reduce itch.

Using Dupixent for severe eosinophilic asthma can reduce severe asthma attacks and improve your breathing. Dupixent may also help reduce the amount of another group of medicines you need to control your severe asthma, called oral corticosteroids, while reducing severe asthma attacks and improving your breathing.

Using Dupixent for CRSwNP can decrease the size of your nasal polyps, decrease your nasal congestion, and improve your sense of smell.

Using Dupixent for EoE can improve the swallowing difficulties associated with eating food and may reduce your need to clear food (e.g., drink liquid, cough, vomit, or seek medical intervention).

Using Dupixent for prurigo nodularis can improve the condition of your skin with reduction of itch and improvement of lesions.

**What are the ingredients in Dupixent?**

Medicinal ingredients: dupilumab

Non-medicinal ingredients: acetic acid, L-arginine hydrochloride, L-histidine, polysorbate 80, sodium acetate, sucrose, water for injection.

**Dupixent comes in the following dosage forms:**

Dupixent comes as a single-use (1 time use) pre-filled syringe with or without needle shield or pre-filled pen. Your healthcare provider will prescribe the type that is best for you.

**Do not use Dupixent if:**

Do not use Dupixent if you are allergic to dupilumab or to any of the ingredients in Dupixent.

Dupixent can potentially cause serious side effects, including generalized allergic (hypersensitivity) reactions and anaphylactic reaction. Check for signs or symptoms 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 taking Dupixent. Stop taking Dupixent and tell your healthcare professional or seek medical help immediately if you experience any signs or symptoms of an allergic reaction (see also the table “Serious side effects and what to do about them” below).

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Dupixent. Talk about any health conditions or problems you may have, including if you:**

- have a parasitic (intestinal parasites) infection. Dupixent 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 Dupixent. If you live in a region where these infections are common or if you are travelling to such a region, check with your doctor.
- are pregnant or plan to become pregnant. It is not known if Dupixent will harm your unborn baby. Tell your healthcare provider if you become pregnant while taking Dupixent.
- are breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you will take Dupixent or breastfeed. You should not do both without talking to your healthcare provider first.
- have other allergic conditions such as asthma and are taking asthma medicines.
- are scheduled to receive a vaccination.
- have eye problems (e.g., itching, redness)

**Other warnings you should know about:**

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

Do not stop or reduce your asthma medicines, unless instructed by your healthcare professional. These medicines (especially ones called *corticosteroids*) must be stopped gradually, under the direct supervision of your healthcare professional. Rarely patients taking Dupixent may develop inflammation of blood vessels or lungs due to an increase of certain white blood cells (eosinophilia).

This usually, but not always, happens in people who also take corticosteroids, which are being stopped or for which the dose is being lowered. Tell your healthcare professional immediately if you develop a combination of symptoms such as a persistent fever, shortness of breath, chest pain, rash, and/or pins and needles or numbness of arms or legs.

There is no experience with Dupixent in children with atopic dermatitis less than 6 months of age. Therefore, the use of Dupixent is not recommended in this age group.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with Dupixent:**

Inform your healthcare professional that you are taking Dupixent if you recently received a vaccine or if you are about to receive a vaccine. Dupixent should not be used at the same time with certain types of vaccines.

**How to take Dupixent:**

Always check the label of your pre-filled syringe or pen before each injection to make sure you have the correct product.

Dupixent should be allowed to reach room temperature by waiting for 45 minutes (for 300 mg pre-filled syringe or pen) and 30 minutes (for 200 mg pre-filled syringe or pen) after removing from the refrigerator before injecting.

The Dupixent pre-filled pen is not intended for use in pediatrics below 2 years of age. For children aged 6 months to 2 years of age, contact your doctor who will prescribe the appropriate Dupixent pre-filled syringe.

In children 6 months to less than 12 years of age, Dupixent should be given by a caregiver. In children 12 years of age and older, it is recommended that Dupixent be administered by or under supervision of an adult.

Dupixent is injected under the skin (subcutaneous use) of your upper leg (thigh), or stomach area (abdomen, except 5 cm around your belly button); if somebody else gives you the injection, you can also use the upper arm. Choose a different spot each time you inject (e.g. right thigh then left thigh, or right abdomen then left abdomen). Do not inject into skin that is tender, damaged or has bruises or scars.

Do not inject Dupixent together with other injectable medicines at the same injection site.

It is important that you do not stop using Dupixent without talking with your healthcare provider. Prior to discontinuing Dupixent check with your healthcare professional if you need to adjust your treatment or need to manage other allergic and or atopic conditions.

Do not use Dupixent for a condition for which it was not prescribed. Do not give Dupixent to other people, even if they have the same signs or symptoms that you have; it may harm them.

***Learning how to use the pre-filled syringe (with or without needle shield) or pre-filled pen***

- Before you use the pre-filled syringe or pen for the first time, your healthcare professional will show you or your caregiver how to inject Dupixent. Do not try to inject Dupixent until you or your caregiver have been shown the correct way by your healthcare provider.

- Always read and use the pre-filled syringe or pen as described by the “Instructions for Use” provided in the box.

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**Usual dose:**

Use Dupixent exactly as prescribed by your healthcare professional.

**Atopic Dermatitis**

**Recommended dose in adults**

In atopic dermatitis, the first time you use Dupixent you will receive 600 mg (two (2) subcutaneous injections of 300 mg each given in 2 different injection sites). Thereafter, Dupixent is given as a 300 mg subcutaneous injection once every other week.

**Recommended dose for pediatrics (6 to 17 years of age)**

The recommended dose of Dupixent for pediatrics (6 to 17 years of age) with atopic dermatitis is based on body weight:

| <b>Body Weight</b>    | <b>Initial Dose</b>            | <b>Subsequent Doses</b>              |
|-----------------------|--------------------------------|--------------------------------------|
| 15 to less than 30 kg | 600 mg (two 300 mg injections) | 300 mg every 4 weeks <b>(Q4W)</b>    |
| 30 to less than 60 kg | 400 mg (two 200 mg injections) | 200 mg every other week <b>(Q2W)</b> |
| 60 kg or more         | 600 mg (two 300 mg injections) | 300 mg every other week <b>(Q2W)</b> |

**Pediatrics (6 months to 5 years of age)**

The recommended dose of Dupixent for pediatrics 6 months to 5 years of age is specified in the below Table.

**Table: Dose of Dupixent for Subcutaneous Administration in Pediatric Patients 6 months to 5 Years of Age with Atopic Dermatitis**

| <b>Body Weight</b>    | <b>Initial Dose</b>           | <b>Subsequent Doses</b>           |
|-----------------------|-------------------------------|-----------------------------------|
| 5 to less than 15 kg  | 200 mg (one 200 mg injection) | 200 mg every 4 weeks <b>(Q4W)</b> |
| 15 to less than 30 kg | 300 mg (one 300 mg injection) | 300 mg every 4 weeks <b>(Q4W)</b> |

**Asthma**

In severe eosinophilic asthma, the recommended dose of Dupixent for adult and adolescents (12 years of age and older) is:

- A first dose of 400 mg (two (2) injections under the skin of 200 mg) followed by 200 mg every two weeks by injection. The dose may be increased to 300 mg every two weeks based on your healthcare professional’s assessment.

In severe asthma needing oral corticosteroids, the recommended dose of Dupixent for adults and adolescents (12 years of age and older) is:

- A first dose of 600 mg (two (2) injections under the skin of 300 mg) followed by 300 mg every two weeks by injection.

The recommended dose of Dupixent for children 6 to 11 years is is based on body weight:

| <b>Body Weight</b>    | <b>Initial and Subsequent Doses</b>  |
|-----------------------|--|
| 15 to less than 30 kg | 300 mg every four weeks <b>(Q4W)</b>   |
| 30 to less than 60 kg | 200 mg every other week <b>(Q2W)</b> or 300 mg every four weeks <b>(Q4W)</b> |
| 60 kg or more         | 200 mg every other week <b>(Q2W)</b>   |

**CRSwNP**

In CRSwNP, Dupixent is given as a 300 mg subcutaneous injection once-every-other week.

**Eosinophilic Esophagitis**

The recommended dose of Dupixent for patients 12 years of age and older, weighing at least 40 kg, is 300 mg given every week (QW).

**Prurigo Nodularis**

The recommended dose of Dupixent for adult patients is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week.

**Overdose:**

|   |
|---|
| If you think you, or a person you are caring for, have taken too much Dupixent, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms. |
|---|

**Missed Dose:**

- If your dose schedule is every week and you miss a dose of Dupixent:** Give the dose as soon as possible, starting a new weekly schedule based on this date.

- 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.

**What are possible side effects from using Dupixent?**

Dupixent may cause **allergic reactions (hypersensitivity)**, including a severe reaction known as anaphylaxis. Stop using Dupixent and tell your healthcare professional or seek medical help immediately if you notice any signs or symptoms of an allergic reaction, such as:

- breathing problems
- swelling of the face, lips, mouth, throat or tongue (angioedema)
- fever
- feeling ill
- swollen lymph nodes
- hives
- itching
- skin rash
- skin or eyelid itching
- joint pain
- fainting, dizziness, feeling lightheaded (low blood pressure)

Dupixent may cause **eye problems**, including eye pain or change in vision. Tell your healthcare professional if you have any new or worsening eye problems.

These are not all the possible side effects you may experience when taking Dupixent. If you experience any side effects not listed here, contact your healthcare professional. Please also see “Do not use Dupixent if” section above.

The most common side effects of Dupixent include:

- injection site reactions
- eye and eyelid inflammation, including redness, swelling, itching, and/or dryness, sometimes with blurred vision
- eye infections
- cold sores in your mouth or on your lips (oral herpes)
- extra high amount of a certain white blood cell (eosinophilia)
- trouble sleeping (insomnia)
- gastritis
- joint pain (arthralgia)

- headache
- facial rash or redness
- parasitic helminth infections

| <b>Serious side effects and what to do about them</b> |   |                     |  |
|---|---|---------------------|--|
| <b>Symptom / effect</b>                               | <b>Talk to your healthcare professional</b> |                     | <b>Stop taking drug and get immediate medical help</b> |
|   | <b>Only if severe</b>                       | <b>In all cases</b> |  |
| <b>UNCOMMON</b>                                       |   |                     |  |
| Allergic reactions (hypersensitivity)                 |   |                     | ✓  |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

|  |
|--|
| <b>Reporting Side Effects</b>  |
| You can report any suspected side effects associated with the use of health products to Health Canada by: <ul style="list-style-type: none"><li>Visiting the Web page on Adverse Reaction Reporting (<a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html</a>) for information on how to report online, by mail or by fax; or</li> <li>Calling toll-free at 1-866-234-2345.</li></ul> <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p> |

**Storage:**

Keep out of reach and sight of children.

Do not use this medicine after the expiry date which is stated on the label and carton.

Store in a refrigerator (2°C - 8°C). Do not freeze.

Keep the syringe or pen in the outer carton in order to protect from light.

Do not expose to extreme heat.

Dupixent should be allowed to reach room temperature by waiting for 45 minutes (for 300 mg pre-filled syringe or pen) or 30 minutes (for 200 mg pre-filled syringe or pen) after removing from the refrigerator before injecting.

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

Do not use this medicine if the solution is discolored or cloudy, or if it contains visible flakes or particles.

The pre-filled pen may either have a round cap and oval viewing window encircled with an arrow or may have a square cap with ridges and an oval viewing window without an arrow. Although there are minor differences in the appearance of the two pre-filled pens, they both function the same.

After use, put the syringe or pen into a puncture-resistant container. Always keep the container out of the reach of children. Ask your health care provider or pharmacist how to throw away the container. Do not recycle the container.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**If you want more information about Dupixent:**

- Talk to your healthcare professional.
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer’s website [www.sanofi.ca](http://www.sanofi.ca), or by calling **1-800-265-7927**.

This leaflet was prepared by sanofi-aventis Canada Inc.

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Manufactured by sanofi-aventis Canada Inc., Toronto, Ontario, Canada M2R 3T4

Questions: **1-800-265-7927**

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