

DUPIXENT® 300 mg SINGLE-USE PRE-FILLED SYRINGE WITH NEEDLE SHIELD

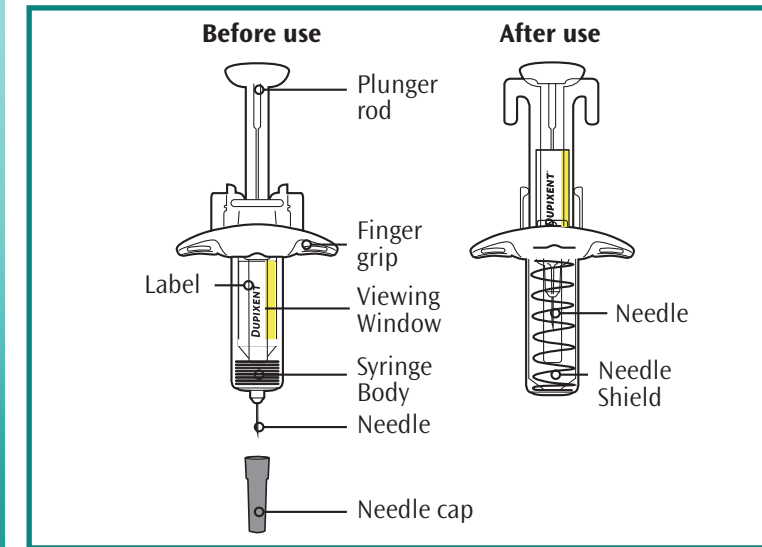
INSTRUCTIONS FOR USE

Read the 'Instructions for Use' before using the DUPIXENT Pre-filled Syringe with needle shield. Do not inject yourself or someone else until you have been trained by a healthcare professional on how to prepare a dose and inject DUPIXENT. In adolescent 12 years of age and older, it is recommended that DUPIXENT be administered by or under the supervision of an adult. In children less than 12 years of age, DUPIXENT should be given by a caregiver.

This device is a **Single-use** Pre-filled Syringe (called "Syringe" in these instructions) with a needle shield. 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 provider or call 1-800-265-7927.

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



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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 healthcare provider.
- Read all of the instructions carefully before using the Syringe.
- Ask your healthcare provider how often you will need to inject the medicine.
- Ask your healthcare provider 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.
- 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** 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.
- ✗ 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 into direct sunlight

How to Dispose of (Throw Away) Used Syringes

Put your used Needles and Syringes in a puncture-resistant container right away after use.

⚠ Do not dispose of (throw away) the Syringes in your household trash.

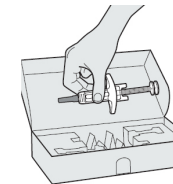
If you do not have a puncture-resistant container, you may use a household container that is:

- made of a heavy-duty plastic;
- can be closed with a tightfitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

When your puncture-resistant container is almost full, you will need to follow your provincial or local regulations for the correct way to dispose of it.

STEP 1: Remove

Remove the Syringe from the carton by holding the middle of the Syringe Body:



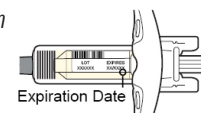
- ⚠ Do not pull off the Needle Cap until you are ready to inject.**
- ⚠ Do not use the Syringe if it has been dropped on a hard surface or damaged.**
- ⚠ Do not keep DUPIXENT at room temperature for more than 14 days.**

STEP 2: Prepare

Ensure you have the following: • the DUPIXENT Pre-filled Syringe with needle shield. • 1 alcohol wipe* • 1 cotton ball or gauze* • a puncture-resistant container* (See Step 12) *Items not included in the carton

Look at the label:

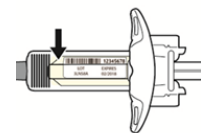
- Check the expiration date
- Check that you have the correct product and dose



⚠ Do not use the Syringe if the expiration date has passed.

STEP 3: Inspect

Look at the medicine through the viewing window on the Syringe: Check if the liquid is clear and colorless to pale yellow.



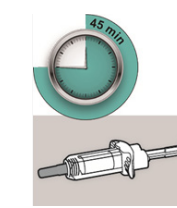
Note: You may see an air bubble; this is normal.

⚠ Do not use the Syringe if the liquid is discolored 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.

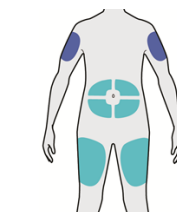
- ⚠ Do not heat the Syringe.**
- ⚠ Do not put the Syringe into direct sunlight.**
- ⚠ Do not keep DUPIXENT at room temperature for more than 14 days.**



STEP 5: Select

Select the injection site.

- You can inject into your thigh or abdomen, except for the 5 cm (2 inches) around your navel (belly-button)
- If somebody else gives you the injection, you can also use the upper arm.
- Change the injection site for each injection.



- Self-injection or by caregiver
- Injection by caregiver only

- ⚠ 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.

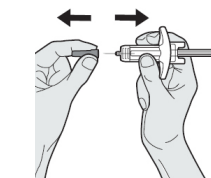


⚠ Do not touch the injection site again or blow on it before the injection.

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.**
- ⚠ Do not inject if the Needle is damaged**



Inject your medicine immediately after removing the Needle Cap.

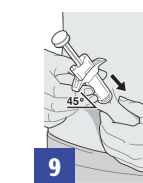
STEP 8: Pinch

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 the skin at roughly a 45° angle.

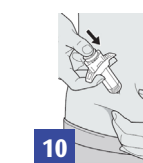


STEP 10: Push

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.**

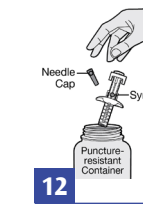
STEP 12: Dispose

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.

See "How to Dispose of (Throw Away) Used Syringes".



PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr Dupixent®

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

Dupixent 100 mg single-use syringe (100 mg / 0.67 mL) in pre-filled syringe with needle shield

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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 and 100 mg pre-filled syringe) after removing from the refrigerator before injecting.

The Dupixent pre-filled pen is not intended for use in children below 12 years of age. For children aged 6 months to 11 years of age with atopic dermatitis, contact your doctor who will prescribe the appropriate Dupixent pre-filled syringe.

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.

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:

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

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

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

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 based on body weight:

Body Weight	Initial and Subsequent Doses
15 to less than 30 kg	100 mg every other week (Q2W) or 300 mg every four weeks (Q4W)
30 to less than 60 kg	200 mg every other week (Q2W) or 300 mg every four weeks (Q4W)
60 kg or more	200 mg every other week (Q2W)

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

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
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.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

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 and 100 mg pre-filled syringe) 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**, 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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