

**PACKAGE
LEAFLET: INFORMATION
FOR THE USER**

Dupilixent[®] 300 mg

**solution for injection
in pre-filled syringe**

dupilumab



▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4..

What is in this leaflet

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

1. WHAT DUPIXENT IS AND WHAT IT IS USED FOR

What Dupixent is
Dupixent 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, and chronic rhinosinusitis with nasal polyposis (CRSwNP).

What Dupixent is used for
Dupixent is used to treat adults and adolescents 12 years and older with moderate-to-severe atopic dermatitis, also known as atopic eczema. Dupixent is also used to treat children 6 to 11 years old with severe atopic dermatitis. Dupixent may be used with eczema medicines that you apply to the skin or it may be used on its own. Dupixent is also used with other asthma medicines for the maintenance treatment of severe asthma in adults and adolescents (12 years of age and older) whose asthma is not controlled with their current asthma medicines.

Dupilixent is also used with other medicines for the maintenance treatment of 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.

How Dupixent works
Using Dupixent for atopic dermatitis (atopic eczema) can improve the condition of your skin and reduce itching. Dupixent has also been shown to improve symptoms of pain, anxiety, and depression associated with atopic dermatitis. In addition, Dupixent helps improve your sleep disturbance and overall quality of life.

Dupilixent helps prevent severe asthma attacks (exacerbations) and can improve your breathing. Dupixent may also help reduce the amount of another group of medicines you need to control your asthma, called oral corticosteroids, while preventing severe asthma attacks and improving your breathing.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DUPIXENT

Do not use Dupixent

- if you are allergic to dupilumab or any of the other ingredients of this medicine (listed in section 6).
- if you think you may be allergic, or you are not sure, ask your doctor, pharmacist or nurse for advice before using Dupixent.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Dupixent:

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

Allergic reactions

- Very rarely, Dupixent can cause serious side effects, including allergic (hypersensitivity) reactions and anaphylactic reaction and angioedema. These reactions can occur from minutes until seven days after Dupixent administration. 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 taking 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

- Rarely 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

- 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.
- Check with your doctor if you have diarrhoea, gas, 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 Dupixent or if your asthma remains uncontrolled or worsens during treatment with this medicine.

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

- The safety and benefits of Dupixent are not yet known in children with atopic dermatitis below the age of 6.
- The safety and benefits of Dupixent are not yet known in children with asthma below the age of 12.
- CRSwNP does not normally occur in children. The safety and benefits of Dupixent are not yet known in children with CRSwNP below the age of 18 years.

Other medicines and Dupixent

- Tell your doctor or pharmacist
- if you are using, have recently used or might use any other medicines.
 - 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 breast-feeding

- If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before using this medicine. The effects of this medicine in pregnant women are not known; therefore it is preferable to avoid the use of Dupixent in pregnancy unless your doctor advises to use it.
- If you are breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine. You and your doctor should decide if you will breast-feed or use Dupixent. You should not do both.

Driving and using machines

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

Dupilixent contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 300 mg dose, i.e., it is essentially "sodium-free".

3. HOW TO USE DUPIXENT

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How Dupixent is given

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

How much Dupixent you will receive

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

Recommended dose in adults with atopic dermatitis

For patients with atopic dermatitis, 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 subcutaneous injection.

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

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

Recommended dose in adolescents with atopic dermatitis

The recommended dose of Dupixent for adolescents (12 to 17 years of age) with atopic dermatitis is based on body weight:

Body Weight of Patient	Initial Dose	Subsequent Doses (every other week)
less than 60 kg	400 mg (two 200 mg injections)	200 mg
60 kg or more	600 mg (two 300 mg injections)	300 mg

Recommended dose in children with atopic dermatitis

The recommended dose of Dupixent for children (6 to 11 years of age) with atopic dermatitis is based on body weight:

Body Weight of Patient	Initial Dose	Subsequent Doses
15 kg to less than 60 kg	300 mg (one 300 mg injection) on Day 1, followed by 300 mg on Day 15	300 mg every 4 weeks*, starting 4 weeks after Day 15 dose
60 kg or more	600 mg (two 300 mg injections)	300 mg every other week

* The dose may be increased to 200 mg every other week based on the doctor's opinion.

Recommended dose in adult and adolescent patients with asthma (12 years of age and older)

For patients with severe asthma and who are on oral corticosteroids or for patients with severe asthma and comorbid moderate-to-severe atopic dermatitis or adults with co-morbid severe chronic rhinosinusitis with nasal polyposis, the recommended dose of Dupixent is:

- An initial dose of 600 mg (two 300 mg injections)
- Followed by 300 mg given every other week administered as subcutaneous injection.

For all other patients with 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 subcutaneous injection.

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

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

Injecting Dupixent

Dupilixent is given by 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 (300 mg). Do not shake the pre-filled syringe.

Read the "Instructions for Use" for the pre-filled syringe carefully before using Dupixent.

If you use more Dupixent than you should

If you use more Dupixent than you should or the dose has been given too early, talk to your doctor, pharmacist or nurse.

If you forget to use Dupixent

If you have forgotten to inject a dose of Dupixent, talk to your doctor, pharmacist or nurse.

If you stop using Dupixent

Do not stop using Dupixent without speaking to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Dupilixent can cause serious side effects, including very rare allergic (hypersensitivity) reactions, including anaphylactic reaction; the signs of allergic reaction or anaphylactic reaction may include:

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

If you develop an allergic reaction, stop using Dupixent and talk to your doctor right away.

Other side effects

Very Common (may affect more than 1 in 10 people) atopic dermatitis and asthma:

- injection site reactions (i.e. redness, swelling, and itching)

Common (may affect up to 1 in 10 people) atopic dermatitis only:

- headache
- eye dryness, redness and itching
- eyelid itching, redness and swelling
- eye infection
- cold sores (on lips and skin)

Uncommon (may affect up to 1 in 100 people):

- inflammation of the eye surface, sometimes with blurred vision (keratitis, ulcerative keratitis)

Not known

The following side effects have been reported since the marketing of Dupixent, but how often they occur is not known:

- joint pain (arthralgia)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DUPIXENT

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C). 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. 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.

Store in the original carton to protect from light.

Do not use this medicine if you notice that the medicine is cloudy, discoloured, or has particles in it. Do not throw away any medicines via wastewater or household waste. Ask your doctor, pharmacist or nurse how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Dupixent contains

- The active substance is dupilumab.
- Each pre-filled syringe contains 300 mg of dupilumab in 2 ml solution for injection (injection).
- The other ingredients are arginine hydrochloride, histidine, polysorbate 80 (E433), sodium acetate, glacial acetic acid (E260), sucrose, water for injections.

What Dupixent looks like and contents of the pack

Dupilixent is a clear to slightly opalescent, colourless to pale yellow solution supplied in a glass pre-filled syringe with or without needle shield.

Dupilixent is available as 300 mg pre-filled syringes in a pack containing 1 or 2 pre-filled syringes or in a pack containing 3 (3 packs of 1) or 6 (3 packs of 2) pre-filled syringes.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

sanofi-aventis groupe
54, rue La Boétie
75008 Paris
France

Manufacturer
SANOFI WINTHROP INDUSTRIE
1051 Boulevard Industriel
76580 LE TRAIT
FRANCE

**This leaflet was last revised in
January 2021**

Instructions for use

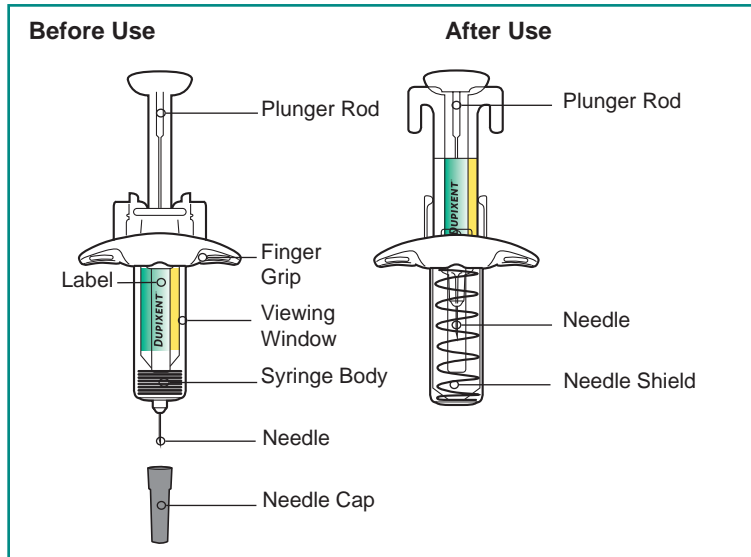
Dupixent®
300 mg

solution for injection in
a pre-filled syringe with
needle shield

dupilumab



The parts of the Dupixent pre-filled syringe with needle shield are shown in this picture.



Important information

This device is a singleuse prefilled syringe. It contains 300 mg of Dupixent for injection under the skin (subcutaneous injection).

You must not try to give yourself or someone else the injection unless you have received training from your healthcare professional. In adolescents 12 years and older, it is recommended that Dupixent be administered by or under supervision of an adult. In children less than 12 years of age, Dupixent should be given by a caregiver.

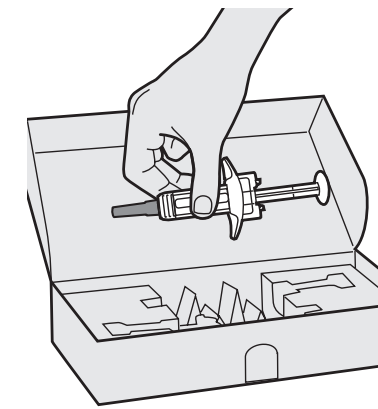
- Read all of the instructions carefully before using the syringe.
- Check with your healthcare professional how often you will need to inject the medicine.

- Ask your healthcare professional to show you the right way to use the syringe before you inject for the first time.
- Change the injection site for each 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.
- To help prevent accidental needle injury, each pre-filled syringe has a needle shield that is automatically activated to cover the needle after you have given your injection.
- **Never** pull back on the plunger rod.
- **Do not** reuse 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.
- **Do not** keep Dupixent at room temperature (< 25°C) for more than 14 days. 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** shake the syringe at any time.
- **Do not** heat the syringe.
- **Do not** freeze the syringe.
- **Do not** place the syringe into direct sunlight.

Step 1: Remove



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

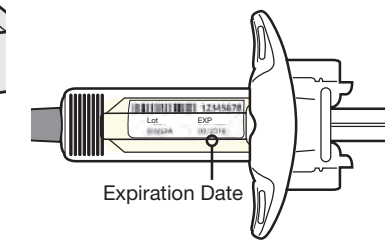
- ⚠ **Do not pull off the needle cap until you are ready to inject.**
- ⚠ **Do not use the syringe if it has been dropped on a hard surface or damaged.**

Step 2: Prepare

Ensure you have the following:

- the Dupixent pre-filled syringe
- 1 alcohol wipe*
- 1 cotton ball or gauze*
- a puncture-resistant container* (See Step 12)

*Items not included in the carton

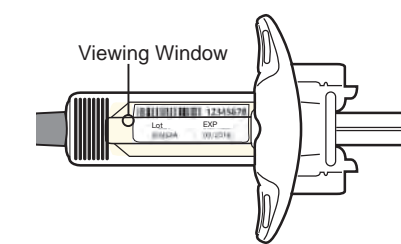


Look at the label:

- Check the expiry date.
- Check that you have the correct product and dose.

- ⚠ **Do not use the syringe if the expiry date has passed.**
- ⚠ **Do not keep Dupixent at room temperature for more than 14 days.**

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 flakes or particles.**

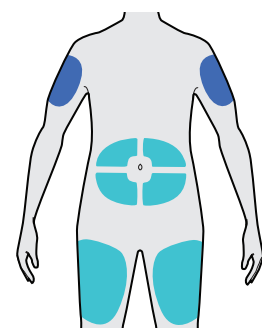
Step 4: Wait 45 minutes



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

- ⚠ **Do not warm the syringe in a microwave, hot water, or direct sunlight..**
- ⚠ **Do not place the syringe in direct sunlight.**
- ⚠ **Do not keep Dupixent at room temperature for more than 14 days.**

Step 5: Choose



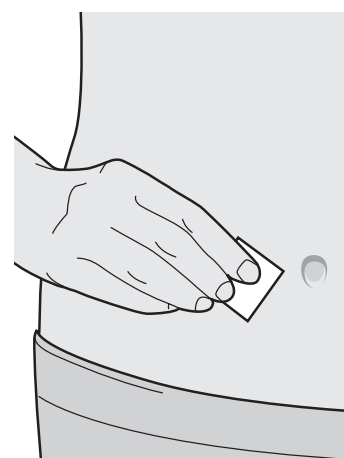
- = Self-injection or by caregiver
- = Injection by caregiver only

Select the injection site.

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

- ⚠ **Do not inject into skin that is tender, damaged or has bruises or scars.**

Step 6: Clean

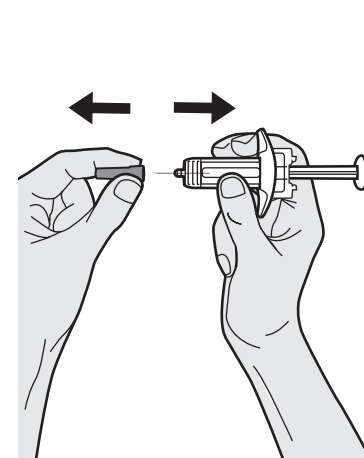


Wash your hands.

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

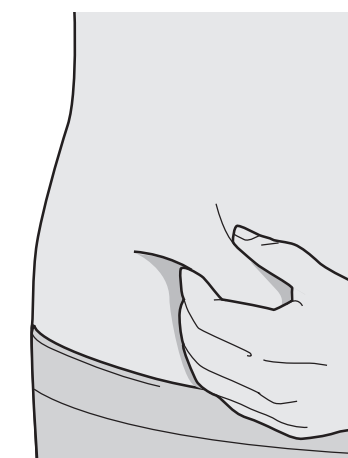


Hold the syringe in the middle of the syringe body with the needle pointing away from you and pull off the needle cap.

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

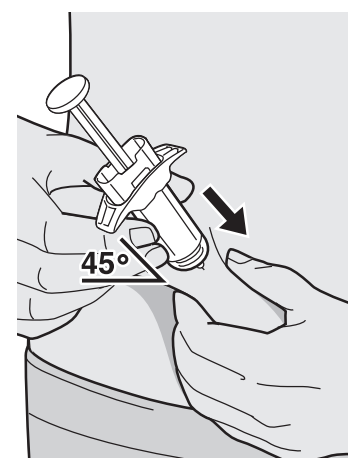
Inject your medicine immediately after removing the needle cap.

Step 8: Pinch



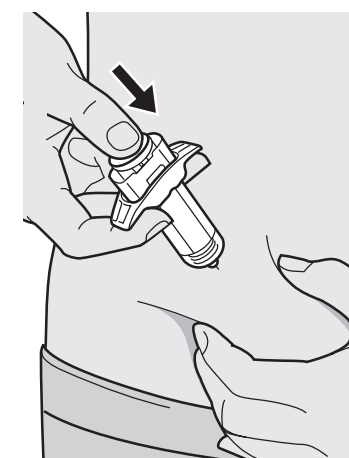
Pinch a fold of skin at the injection site, as shown in the picture.

Step 9: Insert



Insert the Needle completely into the fold of skin at roughly a 45° 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

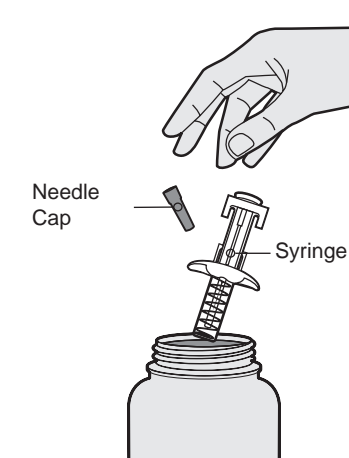


Lift your thumb to release the plunger rod until the needle is covered by the needle shield and then remove the syringe from the injection site.

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.