Package leaflet: Information for the user

Dupixent 300 mg

solution for injection in pre-filled syringe

dupilumab

Is this leaflet hard to see or read? Phone **0800 035 2525 for help** Dupixent is also used to treat adults

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
- you use Dupixent 3. How to use Dupixent
- 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 interleukins (II)-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), prurigo nodularis (PN) and eosinophilic esophagitis (EoE).

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 months 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, adolescents, and children aged 6 years and older whose asthma is not controlled with their current asthma medicines (e.g. corticosteroids)

Dupixent is also used with other medicines for the maintenance treatment of CRSwNP in adults SANOFI GENZYME 🕥 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.

with moderate-to-severe prurigo nodularis (PN), also known as chronic nodular prurigo (CNPG). Dupixent may be used with PN medicines that you apply to the skin or it may be

Dupixent is also used to treat adults and adolescents 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE).

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.

Dupixent helps prevent severe asthma attacks (exacerbations) 2. What you need to know before 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:

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

Every time you get a new pack of Dupixent, it is important that you note down the date and the batch number (which is on the packaging after "Lot") and keep this information in a safe

Allergic reactions

- Rarely, Dupixent can cause serious side effects, including 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 promptly if you have any new or worsening eve problems. These may include watering, itching, redness and swelling, eve dryness, a feeling of gritty eyes or a sensation of a foreign body in the eye. If you experience sudden changes in vision or significant eye pain that does not settle, speak to your doctor straight

- The safety and benefits of Dunixent are not vet known in children with atopic dermatitis below the age of 6 months. The safety and benefits of
- Dupixent are not yet known in children with asthma below the age of 6 years. The safety and benefits of
- Dupixent are not yet known in children with CRSwNP below the age of 18 years. The safety and benefits of
- 18 years. The safety and benefits of Dupixent are not yet known in children with EoE below the age of 12 years

Dupixent are not known in

children with PN below the age of

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

- 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 vour 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

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

Dupixent contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 300 mg dose, that is to say 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 much Dupixent you will

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 600 mg (two 300 mg injections)
- Followed by 300 mg given every other week 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 6 to 11 years of age 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 incre	acad ta

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

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 of patient	Initial dose	Subsequent doses
5 kg to	200 mg (one	200 mg
less than	200 mg	every 4
15 kg	injection)	weeks
15 kg to	300 mg (one	300 mg
less than	300 mg	every 4
30 kg	injection)	weeks
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 co-morbid 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 children with

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

Body weight of patient	Initial and subsequent doses
15 to less than 30 kg	300 mg every 4 weeks
30 kg to less than 60 kg	200 mg every other week or 300 mg every 4 weeks
60 kg or more	200 mg every other week

For patients 6 to 11 years old with asthma and coexisting severe atopic dermatitis, your doctor will decide which dose of Dupixent is right for

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 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

Recommended dose in adult and adolescent patients (12 years of age and older) with eosinophilic esophagitis (EoE) In EoE, the recommended dose

of Dupixent is 300 mg given every week by subcutaneous injection (for patients with body weight of 40 kg or more).

Injecting Dupixent

Dupixent is given by injection under vour skin (subcutaneous injection). You and your doctor or nurse should decide if you should inject Dupixent vourself.

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.

dose of Dupixent (300 mg). Do not shake the pre-filled syringe.

for Use" included at the end of the package leaflet before using Dupixent.

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

If you forget to use Dupixent

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

If your dose schedule is **every week**

• give the Dupixent injection as soon as possible and start a new every week dose schedule from the time you remember to take 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.
- within 7 days, wait until the 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 vou remember to take vour Dupixent injection.

If you stop using Dupixent

If you have any further questions on

or Apple App Store. the use of this medicine, ask your doctor, pharmacist or nurse. By reporting side effects you can help provide more information on the safety of this medicine.

can cause side effects, although not everybody gets them.

and reach of children. Dupixent can cause serious side reaction; the signs may include:

- breathing problems
- fainting, dizziness, feeling lightheaded (low blood pressure)

 fever general ill feeling swollen lymph nodes hives

itching

ioint pain

doctor right away.

Other side effects

1 in 10 people):

bruising)

100 people):

eve drvness³

1.000 people)

reactions

with atopic dermatitis

Rare (may affect up to 1 in

eye infection

If you develop an allergic reaction,

Common (may affect up to

stop using Dupixent and talk to your

• injection site reactions (i.e.

eye redness and itching

• joint pain (arthralgia)

cold sores (on lips and skin)

Uncommon (may affect up to 1 in

an increase in a certain kind of

white blood cell (eosinophils)

swelling of the face, lips, mouth,

throat or tongue (angioedema)

*These eve side effects were common

serious allergic (hypersensitivity)

ulcers on the outer clear layer of

vision (ulcerative keratitis)*

*The side effect of ulcerative keratitis

was uncommon (up to 1 in 100 people)

in patients with atopic dermatitis

6 to 11 years old with asthma

Reporting of side effects

Additional side effects in children

Common: pinworms (enterobiasis)

If you get any side effects, talk to

your doctor, pharmacist or nurse.

effects not listed in this leaflet. You

can also report side effects directly

This includes any possible side

via the Yellow Card Scheme at:

5. How to store Dupixent

Keep this medicine out of the sight

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

to protect from light. If necessary.

www.mhra.gov.uk/vellowcard or

search for MHRA in the Google Play

the eye, sometimes with blurred

(up to 1 in 10 people) in patients

redness, swelling, itching, pain,

skin rash

Each pre-filled syringe contains one

Read carefully the "Instructions

If you use more Dupixent than vou should

pharmacist or nurse.

and you miss a dose of Dupixent:

 eyelid itching, redness and swelling* inflammation of the eye surface, sometimes with blurred vision (keratitis facial rash or redness

- if the missed dose is not given next scheduled dose to give your

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

4. Possible side effects

Like all medicines, this medicine

effects, including rare allergic Do not use this medicine after the (hypersensitivity) reactions, including expiry date which is stated on the anaphylactic reaction, serum label and carton after EXP. The sickness reaction, serum sickness-like expiry date refers to the last day of

- swelling of the face, lips, mouth, throat or tongue (angioedema)

from the refrigerator and kept in the pack for up to 14 days at room temperature up to 25°C, while protected from light. The date of removal from the refrigerator shall be recorded in the space provided on the outer carton. The pack must be discarded if left out of the

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.

refrigerator for more than 14 days

or if the expiry date has passed.

6. Contents of the pack and other information

These measures will help protect

What Dupixent contains

the environment

- 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 L-Arginine monohydrochloride, L-Histidine, L-Histidine monohydrochloride monohydrate, Polysorbate 80 (E 433). Sodium acetate trihydrate, Acetic acid glacial (E 260), Sucrose, Water for

What Dupixent looks like and contents of the pack

injections

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

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

Marketing Authorisation Holder

Not all pack sizes may be

Sanofi Genzyme 410 Thames Valley Park Drive Reading Berkshire RG6 1PT Tel: 0800 035 2525

Manufacturer

SANOFI WINTHROP INDUSTRIE 1051 Boulevard Industriel, 76580 LE TRAIT. FRANCE

uk-medicalinformation@sanofi.com

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

not freeze. Store in the original carton This leaflet was last revised in **December 2023** the pre-filled syringe can be removed

Instructions for use

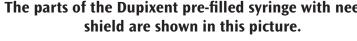
The parts of the Dupixent pre-filled syringe with needle Important information shield are shown in this picture.

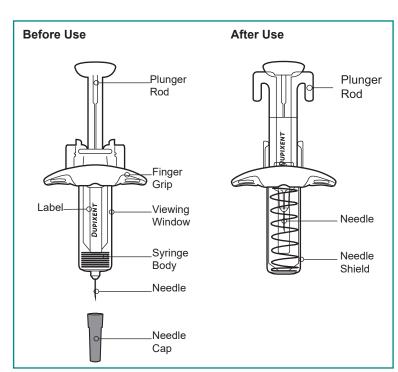
Dupixent® 300 mg

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

dupilumab

SANOFI GENZYME 🗳





This device is a single-use 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 vou 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 • Do not get rid of any air

bubbles in the syringe.

- To help prevent accidental needle injury, each prefilled 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 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.
- **Do not** keep Dupixent at room temperature (<25°C) for more than 14 days. If vou 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.

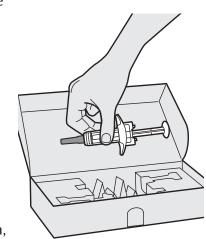
Do not heat the syringe.

Do not freeze the syringe.

• **Do not** place the syringe into

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

Step 2: **Prepare**



Step 1: Remove

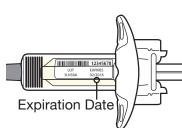
Remove the syringe from the carton by holding the middle of the syringe body.

- - **Do not** use the syringe if

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.
- the expiry date has passed. **▲ Do not** keep Dupixent at room temperature for

more than 14 days.

Step 3: Inspect

Step 4: Wait 45 minutes Step 5: Choose

Viewing Windov

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

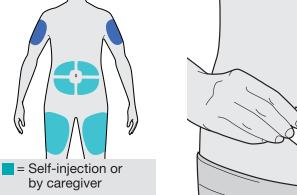
bubble; this is normal.

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



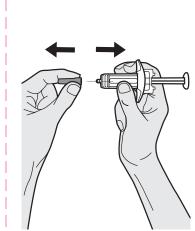
Lay the syringe on a flat surface for at least 45 minutes and let it get to room temperature naturally.

- **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.



- If somebody else gives you the injection, they can also **⚠** Do not touch the use your upper arm.
- each injection. **Do not inject into skin that** is tender, damaged or has bruises or scars.

Step 7: Pull



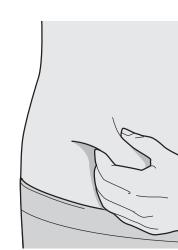
Hold the syringe in the middle of the syringe body with the needle pointing away from you and pull off the needle cap.

A Do not put the needle cap back on.

Do not touch the needle.

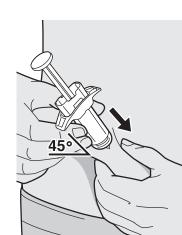
Inject your medicine immediately after removing the needle cap.

Step 8: Pinch



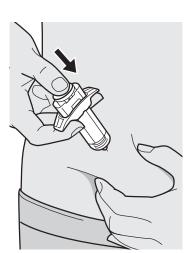
Pinch a fold of skin at the injection site, as shown in the

Step 9: Insert



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

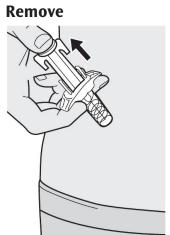
Step 10: Push



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



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

you see any blood. **⚠** Do not put the needle cap

back on.

gauze on the injection site if

⚠ Do not rub your skin after the injection.

any time.

direct sunlight.



Always keep the container out of the reach of children.

Step 12: Dispose



Dispose of the syringe and the needle cap in a punctureresistant container.

⚠ Do not put the needle cap back on.

= Injection by caregiver only Select the injection site. Wash your hands. • You can inject into your thigh Clean the injection site with or belly (stomach), except for an alcohol wipe. the 5 cm around your navel.

Let your skin dry before

Step 6: Clean

injection site again or Change the injection site for blow on it before the injection.