

DUPIXENT

Dupilumab 200 mg/1.14 mL

Dupilumab 300 mg/2 mL

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What DUXENT is used for

DUXENT (dupilumab) is a prescription medicine used:

- to treat adults and children aged 6 months and older with moderate-to-severe atopic dermatitis (eczema) that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies. DUXENT can be used with or without topical corticosteroids. It is not known if DUXENT is safe and effective in children with atopic dermatitis under 6 months of age.
- with other asthma medicines for the maintenance treatment of severe asthma in adults and children 12 years of age and older whose asthma is not controlled with their current asthma medicines. DUXENT helps prevent severe asthma attacks (exacerbations) and can improve your breathing. DUXENT may also help reduce the amount of oral corticosteroids you need while preventing severe asthma attacks and improving your breathing. DUXENT is not used to treat sudden breathing problems.
- with other medicines for the maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adults whose disease is not controlled. It is not known if DUXENT is safe and effective in children with chronic rhinosinusitis with nasal polyps under 18 years of age.

- to 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. DUXENT can be used with or without topical corticosteroids. It is not known if DUXENT is safe and effective in children with prurigo nodularis under 18 years of age.

How DUXENT works

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

Before you use DUXENT

- *When you must not use it*

Do not use DUXENT if you are allergic to dupilumab or to any of the ingredients in DUXENT. See the end of this leaflet for a complete list of ingredients in DUXENT.

Pregnancy and lactation

Talk to your doctor before using DUXENT if you are pregnant or plan to become pregnant. It is not known whether DUXENT will harm your unborn baby.

Talk to your doctor if you are breastfeeding or plan to breastfeed. It is not known whether DUXENT passes into your breast milk.

- *Before you start to use it*

Before using DUXENT, tell your healthcare provider about all your medical conditions, including if you:

- have eye problems
- have a parasitic (helminth) infection
- are scheduled to receive any vaccinations. You should not receive a “live vaccine” if you are treated with DUXENT.
- are pregnant or plan to become pregnant. It is not known whether DUXENT will harm your unborn baby.

- are breastfeeding or plan to breastfeed. It is not known whether DUXENT passes into your breast milk.

- *Taking other medicines*

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you:

- are taking oral, topical, or inhaled corticosteroid medicines
- have asthma and use an asthma medicine
- have atopic dermatitis, chronic rhinosinusitis with nasal polyps, or prurigo nodularis and also have asthma

Do not change or stop your corticosteroid medicine or other asthma medicine without talking to your healthcare provider. This may cause other symptoms that were controlled by the corticosteroid medicine or other asthma medicine to come back.

How to use DUXENT

See the detailed “Instructions for Use” that comes with DUXENT for information on how to prepare and inject DUXENT and how to properly store and throw away (dispose of) used DUXENT pre-filled syringes.

Use DUXENT exactly as prescribed by your healthcare provider.

DUXENT is given as an injection under the skin (subcutaneous injection). If your healthcare provider decides that you or a caregiver can give the injections of DUXENT, you or your caregiver should receive training on the right way to prepare and inject DUXENT. **Do not** try to inject DUXENT until you have been shown the right way by your healthcare provider.

In children 12 years of age and older, it is recommended that DUXENT be

given by or under supervision of an adult.

In children 6 months to less than 12 years of age, DUPIXENT should be given by a caregiver.

Your healthcare provider may prescribe other medicines to use with DUPIXENT. Use the other prescribed medicines exactly as your healthcare provider tells you to.

- How much to use

Your doctor will decide how much DUPIXENT you need and for how long.

Atopic Dermatitis

For adults, the recommended first dose is 600 mg (two 300 mg injections), followed by 300 mg given every other week by subcutaneous injection.

For children 6 months to 17 years of age, the recommended dose is based on body weight:

- 6 months to 5 years of age

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

^a: For children 6 months to 5 years of age with atopic dermatitis, no initial loading dose is recommended.

- 6 years to 17 years of age

Body Weight	Initial Loading Dose	Subsequent Dose
15 to less than 30 kg	600 mg (two 300 mg injections)	300 mg every 4 weeks (Q4W)
30 to less	400 mg (two	200 mg

than 60 kg	200 mg injections)	every other week (Q2W)
60 kg or more	600 mg (two 300 mg injections)	300 mg every other week (Q2W)

Asthma

The recommended dose of Dupixent for adults and children 12 years of age and older is:

- An initial dose of 400 mg (two 200 mg injections) followed by 200 mg given every other week administered as subcutaneous injection.
- For patients with severe asthma 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 first dose is 600 mg (two 300 mg injections) followed by 300 mg given every other week.

Chronic Rhinosinusitis with Nasal Polyposis

The recommended dosage of DUPIXENT for adult patients is 300 mg given every other week.

Prurigo Nodularis

The recommended dosage of DUPIXENT for adult patients is an initial dose of 600 mg (two 300 mg injections) followed by 300 mg given every other week. DUPIXENT can be used with or without topical corticosteroids.

- When to use it

Inject 1 dose of DUPIXENT every other week or every 4 weeks based on the recommended dose.

- How long to use it

Your doctor will decide how much DUPIXENT you need and for how long.

- If you forget to use it

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 the 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.

- If you use too much (overdose)

If you inject more DUPIXENT than prescribed, call your healthcare provider right away.

While you are using it

- Things you must do

If your healthcare provider decides that you or a caregiver can give the injections of DUPIXENT, you or your caregiver should receive training on the right way to prepare and inject DUPIXENT. Do not try to inject DUPIXENT until you have been shown the right way by your healthcare provider.

- Things you must not do

Do not give DUPIXENT to other people, even if they have the same symptoms that you have. It may harm them.

- Things to be careful of

Do not use this medicine if you notice that the medicine is cloudy, discoloured, or has particles in it.

Side effects

DUPIXENT can cause serious side effects, including:

- Allergic reactions. DUPIXENT can cause allergic reactions that can sometimes be severe. Stop using DUPIXENT and tell your healthcare provider or get emergency help right away if you get any of the following signs or symptoms:
 - breathing problem or wheezing
 - fast pulse
 - fever
 - general ill feeling
 - swollen lymph nodes
 - swelling of the face, lips, mouth, throat and tongue

- hives
- itching
- nausea or vomiting
- fainting, dizziness, feeling lightheaded (low blood pressure)
- joint pain
- skin rash
- cramps in your stomach area
- Eye problems. Tell your healthcare provider if you have any new or worsening eye problems, including eye pain or changes in vision, such as blurred vision. Your healthcare provider may send you to an ophthalmologist for an eye exam if needed.
- Inflammation of your blood vessels. Rarely, this can happen in people with asthma who receive DUPIXENT. This may happen in people who also take a steroid medicine by mouth that is being stopped or the dose is being lowered. It is not known whether this is caused by DUPIXENT. Tell your healthcare provider right away if you have:
 - rash
 - worsening shortness of breath
 - persistent fever
 - chest pain
 - a feeling of pins and needles or numbness of your arms or legs
- Joint aches and pain. Joint aches and pain can happen in people who use DUPIXENT. Some people have had trouble walking or moving due to their joint symptoms, and in some cases needed to be hospitalized. Tell your healthcare provider about any new or worsening joint symptoms.

The most common side effects of DUPIXENT include:

- injection site reactions
- cold sores in your mouth or on your lips
- eye and eyelid inflammation, including redness, swelling, and itching, sometimes with blurred vision
- dry eye
- herpes virus infections
- common cold symptoms (nasopharyngitis)
- pain in the throat (oropharyngeal pain)
- high count of a certain white blood cell (eosinophilia)
- dizziness

- muscle pain
 - diarrhea
 - trouble sleeping (insomnia)
 - toothache
 - gastritis
 - joint pain (arthralgia)
 - parasitic (helminth) infections
- The following additional side effects have been reported with DUPIXENT:
- facial rash or redness

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of DUPIXENT. Call your doctor for medical advice about side effects.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of DUPIXENT

- Storage

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

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. Throw away (dispose of) any DUPIXENT that has been left at room temperature for longer than 14 days.

Store in the original carton to protect from light.

Do not heat or put DUPIXENT into direct sunlight.

Do not freeze. Do not shake.

- Disposal

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.

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.

Product Description

- What it looks like

DUPIXENT is a clear to slightly opalescent, colourless to pale yellow solution supplied in a glass pre-filled syringe with needle shield.

Ingredients

- Active ingredient
Dupilumab
- Inactive ingredients
L-arginine hydrochloride, L-histidine, polysorbate 80, sodium acetate, acetic acid, sucrose and water for injections

MAL number

- Dupixent 300 mg/2 mL:
MAL19056001AZ
- Dupixent 200 mg/1.14 mL:
MAL20116006AZ

Manufacturer

Sanofi Winthrop Industrie
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Product Registration Holder

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