DUPIXENT®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using Dupixent?

Dupixent contains the active ingredient Dupilumab. It is used to treat severe atopic dermatitis in patients between 6 months to 11 years of age, moderate to severe atopic dermatitis in patients aged 12 years and older, moderate to severe prurigo nodularis in adults, moderate to severe bullous pemphigoid in adults, moderate to severe asthma in patients aged 6 years and older, adults with uncontrolled chronic obstructive pulmonary disease and adults with chronic rhinosinusitis with nasal polyposis. For more information, see Section 1. Why am I using Dupixent? in the full CMI.

2. What should I know before I use Dupixent?

Do not use if you have ever had an allergic reaction to Dupixent or any of the ingredients listed at the end of the CMI.
Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2. What should I know before I use Dupixent? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Dupixent and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Dupixent?

- Dupixent should be injected under the skin every other week or every 4 weeks. Your doctor will tell you how much you need to use. Change your injection site regularly. Carefully follow the instructions on how to inject under the skin.

More instructions can be found in Section 4. How do I use Dupixent? in the full CMI.

5. What should I know while using Dupixent?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Dupixent. • If you have asthma and are taking asthma medicines, do not change or stop your asthma medicine without talking to your doctor. • It is important to keep using Dupixent even if you feel well.
Things you should not do	• Do not use in patients under 6 months old with atopic dermatitis, under 18 years old with prurigo nodularis, under 18 years old with bullous pemphigoid, under 6 years old with asthma, under 18 years old with chronic obstructive pulmonary disease, or under 18 years old with nasal polyposis.

	• Do not stop taking your corticosteroid medicines unless instructed by your doctor. • Do not stop taking your medicine without checking with your doctor. • Do not use Dupixent if you think it has been frozen or exposed to excessive heat
Looking after your medicine	• Keep Dupixent in a refrigerator (2°C - 8°C). Do not freeze. Do not expose to extreme heat. • Before use, keep Dupixent syringes/ pens in a refrigerator where the temperature is between 2-8°C. If necessary, pre-filled syringes/pens can be kept at room temperature up to 25°C for a maximum of 14 days. • Dupixent should be removed from the refrigerator before your injection so

	that it reaches room temperature (at least 45 minutes before injection for 300mg syringes/pens and at least 30 minutes for 200mg syringes/ pens).

For more information, see Section 5. What should I know while using Dupixent? in the full CMI.

6. Are there any side effects?

Serious side effects may include an allergic reaction. Common side effects may include eye dryness, eye infection, eye and eyelid inflammation. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Dupixent®

Active ingredient(s): *dupilumab* (du-pil-u-mab)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Dupixent. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Dupixent.**

Where to find information in this leaflet:

1. Why am I using Dupixent?
2. What should I know before I use Dupixent?
3. What if I am taking other medicines?
4. How do I use Dupixent?
5. What should I know while using Dupixent?
6. Are there any side effects?
7. Product details

1. Why am I using Dupixent?

Dupixent contains the active ingredient dupilumab. Dupixent belongs to a class of medicines called monoclonal antibodies.

Dupixent is used to treat the following conditions:

1) moderate to severe atopic dermatitis (also known as atopic eczema), in patients aged 12 years and older. Dupixent is also used to treat severe atopic dermatitis in patients between 6 months to 11 years old.

In atopic dermatitis, Dupixent may be used with or without prescribed atopic dermatitis medicines that you apply to the skin.

2) moderate to severe prurigo nodularis in adult patients whose disease is not controlled with their current medication.

3) moderate to severe bullous pemphigoid in adults.

4) maintenance treatment of moderate-to-severe asthma in patients 6 years and older whose asthma is not controlled with their current asthma medicines.

In asthma, Dupixent should be used in addition to your existing asthma medicines. Dupixent may also help reduce the amount of oral corticosteroids you need while preventing severe asthma attacks and improving your breathing.

5) maintenance treatment of chronic obstructive pulmonary disease (COPD) in adults not well enough controlled with your current inhaler medication. Adding

Dupixent helps prevent moderate or severe COPD attacks (exacerbations) and can improve your breathing. Dupixent may also help to improve overall symptoms of COPD.

6) maintenance treatment of chronic rhinosinusitis in adults with nasal polyposis (CRSwNP) in adults whose disease is not controlled with their current CRSwNP medicines.

Your doctor will assess if Dupixent is appropriate for your condition.

2. What should I know before I use Dupixent?

Warnings

Do not use Dupixent if:

- You are allergic to dupilumab, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- The product appears cloudy, discoloured or contains particles, or if the syringe, pen and/or needle cap appear damaged.

Check with your doctor if you:

- Have a parasitic (helminth) infection

- Have any other medical conditions, including any new or worsening eye problems, including eye pain or changes in vision
- Take any medicines for any other condition including oral, or using topical, or inhaled corticosteroid medicines
- Have recently received or are scheduled to receive a vaccine

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Atopic Dermatitis

- **Do not use Dupixent in patients under 6 months old.** The safety and benefits of Dupixent are not yet known in this patient group.

Prurigo Nodularis

- **Do not use Dupixent in patients under 18 years old.** The safety and benefits of Dupixent are not yet known in this patient group.

Bullous Pemphigoid

- **Do not use Dupixent in patients under 18 years old.** The safety and benefits of Dupixent are not yet known in this patient group.

Asthma

- **Do not use Dupixent in patients under 6 years old.** The safety and benefits of Dupixent are not yet known in this patient group.
- **Dupixent is not a rescue medicine** and should not be used to treat a sudden asthma attack

Chronic Obstructive Pulmonary Disease (COPD)

- **Do not use Dupixent in patients under 18 years old.**
  The safety and benefits of Dupixent are not yet known in this patient group. COPD does not normally occur in children.
- **Dupixent is not a rescue medicine** and should not be used to treat a sudden COPD attack (exacerbation).

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

- **Do not use Dupixent in patients under 18 years old.** The safety and benefits of Dupixent are not yet known in this patient group.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Do not stop taking your corticosteroid medicines unless instructed by your doctor.

This may cause other symptoms that were controlled by the corticosteroid medicine to come back**.**

You should not receive certain type of vaccines while taking Dupixent. Tell your doctor if you have recently received a vaccine or planned to receive a vaccine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Dupixent.

4. How do I use Dupixent?

Follow all directions given to you by your doctor and pharmacist carefully.

Carefully read the "Dupixent Instructions for Use" provided in the carton. If you do not understand the instructions on the label or in this leaflet, ask your doctor or pharmacist for help.

How much to use

- Use the dose that your doctor prescribes for you
- Dupixent is given as an injection under the skin (subcutaneously) every other week or every 4 weeks.

How long to use Dupixent

- Continue using Dupixent for as long as your doctor recommends.
- Make sure you keep enough Dupixent to last when you go on holidays.

How to use Dupixent

Always check the syringe/pen label before each injection to make sure you are using the right medicine.

Dupixent is a clear and colourless to pale yellow solution that should not be shaken before use.

Do not use Dupixent if it is not clear to pale yellow or if it contains particles.

To avoid discomfort, Dupixent should be removed from the refrigerator before your injection so that it reaches room temperature.

- Remove Dupixent 300mg syringes/pens from the refrigerator at least 45 minutes before injection.
- Remove Dupixent 200mg syringes/pens from the refrigerator at least 30 minutes before injection.

In adult patients, the injection can be self-administered or given by another person, after proper training in injection technique.

In adolescents 12 years of age and older, it is recommended that Dupixent be given by or under the supervision of an adult.

Dupixent should be given by a caregiver in children 6 months to 11 years of age. The pre-filled syringe presentation is for children aged 6 months and older. The pre-filled pen is for children aged 2 years and older.

Dupixent is injected under the skin (subcutaneous injection). You can inject into the thigh or abdomen, except for the 2 inches (5 cm) around the navel, using a single-dose pre-filled syringe or pen. If somebody else administers the injection, the upper arm can also be used. Use a different injection site each injection so that the same site is not used.

Do not inject in an area where the skin that is tender, damaged, sunburnt or has bruises or scars.

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

If you forget to use Dupixent

If your dose schedule is every other week and you miss a dose of Dupixent, give the 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.

In case you are not sure when to inject Dupixent, call your doctor or pharmacist.

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 take your Dupixent injection.

It is important to use Dupixent as prescribed by your doctor.

If you use too much Dupixent

If you think that you have used too much Dupixent, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Dupixent?

Things you should do

Always follow your doctor's instructions carefully.

If you have asthma and are taking asthma medicines, do not change or stop your asthma medicine without talking to your doctor.

It is important to keep using Dupixent even if you feel well.

Continuous use of Dupixent helps to control your condition.

Call your doctor straight away if you:

- Experience any of the following symptoms:
- a flu-like illness
- pins and needles or numbness of arms or legs
- worsening of lung symptoms including breathing problems,
- and/or rash.

Remind any doctor, dentist or pharmacist you visit that you are using Dupixent.

Things you should not do

- Do not expose the syringe or pen to heat or direct sunlight.

- Do not use a syringe or pen if it is damaged or you are not sure that it is working properly. Use a new syringe or pen.
- Do not use Dupixent if you think it has been frozen or exposed to excessive heat (temperatures above 25°C).
- Do not give Dupixent to anyone else, even if they have the same condition as you.
- Do not stop taking your corticosteroid medicines unless instructed by your doctor.
- This may cause other symptoms that were controlled by the corticosteroid medicine to come back
- Do not stop taking your medicine without checking with your doctor.

Driving or using machines

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

Looking after your medicine

Before use, keep Dupixent syringes and pens in a refrigerator where the temperature is between 2-8°C. If necessary, pre-filled syringes and pens can be kept at room temperature up to 25°C for a maximum of 14 days.

Keep the syringes and pens in the original carton to protect from light.

Do not allow it to freeze. Discard if frozen.

Do not expose to heat. Do not shake.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

When and how to discard your medicine

After injecting Dupixent, immediately throw away the used pre-filled syringe or pen in a sharps container as instructed by your doctor or pharmacist.

After removal from the refrigerator, Dupixent must be used within 14 days or discarded.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Injection site-related: • Redness, swelling or itching at the injection site • Hollowing or thickening of the skin around the injection site **Eye-related**: • Eye dryness, eye infection, eye and eyelid inflammation (including redness/swelling/ itching) (if you also have atopic dermatitis) • eye pain • blurred vision • sensitivity to light **Skin-related** • Rash on the face	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Allergic reaction-related: • Shortness of breath • Wheezing or difficulty breathing • Swelling of the face, lips, tongue or other parts of the body • Fever • Feeling generally unwell • Joint pain • Dizziness, feeling light-headed • Rash, itching or hives on the skin	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Dupixent contains

Active ingredient **(main ingredient)**	Dupilumab
Other ingredients **(inactive ingredients)**	• arginine hydrochloride • histidine • histidine hydrochloride monohydrate • polysorbate 80 • sodium acetate trihydrate • sucrose • glacial acetic acid • water for injections

What Dupixent looks like

Dupixent is a clear and colourless to pale yellow, preservative-free liquid solution available in a pre-filled syringe with needle shield or a pre-filled pen.

The needle shield reduces the risk of accidental needle stick injuries.

Dupixent is available in two different strengths:

- 300 mg in 2 mL solution
- 200 mg in 1.14 mL solution

Dupixent 300 mg (150 mg/mL) pre-filled syringe with needle shield (AUST R 283127)

Dupixent 300 mg (150 mg/mL) pre-filled pen (AUST R 382594)

Dupixent 200 mg (175 mg/mL) pre-filled syringe with needle shield (AUST R 302463)

Dupixent 200 mg (175 mg/mL) pre-filled pen (AUST R 382593)

Who distributes Dupixent

Dupixent is supplied in Australia by:

sanofi-aventis australia pty ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

E-mail: medinfo.australia@sanofi.com

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