▼ 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®

dupilumab (du-pil-u-mab)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Dupixent.

It does not contain all the available information. It does not take the place of talking to your Doctor or Pharmacist.

All medicines have risks and benefits. Your Doctor has weighed the risks of you using Dupixent against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your Doctor or Pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What DUPIXENT is used for

Dupixent contains the active substance dupilumab.

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.

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

2) maintenance treatment of moderate-to-severe asthma in patients 12 year 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.

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

How it works

Dupixent is an injectable medicine that inhibits IL-4 and IL-13 proteins by blocking a shared receptor. IL-4 and IL-13 play a major role in the symptoms of atopic dermatitis and asthma.

Dupixent belongs to a class of medicines called monoclonal antibodies. Monoclonal antibodies are proteins that specifically recognise and bind to other unique proteins in the body.

Ask your Doctor if you have any questions about why Dupixent has been prescribed for you.

Before you use DUPIXENT

When you must not use Dupixent

Do not use Dupixent if you have an allergy to:

- **any medicine containing dupilumab (the active ingredient) or any of the ingredients listed at the end of this leaflet**

Some of the symptoms of an allergic reaction may include:

- rash, itching or hives on the skin
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

Tell your doctor if you are experiencing these symptoms

Dupixent should not be used after the expiry date (exp) printed on the pack.

If you use this medicine after the expiry date has passed, it may not work as well, or have an unexpected effect.

Dupixent should not be used if the packaging is torn or shows signs of tampering.

Do not use Dupixent if the product appears cloudy, discoloured or contains particles, or if the syringe and/or needle cap appear damaged.

Atopic Dermatitis:

Do not use Dupixent in patients under 12 years old.

The safety and benefits of Dupixent are not yet known in this patient group.

Asthma:

Do not use Dupixent in patients under 12 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.

If you are not sure whether you should start using this medicine, talk to your Doctor.

Before you start to use DUPIXENT

Tell your doctor or pharmacist if you have allergies to any other medicines, or substances such as foods, preservatives or dyes.

Tell your Doctor if you have any of the following, or if any of the following apply to you:

- have a parasitic (helminth) infection
- are pregnant or plan to become pregnant. It is not known if Dupixent will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known whether Dupixent passes into breast milk.
- have recently received or are scheduled to receive a vaccine
- any new or worsening eye problems, including eye pain or changes in vision.
- are taking oral, or using topical, or inhaled corticosteroid medicines
- have any other medical conditions

If you have not told your Doctor about any of the above, tell them before you start using Dupixent.

Taking other medicines

Tell your Doctor or pharmacist if you are taking any other medicines, have recently taken, or might take any other medicines, including any that you get 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.

How to use DUPIXENT

Dupixent comes as a single-dose (1 time use) pre-filled syringe with or without needle shield. Your healthcare provider will prescribe the type that is best for you. 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 to use it

Always check the syringe 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 from the refrigerator at least 45 minutes before injection.

Remove Dupixent 200mg syringes from the refrigerator at least 30 minutes before injection.

The syringe should not be exposed to heat or direct sunlight.

The injection can be self-administered or given by another person, after proper training in injection technique.

Dupixent syringes are pre-filled and ready to use. Once the contents have been injected, the syringe cannot be re-used.

Never use a syringe if it is damaged, or you are not sure that it is working properly. Use a new syringe.

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

Dupixent is intended for injection under the skin.

If you do not understand the instructions, ask your Doctor or Pharmacist.

How much to use

Use the dose that your doctor prescribes for you.

Dupixent is given as an injection under the skin (subcutaneously) once every two weeks.

Where to inject

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. 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.

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.

If you forget to use it

If 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.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (13 11 26) or go to accident and emergency at your nearest hospital, if you think that you have taken too much Dupixent.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Always take the outer carton of the medicine with you.

While you are using DUPIXENT

If you experience any symptoms of an allergic reaction, stop using Dupixent and talk to your doctor immediately.

Things you must do

Always follow your doctor's instructions carefully.

Keep Dupixent in a refrigerator (2°C - 8°C). Do not freeze. Do not expose to extreme heat.

Dupixent should be removed from the refrigerator at least 45 minutes before your injection to avoid discomfort.

Dupixent 300 mg syringes should be removed from the refrigerator at least 45 minutes before your injection.

Dupixent 200 mg syringes should be removed from the refrigerator at least 30 minutes before your injection.

Dupixent should not be exposed to heat or direct sunlight.

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

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

Continuous use of Dupixent helps to control your condition.

If you become pregnant while you are using Dupixent, tell your doctor.

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

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

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Dupixent.

Things you must not do

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.

Things to be aware of

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

Side effects

Tell your Doctor as soon as possible if you do not feel well while you are using Dupixent.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your Doctor or Pharmacist to answer any questions you may have.

Tell your doctor if you notice any of them and they worry you or it does not go away:

- Injection site reactions
- headache
- Eye dryness, eye infection, eye and eyelid inflammation (including redness/swelling/ itching) (if you also have atopic dermatitis)
- oral herpes (cold sores)
- a specific form of allergic reaction resulting in inflammation of your blood vessels. Rarely, this can happen in people with asthma who receive Dupixent.

In rare cases, patients taking an asthma medicine may develop an inflammation of blood vessels or lungs. 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 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.

Dupixent can cause serious side effects, including: generalized allergic (hypersensitivity) reactions including anaphylaxis can happen after you get your Dupixent injection.

If you have any signs of allergic (hypersensitivity) reaction stop using Dupixent, tell your Doctor immediately or go to Accident and Emergency at your nearest hospital.

Symptoms of allergic reactions include:

- shortness of breath
- persistent fever
- chest pain
- general ill feeling
- swollen lymph nodes
- swelling of the face, mouth, and tongue
- hives
- itching
- fainting, dizziness, feeling lightheaded (low blood pressure)
- joint pain
- skin rash
- a feeling of pins and needles or numbness of your arms or legs

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

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

After using DUPIXENT

Storage

All medicines should be kept where children cannot reach them.

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

Keep the syringes 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.

If you need to travel, make sure the medicine is kept at the right temperature. This is important whether travelling by car, bus, train, plane or any other form of transport.

Disposal

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

If your Doctor tells you to stop using Dupixent or the expiry date has passed, ask your Pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Dupixent is a clear and colourless to pale yellow, preservative-free liquid solution available in a pre-filled syringe with or without needle shield.

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

Ingredients

Active Ingredient:

- dupilumab

Inactive Ingredients:

- acetic acid,
- arginine hydrochloride,
- histidine,
- polysorbate 80,
- sodium acetate,
- sucrose,
- water for injections

Supplier

Dupixent is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall No: 1800 818 806

sanofi-aventis new zealand limited

Level 8, James and Wells Tower

56 Cawley Street, Ellerslie,

Auckland

New Zealand

Freecall No:0800 283 684

Dupixent 300 mg

(150 mg/mL) pre-filled syringe with needle shield

AUST R 283127

Dupixent 300 mg

(150mg/mL) pre-filled syringe
AUST R 282981

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

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