

Dupixent® 200 mg solution for injection in pre-filled pen

(dupilumab)

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.

This product is called Dupixent 200 mg solution for injection in pre-filled pen but will be referred to as Dupixent throughout the leaflet.

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 interleukins (IL)-4 and IL-13. Both play a major role in causing the signs and symptoms of atopic dermatitis, asthma and chronic spontaneous urticaria (CSU).

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 (see section Children and adolescents). 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 to treat chronic spontaneous urticaria (CSU) in adults and adolescents aged 12 years and older.

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) 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 name of the medicine, the date of the administration and the batch number (which is on the packaging after "Lot") and keep this information in a safe place.

Allergic reactions

- 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 promptly if you have any new or worsening eye problems. These may include watering, itching, redness and swelling, eye 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 away.

Children and adolescents

- The Dupixent pre-filled pen is not intended for use in **children below 2 years of age**.
- For children aged 6 months to less than 2 years of age contact your doctor who will prescribe the appropriate Dupixent pre-filled syringe.
- In children 6 months to less than 12 years of age, dupilumab should be given by a caregiver.
- In children 12 years of age and older, it is recommended that dupilumab is administered by or under supervision of an adult.
- The safety and benefits of Dupixent are not yet 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 CSU below the age of 12 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

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 200 mg dose, that is to say essentially 'sodium-free'.

Dupixent contains polysorbate

This medicine contains 2.28 mg of polysorbate 80 in each 200 mg dose (1.14 mL). Polysorbates may cause allergic reactions. Tell your doctor if you have or your child has any known allergies.

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 receive

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

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 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 less than 15 kg	200 mg (one 200 mg injection)	200 mg every 4 weeks
15 kg to less than 30 kg	300 mg (one 300 mg injection)	300 mg every 4 weeks

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

For most 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.

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.

Recommended dose children with asthma

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 you.

Recommended dose in adults with chronic spontaneous urticaria (CSU)

The recommended dose of Dupixent for adult patients is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week.

Recommended dose in adolescents with chronic spontaneous urticaria (CSU)

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

Body Weight	Initial Dose	Subsequent Doses
30 to less than 60 kg	400 mg (two 200 mg injections)	200 mg every other week (Q2W)
60 kg or more	600 mg (two 300 mg injections)	300 mg every other week (Q2W)

Injecting Dupixent

Dupixent 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 pen contains one dose of Dupixent (200 mg). Do not shake the pre-filled pen.

Read carefully the "Instructions for Use" included at the end of the package leaflet 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. In addition,

If your dose schedule is **every week** and you miss a dose of Dupixent:

- 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.
- 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 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.

Dupixent can cause serious side effects, including rare allergic (hypersensitivity) reactions, including anaphylactic reaction, serum sickness reaction, serum sickness-like reaction; the signs 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

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

- injection site reactions (e.g. localized redness, swelling, itching, pain, bruising)
- eye redness and itching
- eye infection

- cold sores (on lips and skin)
- an increase in a certain kind of white blood cell (eosinophils)
- joint pain (arthralgia)

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

- swelling of the face, lips, mouth, throat or tongue (angioedema)
- eyelid itching, redness and swelling*
- inflammation of the eye surface, sometimes with blurred vision (keratitis)
- facial rash or redness
- eye dryness*

*These eye side effects were common (up to 1 in 10 people) in patients with atopic dermatitis

Rare (may affect up to 1 in 1000 people):

- serious allergic (hypersensitivity) reactions
- ulcers on the outer clear layer of the eye, sometimes with blurred vision (ulcerative keratitis)*

*The side effect of ulcerative keratitis was uncommon (up to 1 in 100 people) in patients with atopic dermatitis

Additional side effects in children 6 to 11 years old with asthma

Common: pinworms (enterobiasis)

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA in the Google Play or Apple App Store. 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). Do not freeze. Store in the original carton to protect from light. If necessary, the pre-filled pen can be removed 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 refrigerator for more than 14 days or if the expiry date has passed.

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.

If the medicine becomes discolored or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6. Contents of the pack and other information

What Dupixent contains

- The active substance is dupilumab.
- Each pre-filled pen contains 200 mg of dupilumab in 1.14 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 injections.

What Dupixent looks like and contents of the pack

Dupixent is a clear to slightly opalescent, colourless to pale yellow solution supplied in a pre-filled pen.

The pre-filled pen may either have a round cap and oval viewing window encircled with an arrow or may have a square cap with ridges and an oval viewing window without an arrow. Although there are minor differences in the appearance of the two pre-filled pens, they both function the same.

Dupixent is available as 200 mg pre-filled pens in a pack containing 2 pre-filled pens.

Manufacturers

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

or

Sanofi-Aventis Deutschland GmbH
Brüningstrasse 50
Industriepark Hoechst
65926 FRANKFURT AM MAIN
GERMANY

or

Genzyme Ireland Limited
IDA Industrial Park
Old Kilmeaden Road
Waterford
Ireland

Procured from within the EU and repackaged for the PL Holder:

Abacus Medicine Ltd., Abbey House,
282 Farnborough Road, Farnborough,
GU14 7NA, United Kingdom

Dupixent 200 mg solution for injection
in pre-filled pen

PL 45763/0587

POM

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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.

For any information about this medicine, please contact the local representative of the Product Licence Holder:
Abacus Medicine Ltd.
tel: +44(0)2036301244,
email: MedInfo@abacusmedicine.co.uk or drugsafetyuk@abacusmedicine.co.uk

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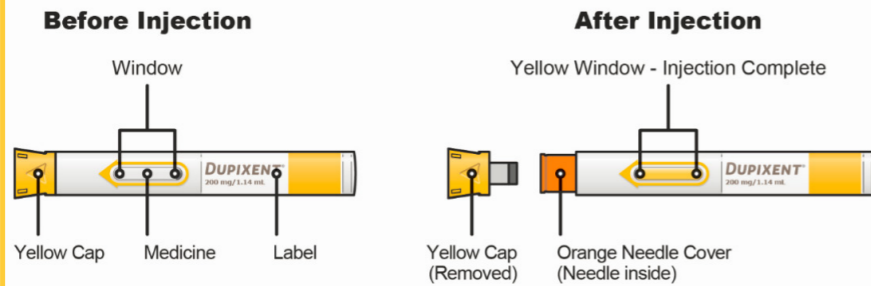
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Call 02036301310
or write to
info@abacusmedicine.com
to obtain the leaflet in a format suitable for you.**

Dupixent® 200 mg solution for injection in a pre-filled pen

(dupilumab)

Instructions for use

The parts of the Dupixent pre-filled pen are shown in this picture.



Important information

This device is a single-use pre-filled pen.

It contains 200 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 is administered by or under supervision of an adult. In children less than 12 years of age, Dupixent should be given by a caregiver. The Dupixent pre-filled pen is only for use in adults and children aged 2 years and older.

• Read all of the instructions carefully before using the pre-filled pen.

- Ask your healthcare professional how often you will need to inject the medicine.
- Choose a different injection site for each injection
- Do not use the pre-filled pen if it has been damaged.
- Do not use the pre-filled pen if the yellow cap is missing or not securely attached.
- Do not press or touch the orange needle cover with your fingers.
- Do not inject through clothes.
- Do not remove the yellow cap until just before you give the injection.
- Do not try to put the yellow cap back on the pre-filled pen.
- Do not re-use the pre-filled pen.

How to Store Dupixent

- Keep the pre-filled pen(s) and all medicines out of the reach of children.
- Keep unused pre-filled pens in the original carton and store in the refrigerator between 2°C and 8°C.
- Store pre-filled pens in the original carton to protect it from light.
- Do not keep pre-filled pens 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 pre-filled pen at any time.
- Do not heat the pre-filled pen.
- Do not freeze the pre-filled pen.
- Do not place the pre-filled pen into direct sunlight.

A Prepare

A1 Gather supplies

Ensure you have the following:

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

*Items not included in the carton

A2 Look at the label



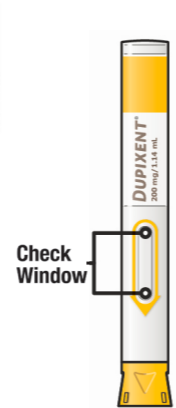
- Confirm that you have the correct product and dose.

A3 Check expiration date



- Check the expiration date.
- ⚠ Do not use the pre-filled pen if the expiration date has passed.
- ⚠ Do not keep Dupixent at room temperature for more than 14 days.

A4 Check the medicine



Look at the medicine through the window on the pre-filled pen.

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 pre-filled pen if the liquid is discolored or cloudy, or if it contains visible flakes or particles.

- ⚠ Do not use the pre-filled pen if the window is yellow.

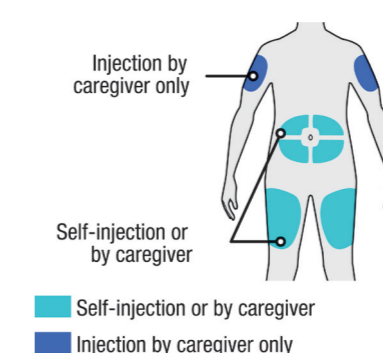
A5 Wait 30 minutes

Lay the pre-filled pen on a flat surface and let it naturally warm up at room temperature (less than 25°C) for at least 30 minutes.

- ⚠ Do not warm the pre-filled pen in a microwave, hot water, or direct sunlight.
- ⚠ Do not put the pre-filled pen into direct sunlight.
- ⚠ Do not keep Dupixent at room temperature for more than 14 days.

B Choose your injection site

B1 Recommended injection sites are:



- **Thigh**
- **Stomach** except for the 5 cm around your belly button (navel).
- **Upper Arm** If a caregiver gives your dose, they can also use the outer area of the upper arm.

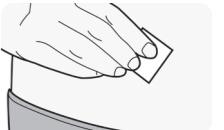
Choose a different injection site for each Dupixent injection.

- ⚠ Do not inject through clothes.
- ⚠ Do not inject into skin that is tender, damaged, bruised or scarred.

B2 Wash your hands



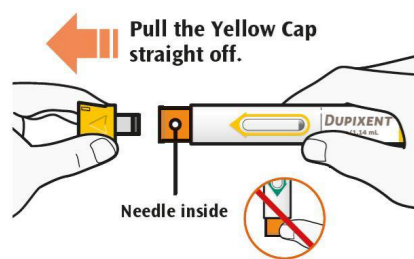
B3 Prepare the injection site



- 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.

C Give injection

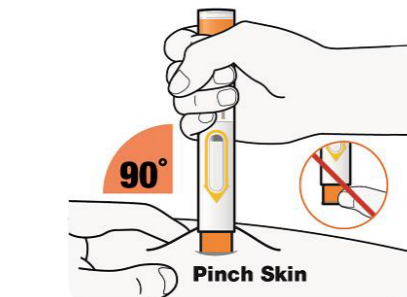
C1 Remove yellow cap



Pull the yellow cap straight off. Do not twist the yellow cap off. Do not remove the yellow cap until you are ready to inject. Do not press or touch the orange needle cover with your fingers. The needle is inside.

- ⚠ Do not put the yellow cap back on the pre-filled pen after you have removed it.

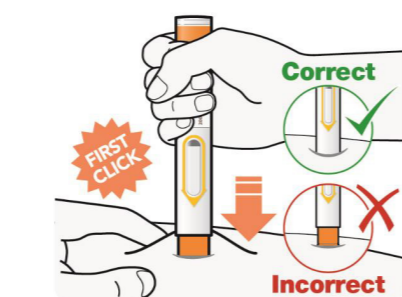
C2 Pinch and Place



- Pinch the skin before and during the injection.
- Pinching is not needed for adults and children aged 12 years and older.
- When placing the orange needle cover on your skin, hold the pre-filled pen so that you can see the window.
- Place the orange needle cover on your skin at approximately a 90-degree angle.

- ⚠ Do not press or touch the orange needle cover with your fingers. The needle is inside.

C3 Press down

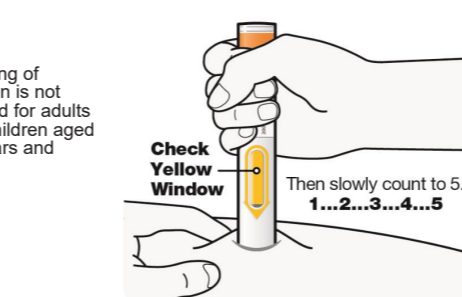


Press the pre-filled pen firmly against your skin until you cannot see the orange needle cover, and hold.

- There will be a "click" when the injection starts.
- The window will start to turn yellow.

The injection can take up to 20 seconds.

C4 Hold firmly



Pinching of the skin is not needed for adults and children aged 12 years and older.

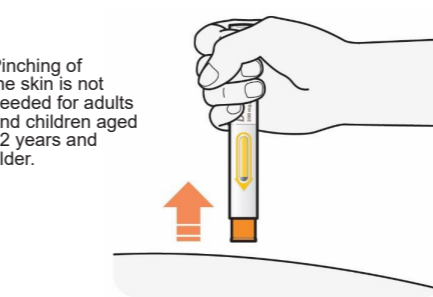
Keep holding the pre-filled pen firmly against your skin.

- You may hear a second click.
- Check that the entire window has turned to yellow.
- Then slowly count to 5.
- Then lift the pen up off the skin, your injection is complete.

If the window does not turn completely yellow, remove the pen and call your healthcare provider.

- ⚠ Do not give yourself a second dose without speaking to your healthcare provider.

C5 Remove

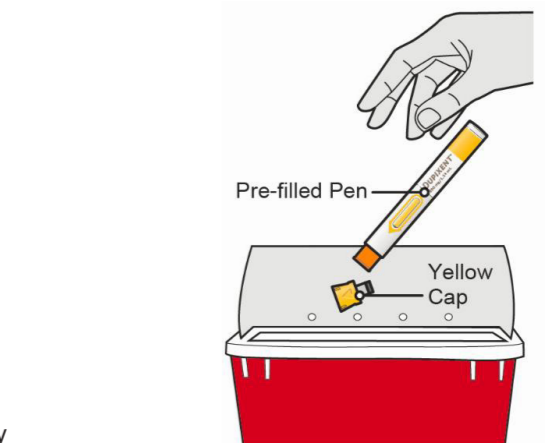


After you have completed your injection pull straight up to remove pre-filled pen from the skin and dispose of immediately as described in section D.

- If you see any blood at the site, lightly dab a cotton ball or gauze pad.

- ⚠ Do not rub your skin after the injection.

D Dispose



- Dispose of the pre-filled pens, (needle inside), and yellow caps in a puncture resistant container right away after use.

Do not dispose of (throw away) pre-filled pens (needle inside), and yellow caps in your household trash.

- ⚠ Do not put the yellow cap back on.