10th Edition

For asthma patients starting treatment with DUPIXENT®

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sanofi | REGENERON

CONTENTS

Your present condition

Have you experienced any of the following **in the past 2 to 4 weeks or past year**? If so, your asthma is not well controlled.

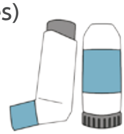
In the past 2 to 4 weeks

☐ I have had symptoms of asthma (cough, difficulty breathing, whistling or wheezing sounds when breathing) during the day or at night at least once a week.



☐ I have used medicine for asthma attacks at least once a week.

(Examples)


Rescue inhalants


Oral steroids

☐ Asthma interfered with normal activities.


Sports


Housekeeping


Work


Going out

Over the past year

☐ I had an unscheduled office visit, went to the ER, or was hospitalized because of a severe asthma attack.

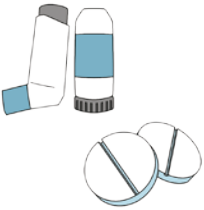

Adapted from Japanese Society of Allergology: Japanese Guidelines for Preventing and Managing Asthma 2021, Kyowa Kikaku, Ltd., 2021, p. 107

Your present shapes your future

Your present condition is closely related to future risks such as attacks, reduced respiratory function, etc. Since it takes a long time to treat asthma, it is important to get rid of current symptoms keeping future risks in mind.

Your present condition

I often use medicine for asthma attacks



I have symptoms of asthma during the day and at night

I have to go for unscheduled hospital visits or hospitalization

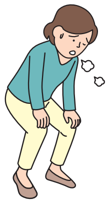
If poor control of asthma continues...

Future risks

Drug side effects

Future attacks

Reduced respiratory function over time



Adapted from Japanese Society of Allergology: Japanese Guidelines for Preventing and Managing Asthma 2021, Kyowa Kikaku, Ltd., 2021. p.2-3
Adapted from Japan Asthma Society: Practical Guidelines for Asthma Management 2023; Kyowa Kikaku, Ltd., 2023. p.23

Future management goals (present and future goals)

Be sure to consult your doctor about treatment that will allow you to reach your goals so that you do not have to give up on what you want to do right now or in the future because of asthma symptoms.

Present | **Your goals** | **Future**

years after (yr-old)

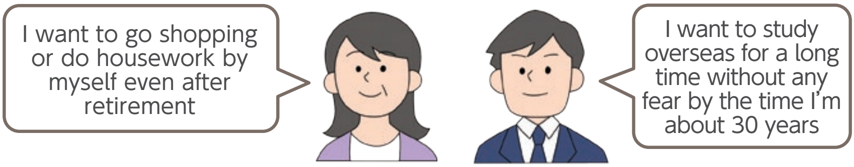
years after (yr-old)

years after (yr-old)

For example...

Present

Future

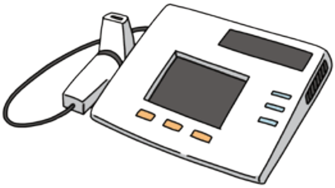


Adapted from Japanese Society of Allergology: Japanese Guidelines for Preventing and Managing Asthma 2021, Kyowa Kikaku, Ltd., 2021. p.2-3

Asthma control status can be checked

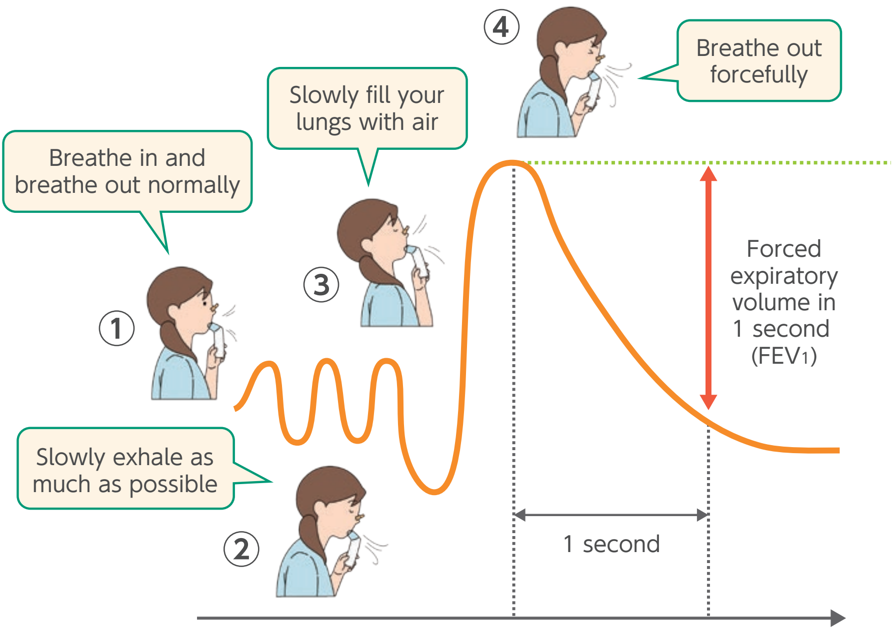
Respiratory function test (spirometry)

This test uses a machine called a spirometer to check your respiratory function. The amount of air that you can forcefully exhale in 1 second after taking a deep breath is called "forced expiratory volume in 1 second" (FEV_1). It is used to determine the severity of asthma. If your airways become narrowed, the "forced expiratory volume in 1 second" decreases.



(Spirometer)

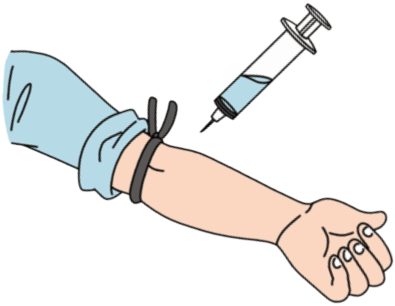
How to measure FEV_1



Blood tests

These tests measure blood eosinophil count, total IgE level, antigen-specific IgE antibodies, etc.

Eosinophil count	If the count is large, the airways are judged to be inflamed.
Total IgE level	Level increases if an allergy is present.
Antigen-specific IgE antibodies	These tell us what is causing the allergy (allergens such dust mites, pets, and mold).



Fractional exhaled nitric oxide (FeNO) test

In this test, you breathe directly into the machine that evaluates inflammation in your airway.
The concentration of nitric oxide (NO) in your exhaled breath is measured.
An elevated FeNO indicates that you have inflammation in your airway.

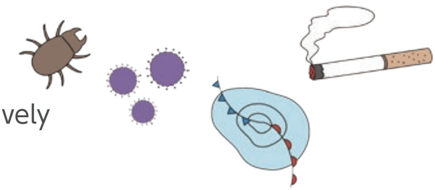
Watch the video for more information
(Only available in Japanese)

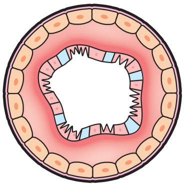
What is happening in your airways

When attacks occur, and even when they don’t, patients with uncontrolled

Without an attack

Inflammation is still present, and the airway reacts sensitively to minor stimuli

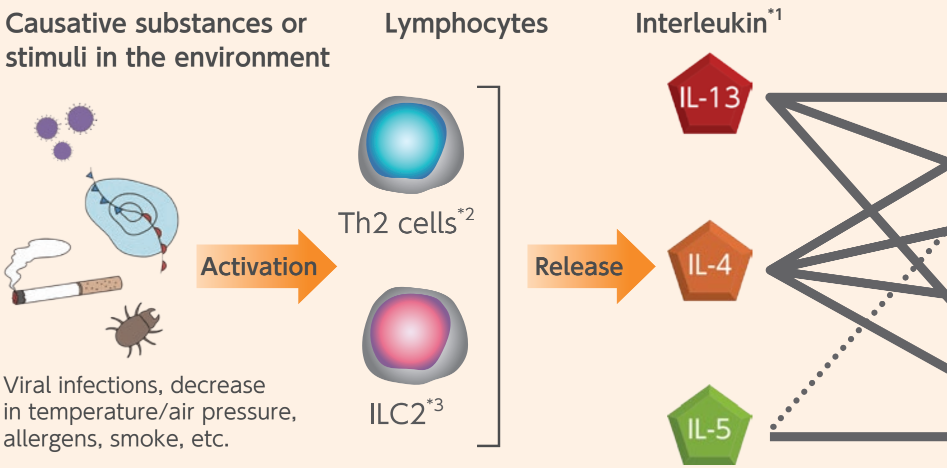




Cross-section of airway

Causative substances or stimuli in the environment

What is happening in your airways



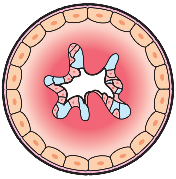
When the airways are stimulated by allergens or viral infections and Th2 cells and ILC2 c
not only harms the airways directly; it also stimulates other allergic cells to release even r

*1 Interleukin (IL): A protein involved in cell-to-cell communication. Action differs depending on the IL number. *2 Th2 cells:
cells but respond less to steroids. *4 B cells: Cells that change into plasma cells and release IgE antibodies when stimulated by
substances when allergens bind to those antibodies. *6 Eosinophils: Cells that release inflammatory substances when activated.

asthma have inflamed airways, so they are sensitive to stimuli.

When you have an attack

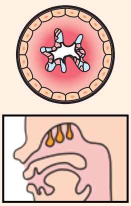
Inflammation increases,
the airway narrows, and airflow is obstructed

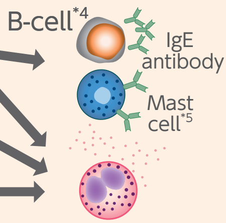


Chest tightness, cough,
difficulty breathing

Attack occurs

Actions (partial listing)





- Thickening of airway wall
- Excessive secretion of mucus (sputum)

- Nasal polyps develop
- Excessive secretion of mucus (nasal mucus)

Mast cells are activated and lots of inflammatory substances are released

Eosinophils are activated in the airway and destroy cells in the airway

〈Symptoms〉

Difficulty breathing
(reduced respiratory function)

Loss of sense of smell.
Nasal discharge/stuffy nose

Airway becomes hypersensitive
(more apt to react to stimuli)

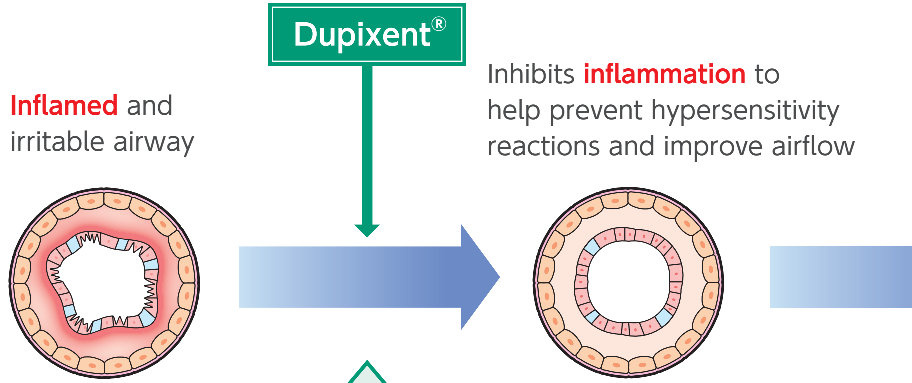
Airway becomes **narrower and stiffer**

ells are activated, key inflammatory substances such as IL-4, -5 and -13 are released. This more inflammatory substances, further narrowing and irritating the airways.

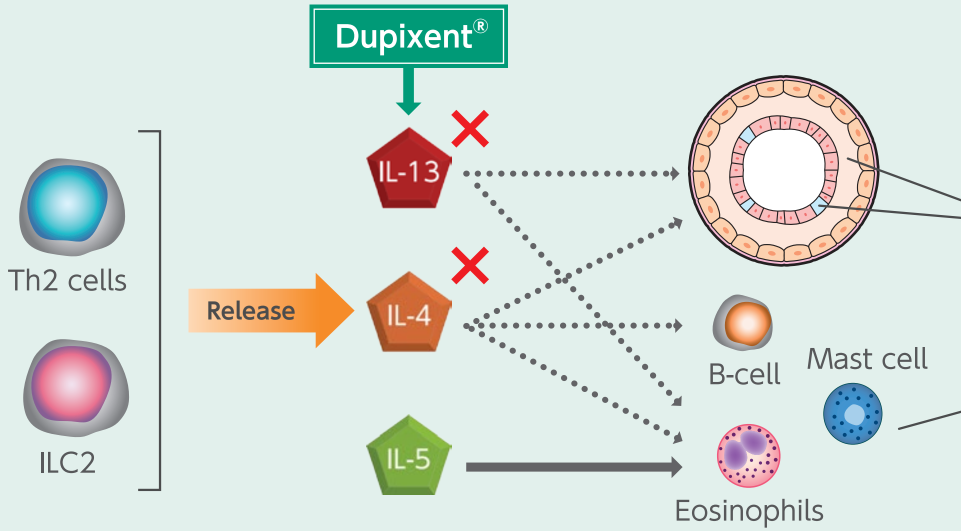
Lymphocytes that play a major role in allergic inflammation. *3 ILC2: Type 2 innate lymphoid cells. Have the same action as Th2 IL-4. *5 Mast cells: Cell that binds to IgE antibodies released by B-cells (plasma cells), causing release of more inflammatory

How Dupixent® works (in bronchial ast

Dupixent® improves airflow so stimuli are less likely to cause attacks and



■ Dupixent® inhibits the function of substances called IL-4 broad-range improvement in airway inflammatory narrowing and hypersensitivity and preventing the



hma)

coughing.

Patient is less likely to have a reaction even if substances or stimuli that cause asthma are present in the environment

〈 Expected response to Dupixent® 〉

Ease of breathing	Improves
Number of exacerbations (attacks)	Decreases
Levels of airway inflammation indicators • Total serum IgE • Fractional exhaled nitric oxide (FeNO) concentration	Decreases

and IL-13. This brings about a routes, thereby reducing airway onset of inflammation.

Watch videos for details
*Only available in Japanese

〈 What happens in your airways 〉

- Inhibits thickening of airway wall
- Inhibits excessive secretion of mucus (sputum)

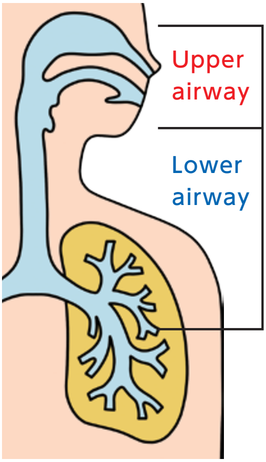
Inhibits the activation of allergic cells and release of inflammatory substances

Reduces narrowing of airways (Airflow is improved)

Reduces airway hypersensitivity (Less apt to react to stimuli)

Inhibits airway inflammation

Dupixent® works against nasal symptoms, too



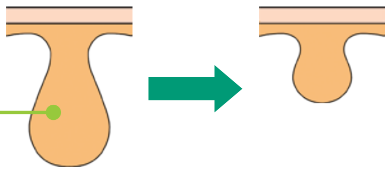
- The path of air is called the "airway" and is divided into the "upper airway" and the "lower airway" (left figure).
- Asthma that occurs in the "lower airway" and nasal symptoms that occur in the "upper airway" both occur due to airway inflammation. Nasal symptoms may worsen asthma.
- Because Dupixent® is effective in inhibiting airway inflammation, it is expected to be effective not only for asthma but also for nasal symptoms.

Expected effects of Dupixent® against nasal symptoms

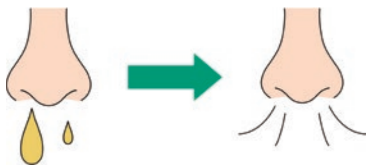
- Makes nasal polyps smaller

A protruding growth that forms when the inner walls of the nasal cavity become swollen with inflammation and hang down. Can cause nasal congestion, etc.

Nasal polyp



- Improves nasal congestion
- Improves loss of smell
- Improves nasal discharge



Who can use Dupixent®?

Dupixent® may be right for you if the following apply.

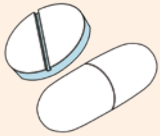
Your daily treatment is:

Moderate- to high-dose inhaled corticosteroid

+

Other long-term control medications

(long-acting beta 2 stimulator, leukotriene receptor antagonist, etc.)



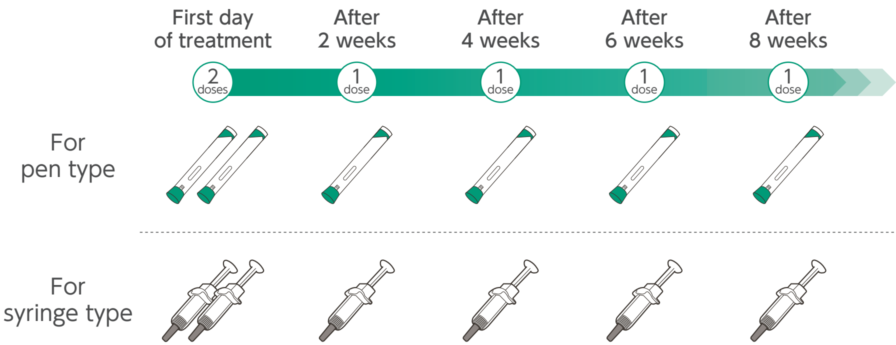
You still have problems even if you are following treatment correctly.

You cannot control your asthma

You often use oral steroids and cannot stop taking them

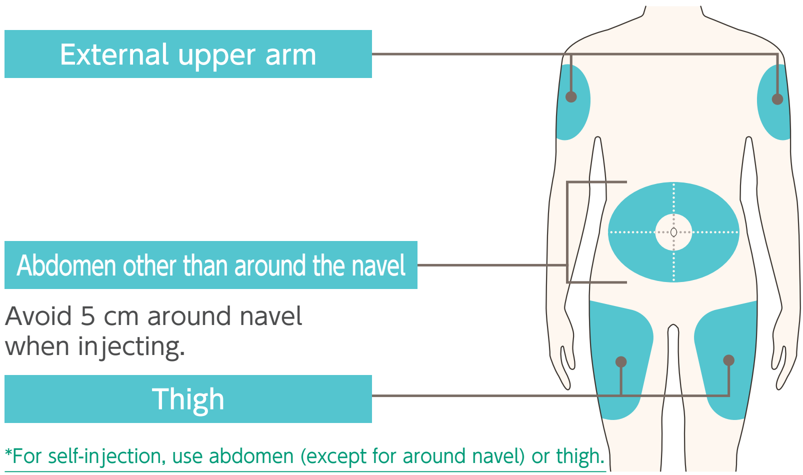
What happens in treatment with Dupixent® ?

The first time you use Dupixent®, you will need to inject 2 doses at once. After that, you will only have to inject one dose every 2 weeks.



Dupixent® is a "long-term control medication" that is used continuously to achieve good control of asthma. It can be administered without interruption even when you are feeling poorly, such as during an asthma attack.

Inject into upper arm, abdomen, thigh, etc.



*For self-injection, use abdomen (except for around navel) or thigh.

What should I do about the medicine I am already taking?

Continue the long-term control medication you have been taking thus far, and add treatment with Dupixent®.

Dupixent® **is not a rescue medication (reliever).** Follow your doctor's instructions when you have an asthma attack.

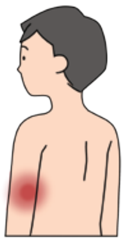
If you have been taking oral steroids for a long time, **do not suddenly stop taking them at your own discretion.** If you need to reduce the dose, consult your doctor.

Be sure to consult your doctor **if your asthma worsens or there is a change in your condition** after you start treatment with Dupixent®.

Major known side effects

Injection site reaction

This is a reaction in which pain, redness, swelling, itching, or bleeding occurs in the part you injected (arm, abdomen, thigh).



Redness, swelling

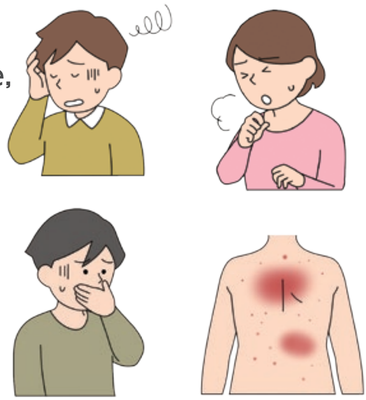
Itching

Side effects that are unlikely but require special attention

Symptoms due to anaphylactic reaction

This is a hypersensitivity reaction that generally occurs immediately after administration of medication. It has the following symptoms.

- Dizziness, lightheadedness, dizziness on standing up, lassitude, decreased consciousness
- Respiratory distress, wheezing when you breathe
- Abdominal pain, nausea, vomiting
- Itching, redness, swelling of skin, systemic rash
- Swollen lips or tongue, etc.



Japanese Society of Allergology: Anaphylaxis Guidelines 2022 (1st Edition), Medical Review Co., Ltd., 2023, p.2, 17, 18

Symptoms due to acute generalized exanthematous pustulosis

Dupixent® may cause acute generalized exanthematous pustulosis. The main symptoms include the following:

- Fever
- Widespread appearance of red skin, a rash with tiny pustules appears here and there, etc.

Symptoms due to increase in eosinophil count

Dupixent® may cause a temporary increase in blood eosinophil count in some patients. A slight increase in eosinophil count alone is not usually associated with symptoms, but the following symptoms may occasionally occur:

- Cough, fever, lassitude, shortness of breath, respiratory distress, wheezing when you breathe, bloody sputum (phlegm mixed with blood)
- Palpitations, difficulty breathing
- Rash, swelling
- Hand and foot numbness, paralysis(difficulty moving), etc.

Administration of Dupixent® can cause side effects. If you experience side effects, tell your doctor, nurse, or pharmacist immediately.

"Self-injection" is possible with Dupixent®

Dupixent® gives you 2 options: you can choose to receive it at hospital every 2 weeks or take it home and inject it yourself (self-injection).

Self-injection can save you time and reduce your burden of hospital visits; the following patients will find it easier to continue treatment.

If you have experienced any of these, consult your doctor

- You have to take a day off when you have to see a doctor
- You planned to go on a trip during a long holiday, but the schedule conflicted with a hospital visit
- Visiting a hospital is not easy because it is very far
- When there is an epidemic outbreak of an infectious disease, you want to stay home as far as possible etc.

*Hospital visit frequency depends on asthma control status. Consult with your doctor when making office visit appointments.

How to start self-injection

First, get instructions from the doctor or nurse about self-injection of Dupixent® and practice at the hospital. When the doctor or nurse has confirmed that you can inject yourself properly, they allow you to start self-injection.

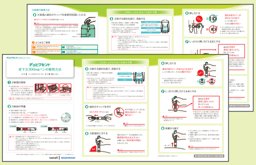
Support tool for self-injection

Dupixent® is equipped with a support tool that helps you inject it with peace of mind. You can also get information on how to use it and the high-cost medical care benefit system on the website for patients or Dupixent® Consultation Office (▶See the back cover).

Dupixent® starter kit

Self-injection Guidebook

How to use Dupixent®



Treatment Diary

Preparation Mat

Cooling bag for injection

Bag with cold retaining function to carry the medication

Disposal bag

Bag to dispose of used injectors

Email service to inform you of injection date

Informs you of injection date by email

Pocket card for patients with allergic diseases other than asthma

After starting treatment with Dupixent®, cut off the card on the right-side and fill out the necessary information. Then, show the card to your allergy doctor.

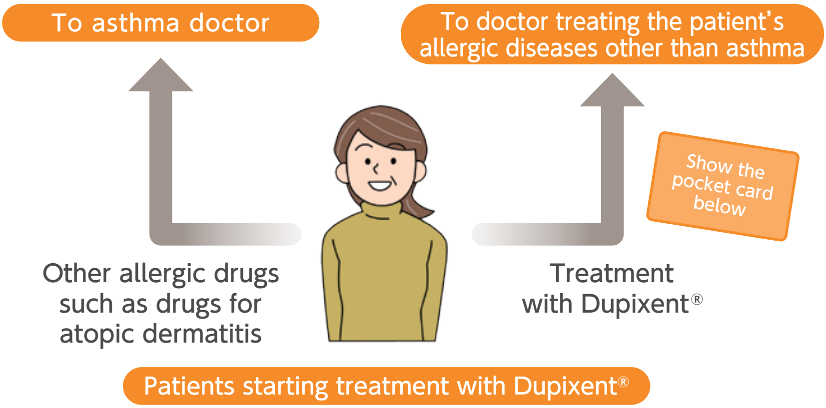
▼ Cut along the dotted line.

To doctor treating the patient's allergic condition other than asthma

This patient or his/her family member just started Dupixent® for treatment of asthma. Dupixent® is a monoclonal antibody agent that inhibits the binding of IL-4 and IL-13 to receptors. Treatment with Dupixent® may affect symptoms of allergic diseases other than asthma. Please advise your patient or his/her family not to reduce or discontinue any medications, including those for allergic conditions, based on their own discretion.

Precautions for allergic conditions other than asthma

Dupixent® can cause changes in the symptoms of allergic conditions other than asthma. If you are seeing another doctor about some other allergic condition, you need to keep both doctors informed about your treatment from the time you start taking Dupixent® until after you stop. **Be sure to tell your asthma doctor if you have allergic diseases other than asthma (atopic dermatitis, chronic sinusitis, allergic rhinitis, urticaria, etc.). Also, tell the doctor treating you for the other allergic condition that you are using Dupixent®.**
Don't reduce or stop medication for atopic dermatitis, chronic sinusitis, allergic rhinitis, or urticaria at your own discretion. Be sure to follow your doctor's instructions.



▼ Cut along the dotted line.

To patient who has been treated for allergic diseases other than asthma and his/her family

Please show the back side of this card to your allergy doctor.

Start date of Dupixent® :　　　/　　　/

On Dupixent® treatment

Hospital:

Doctor-in-charge:

Hospital contact:

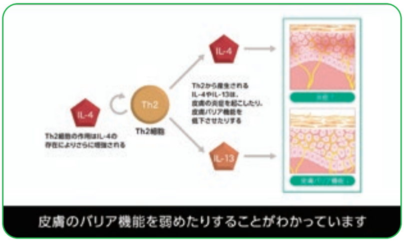
Pocket card for patients with allergic diseases other than asthma

After starting treatment with Dupixent®, cut off the card on the left side and fill out the necessary information. Then, show the card to your allergy doctor.

Learn about Dupixent® through the videos

Videos and websites shown here help you to use Dupixent® properly. Scan the QR codes below using your smartphone to watch videos or access websites.

1. How Dupixent® works

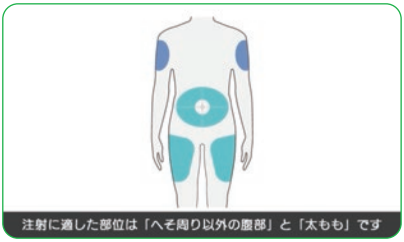


Check here for more information
(Only available in Japanese)

Viewing time:
2 m 44 s

Viewing time:
5 m 58 s

2. How to perform self-injection



Viewing time:
1 m 49 s

3. What is the starter kit?

Viewing time:
2 m 24 s
*Only available in Japanese

For patients using syringe-type Dupixent®

*Only available in Japanese

Website for patients who use Dupixent®

https://www.support-allergy.com

Explains the symptoms of bronchial asthma and provides product information on Dupixent® and other useful information.
*Japanese-language website

Website for patients with allergic diseases in Japan

アレルギーi

https://www.allergy-i.jp

Allergy information site for patients aiming to maintain their usual performance while dealing with allergies.
*Japanese-language website

For questions about how to operate Dupixent® injectors or the medical fee support system, please contact the Dupixent® Consultation Office.

Dupixent® Consultation Office

An expert staff member will take your call

Toll-free number **0120-50-4970**

1 Questions about how to operate injectors
24 hours a day, 365 days a year

2 Questions about the medical fee support system
Mon. to Sat. (closed Sun.and holiday) **9:00 to 21:00**

* Service 2 offers a rough estimate of medical fees based on the medical fee support system; we cannot respond to queries about medical practices or the details of treatment. Furthermore, as the medical fee support system varies according to municipality, please contact the city, town, or village in which you live.
* Dupixent® Consultation Office records calls for the purpose of improving our customer service. Thank you in advance for your understanding.

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