

Risk Management Plan (RMP)

This material was prepared based on the Risk Management Plan.

For Persons Undergoing Treatment for Psoriasis with Bimzelx®

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Introduction

What would you like to do if your psoriasis symptoms improve?



In the treatment of a disease, it is extremely important to understand well the disease and treatment and set a goal for treatment. Psoriasis is considered a disease that affects patients both mentally and physically because they become unable to do what they want depending on their symptoms. Among several therapeutic options for psoriasis, you may have chosen Bimzelx®, one of the biologic therapies, to become able to do what used to be difficult for you.

All healthcare professionals engaged in psoriasis treatment are your supporters who will help you attain your treatment goal.

Consult them if you have any concerns during your treatment.

Proceed together with your doctor toward your treatment goal.

Features of Bimzelx® < For Psoriasis Vulgaris, Pustular Psoriasis, and Psoriatic Erythroderma >

Bimzelx® Dosing Regimen < For Psoriasis Vulgaris, Pustular Psoriasis, and Psoriatic Erythroderma >



About Bimzelx®

Psoriasis is a condition characterized by inflammation in the skin caused by immune cytokines such as IL-17A and IL-17F. Bimzelx® binds to IL-17A and IL-17F and inhibits their action, thereby improving the symptoms of psoriasis.¹⁾

Inflammation caused by excessive action of proinflammatory cytokines IL-17A and IL-17F

(Image diagram)

Erythema, scales

Stratum corneum

Epidermis

IL-17A/F

IL-17A/F

IL-17A/F

IL-17A/F

IL-17A/F

IL-17A/F

IL-17A/F

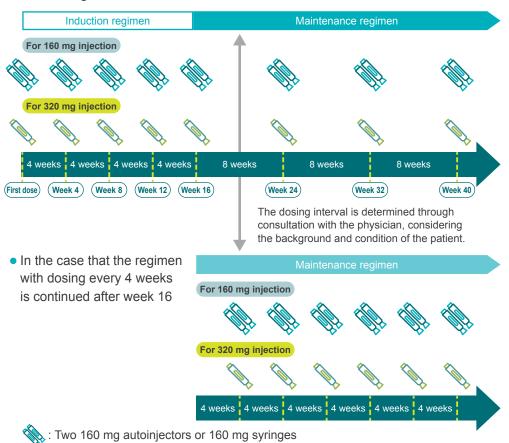
* Cytokines are substances that protect the body from bacteria and fungi. However, when produced in large amounts, they can cause inflammation of the skin and swelling of joints.²⁾

Normally, 320 mg (two 160 mg injections or one 320 mg injection) is subcutaneously administered every 4 weeks from the first dose through week 16, and every 8 weeks thereafter.

Self-injection is an option only for administration every 4 weeks.

- * Subcutaneous injection every 4 weeks may be continued after week 16 depending on the condition of the patient.
- Normal regimen

: One 320 mg autoinjector



1) Based on the Bimzelx package leaflet, modified May 2025 (7th edition)

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¹⁾ Based on the Bimzelx package leaflet, modified modified May 2025 (7th edition)
2) Komine M, et al., eds.: Chapter 1. Basic Understanding of Psoriasis. In: Helpful in Need: STEP UP Diagnosis and Treatment of Psoriasis.

Tokyo: Medical Review Co., Ltd.; 2019: 30–33, 42–51

Features of Bimzelx® < For Psoriatic Arthritis >

Bimzelx® Dosing Regimen < For Psoriatic Arthritis >

About Bimzelx®

Psoriatic arthritis is a condition characterized by inflammation and bone destruction in the joints caused by immune cytokines such as IL-17A and IL-17F. Bimzelx® binds to IL-17A and IL-17F and inhibits their action, thereby improving the symptoms of psoriatic arthritis.¹)

Inflammation and bone destruction caused by excessive action of proinflammatory cytokines IL-17A and IL-17F

(Image diagram)

Pain or swelling in joints, joint deformity

Bone destruction in the joints, with expected improvement in psoriatic arthritis

(Image diagram)

IL-17F

Bone destruction

IL-17A/F

IL-17A/F

IL-17A/F

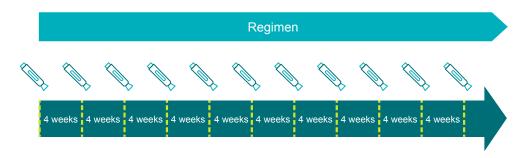
IL-17A/F

IL-17A/F

IL-17A/F

* Cytokines are substances that protect the body from bacteria and fungi. However, when produced in large amounts, they can cause inflammation of the skin and swelling of joints.²⁾

Normally, 160 mg per dose (one 160 mg injection) is subcutaneously injected every 4 weeks.



: One 160 mg autoinjector or 160 mg syringe

Bimzelx[®] Injection

Bimzelx® is an injectable treatment. Bimzelx® injection is administered by a healthcare professional at a medical institution or may be self-injected.* Self-injection is an option only for administration every 4 weeks.

Injected at a medical institution



Self-injection*



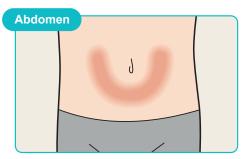
Please use this Guide Booklet for self-injection.

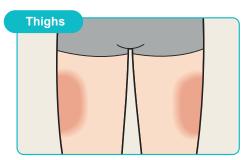


* Observe the decision by a physician regarding the availability of self-injection. For self-injection, it is necessary to receive training by healthcare professionals to ensure adequate understanding and a safe procedure.

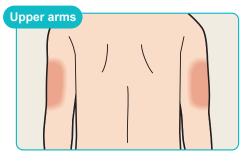
Bimzelx® Injection Sites

Recommended injection sites are the abdomen, thighs, and upper arms. If injection is performed by the patient, subcutaneously inject in the abdomen or thigh. If persons other than the patient perform the injection, the upper arm is also an option.





Avoid the area around the navel (about 5 cm).



For injection by other persons

* Even if the injection is given by any person other than you, be sure to receive guidance on how to inject Bimzelx®.

Precautions

- When two syringes are administered in one dose, the sites of the two injections should be at least 3 cm apart.
- Inject at a site different from the previous injection.
- Avoid a 5 cm area around the navel for injection in the abdomen.
- Avoid areas with dermal symptoms (such as redness, rash, peeling scales, bumps, and hardness), injury, or pain.
- If you are allergic to alcohol swabs, notify your doctor, nurse, or pharmacist.

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Before Starting Treatment with Bimzelx®



If you have history of the following diseases, be sure to notify your doctor before starting treatment with Bimzelx[®].

Tuberculosis

(TB may become active.)

☐ Inflammatory bowel disease (Including Crohn's disease and ulcerative colitis)

(Inflammatory bowel disease may worsen.)

Please also notify your doctor if:

- You have an infection or may be infected.
 (The infection may worsen.)
- You are pregnant or may be pregnant.
 (Treatment with Bimzelx® is an option only if the therapeutic benefits outweigh the risks.)
- You are lactating.
 (Continuation or discontinuation of lactation is determined by comparing the therapeutic benefits with the benefits of breast milk feeding.)
- You have received administration of a biologic.
 (If possible, notify the name of the medicine used.)

Before Starting Treatment with Bimzelx®

Most common adverse reactions with Bimzelx®

Most common adverse reactions with Bimzelx® reported in Japan and overseas include the following.

Oral candidiasis

Due to compromised immune function and a deteriorated oral condition, Candida, a type of resident fungus, abnormally increases, causing oral or tongue pain, white tongue fur adhesion, taste disorder, and other symptoms.



Upper respiratory tract infection / nasopharyngitis

Infection is usually caused by viral adhesion to the nasopharynx through the pharyngeal mucosa, causing runny nose, sneezing, nasal congestion, sore throat, and other symptoms.



Hypersensitive reaction

In rare cases, anaphylaxis (with a drop in blood pressure, difficulty breathing, etc.), atopic dermatitis, and other allergic reactions may result from treatment.



Be sure to notify your doctor if you notice any of these conditions.

Before Starting Treatment with Bimzelx®



Day of injection

Do not rub the injection site, and avoid stimulation.

Daily living

- To avoid infection, practice gargling, wash your hands, and keep regular hours.
- Be sure to consult your doctor before taking any vaccinations.
- Promptly consult your doctor if you hope to become pregnant and lactate.



If you suspect an adverse reaction

In addition to the most common adverse reactions mentioned on page 10, immediately consult your doctor, nurse, pharmacist, etc. if you have any of the following conditions.

- Oral pain, tongue pain or taste disorder
- Persistent cold-like condition, such as fever, coughing, runny nose, sore throat, headache, and chills
- Unusual rash (such as nettle rash) and itchiness of the skin
- Shortness of breath
- · Cold sweats or palpitations
- Sluggishness
- Abdominal pain, diarrhea, mucous or bloody feces
- Loss of weight or appetite
- Anal discomfort, pain, or abscess

Instructions for Daily Living

To prevent the worsening of psoriasis

Exercise and diet

- Because psoriasis is considered to be related to obesity, make a habit of adequate exercise.
- Because a fatty diet worsens psoriasis, eat moderately.
- Try to eat a balanced diet with vegetables full of minerals and vitamins.
- Avoid excess spicy or hot foods, as they may increase itchiness.
- Avoid excess alcoholic drinks, as they may increase itchiness due to increased blood circulation.

Clothing

- Choose loose-fitting clothes that do not rub against your skin.
- Choose soft materials that do not stimulate skin reactions.

Bathing

- Bathe in lukewarm water and avoid long baths, as hot water and excessive bathing may increase itchiness.
- Lather soap well and gently wash your body without scrubbing.

Others

- Avoid scratching as far as possible, as it may worsen the psoriasis.
- Although UV rays are considered effective for psoriasis, avoid excessive sun exposure in the summer.
- Keep your skin hydrated, especially in the winter, because dryness may worsen skin conditions.
- Try to quit smoking, as smoking may worsen the symptoms of psoriasis.