

For Persons Undergoing Treatment for Axial Spondyloarthritis with Bimzelx[®]

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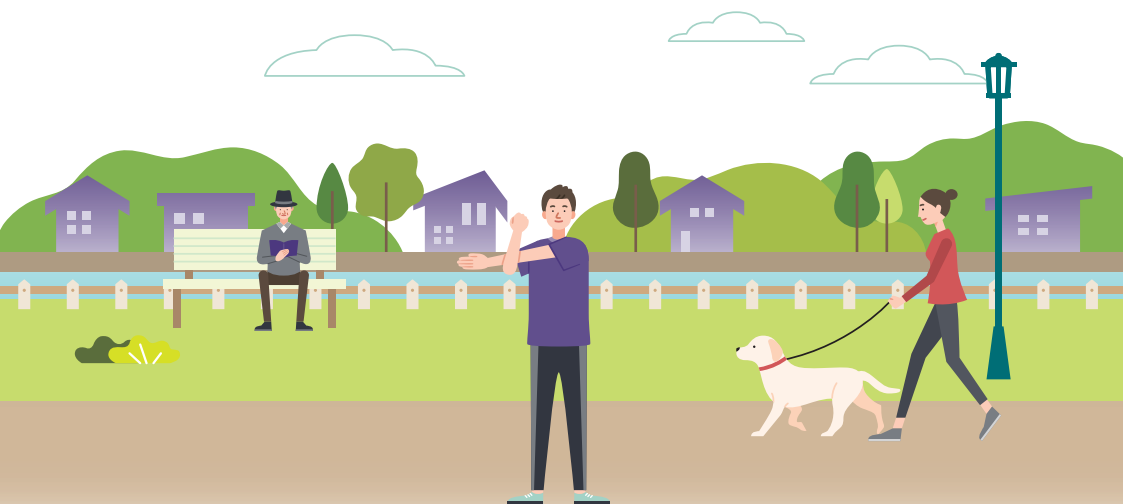
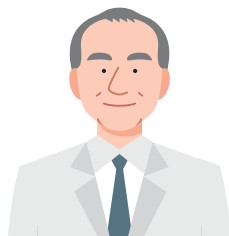


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Introduction

Working together to proceed with treatment for axial spondyloarthritis



Axial spondyloarthritis is a disease that includes “ankylosing spondylitis” and “non-radiographic axial spondyloarthritis (nr-axSpA).” The disease affects areas such as the hip, lower back, and neck, influencing daily life, work, and more. Since the disease itself is not well recognized, it can take a long time to diagnose after the patient develops symptoms. You may have visited many medical institutions before finally receiving a diagnosis of axial spondyloarthritis.

You have been properly diagnosed, so we can provide treatment tailored to your condition. Bimzelx® is one of the treatment options available to you.

Please talk with us if you have any questions or concerns about your treatment. We as healthcare professionals want to treat this disease together with you. Let’s work together to proceed with your treatment.

Characteristics of Bimzelx®

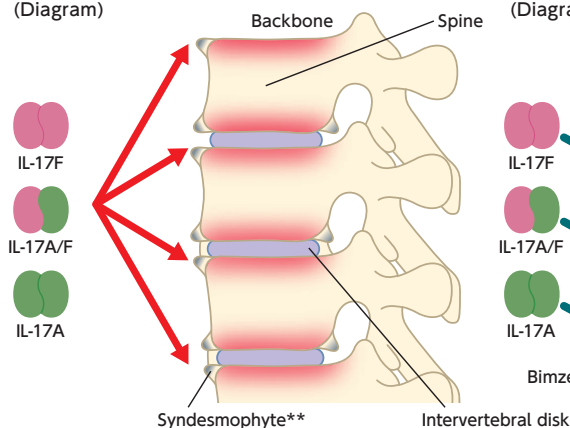
What is Bimzelx®?

Bimzelx® is a drug targeting IL-17A and IL-17F, cytokines* that trigger the symptoms of axial spondyloarthritis. Bimzelx® binds to these cytokines to inhibit their action, thereby preventing inflammation of the enthesis and joints and improving the symptoms of axial spondyloarthritis.¹⁾

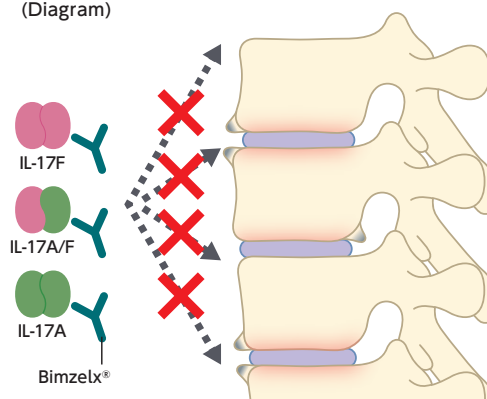
Inflammation and bone destruction caused by overactivation of proinflammatory cytokines IL-17A and IL-17F

Bimzelx® acts to inhibit inflammation and bone destruction in the joints, with expected improvement in both ankylosing spondylitis and axial spondyloarthritis

(Diagram)



(Diagram)



*Cytokines are substances released in the body by immune cells to protect the body from foreign matter. It is thought that axial spondyloarthritis and many other diseases develop if cytokines are produced in excess due to defects in the immune system. Increases in IL-17A and IL-17F are believed to cause inflammation and bone destruction in the joints, leading to onset and worsening of axial spondyloarthritis.²⁾

**As bone destruction progresses, a “spine-like” bony protrusion called a syndesphymite is formed. If the bone destruction becomes more advanced, syndesphymites grow and merge, making it difficult to bend the spine.³⁾

1)Package insert for Bimzelx, revised in May 2025 (7th edition)

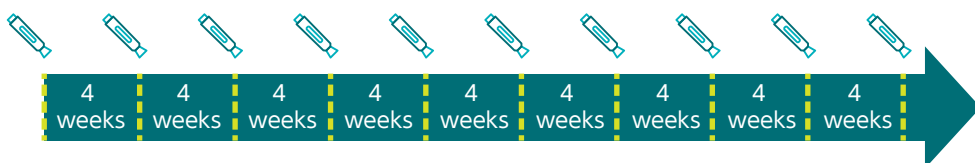
2)Sánchez-Rodríguez G, et al.: Int J Mol Sci. 18;24(12):10305, 2023.

3)The Japan Spondyloarthritis Society, ed.: Clinical Practice Guide for Spondyloarthritis in 2020. SHINDAN TO CHIRYO SHA, 2020.

Dosing Schedule for Bimzelx®

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

Treatment period



 : One 160-mg autoinjector or 160-mg syringe

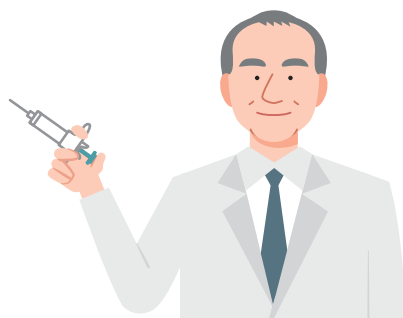
Bimzelx[®] Injection

Bimzelx[®] is supplied as an injection. Bimzelx[®] is self-injected* or may be administered at a medical institution.

Self-injection*



Injection at a medical institution



Please use this Guide for self-injection.

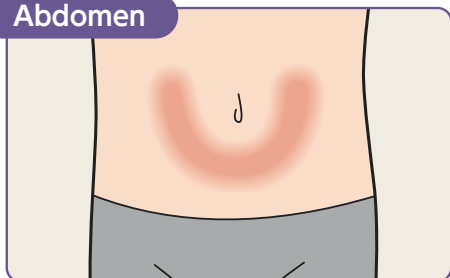


*A physician decides whether or not to allow self-injection of Bimzelx[®]. It is necessary to receive training from healthcare professionals to ensure adequate understanding of self-injection and proper procedures.

Bimzelx[®] Injection Sites

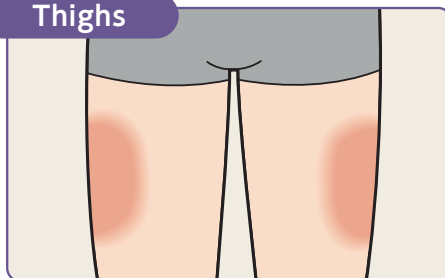
The recommended injection sites are the abdomen, thighs, and upper arms. For self-injection, inject the drug subcutaneously into the abdomen or thigh, not into the upper arm. If the drug is administered by individuals other than the patient, it can be injected into the upper arm.

Abdomen

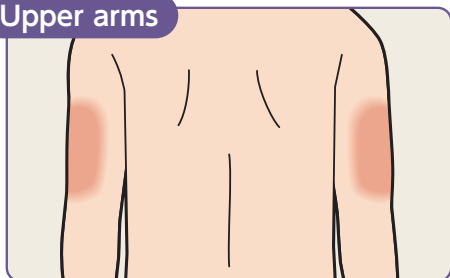


Avoid the area around the navel (about 5 cm).

Thighs



Upper arms



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

- Inject at a different site from the previous injection.
- Avoid the area around the navel (5 cm) for injection in the abdomen.
- Avoid areas with skin 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.

Before Starting Treatment with Bimzelx[®]

What you need to check before starting treatment

If you have had any of the diseases listed below, make sure to notify your doctor before starting treatment with Bimzelx[®].

☐ **Tuberculosis**

(Tuberculosis may become active.)

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

(Inflammatory bowel disease may worsen.)

Also, please notify your doctor if:

- **You have or may have an infection.**
(The infection may worsen.)
- **You are or may be pregnant.**
(You can receive Bimzelx[®] only when the expected therapeutic benefits outweigh the potential risks associated with treatment.)
- **You are breastfeeding.**
(Continuation or discontinuation of breastfeeding is determined by taking into account the benefits of treatment and breastfeeding.)
- **You have received biological agents.**
(If possible, notify the name[s] of the drug[s] you have used.)

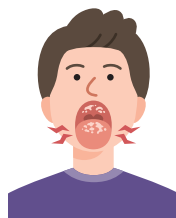
Before Starting Treatment with Bimzelx[®]

Most common adverse reactions to Bimzelx[®]

The most common adverse reactions to Bimzelx[®] reported in Japan and overseas include the following:

Oral candidiasis

Because of 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 pharyngeal mucosa through the nasopharynx, causing symptoms such as runny nose, sneezing, nasal congestion, and sore throat.



Hypersensitivity reaction

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



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

Before Starting Treatment with Bimzelx[®]

What you should consider when receiving Bimzelx[®]

Day of injection

- Do not rub or irritate the injection site.

Daily living

- To avoid infection, gargle, wash your hands, and keep regular hours.
- Make sure to consult your doctor before being vaccinated.
- Immediately talk with your doctor if you wish to become pregnant and breastfeed.



If you suspect that you are having an adverse reaction

In addition to the most common adverse reactions mentioned on page 8, immediately talk with your doctor, nurse, pharmacist, and other personnel if you have any of the following conditions:

- Oral pain, tongue pain, or taste disorder
- Persistent cold-like conditions, such as fever, coughing, runny nose, sore throat, headache, and chills
- An unusual rash (such as nettle rash) and itching
- 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 worsening of axial spondyloarthritis

Posture

- Pay attention to your posture at all times and try to straighten your back.
- Do not remain in the same position for a long time, and move as frequently as possible.
- Bend your knees when picking up objects.

Exercise

- Do stretching exercises after waking up and gradually increase movement of your body.
- For the movable parts of the body (spine and joints), try to move each part of the body equally.
- Actively engage in exercise and play sports comfortably; however, be very careful not to bump into others or fall.

Sleeping

- Use a flat hard bed if possible (but not too hard for you to sleep on).
- When you lie on your side, put a small, low pillow under your neck to stabilize it.
- Use a soft comforter to prevent your body from being compressed by bedclothes while sleeping.

Other

- Try to quit smoking, as smoking may worsen your condition.
- Try not to gain weight as much as possible in order to reduce pressure on the spine and joints.
- You are recommended to take a bath because it helps relax your body and mind, alleviate pain, and loosen the muscles.



For inquiries about our products, please contact the following:

UCBCares[®]

UCBCares[®] Contact Center

Tel: 0120-093-189

**Business hours: 9:00 a.m.–5:30 p.m. (excluding Saturdays,
Sundays, national holidays, and company holidays)**

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