PSORIATIC ARTHRITIS

STARTING TREATMENT WITH ERELZI®

HELPING YOU ACHIEVE YOUR TREATMENT GOALS

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 at https://www.report.novartis.com/

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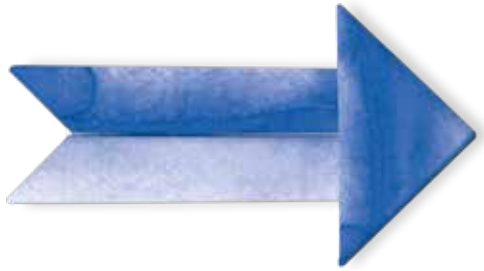
STARTING YOUR NEW TREATMENT

Your doctor has recommended that you start taking a biological medicine, known as a biologic.[1p26] This might be because your current medicine is not controlling your symptoms well enough or is causing side effects.[2p2]

BIOLOGICS HAVE MADE A BIG DIFFERENCE IN THE TREATMENT OF PEOPLE WITH PSORIATIC ARTHRITIS[3]

Your doctor has recommended that you start treatment with Erelzi®, which contains the active ingredient etanercept.[1p1,4p1] You will start to use it as soon as you or your carer learn how to inject it.[4p12]



THIS GUIDE WILL HELP YOU UNDERSTAND WHAT ERELZI® IS, WHY IT HAS BEEN PRESCRIBED TO YOU, AND HOW IT CAN HELP YOU.

BIOLOGICS — A SPECIAL TYPE OF MEDICINE THAT CAN MAKE A BIG DIFFERENCE[3]

BIOLOGICS MAY BE DIFFERENT FROM ANY TREATMENT YOU HAVE TRIED BEFORE. THEY ARE SPECIAL PROTEINS THAT ARE POWERFUL AND TARGETED THERAPIES.[5,6]

Most drugs are made by combining chemical ingredients.[5,7p4&p12] Biologics are different because they contain proteins that are made by living cells.[5,7p4] They are designed to act on a particular molecule, cell or other structure inside the body (a specific target).[8p25]

Biologics are often administered by an injection through the skin, while some are given by intravenous infusion (a drip).[8p29]

BIOLOGICS HAVE MADE A BIG DIFFERENCE TO PEOPLE WITH PSORIATIC ARTHRITIS[3]

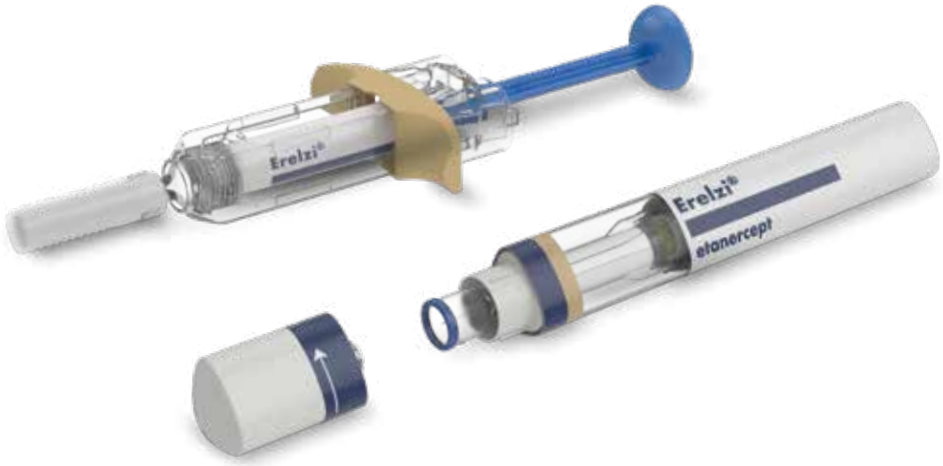
Inflammation is a normal process and occurs when the body fights against bacteria and viruses.[9] In autoinflammatory conditions such as rheumatoid arthritis,[10] psoriatic arthritis,[11] axial spondyloarthritis[12] and psoriasis,[13] the process is not controlled and the body targets its own tissue.[10] A substance called tumour necrosis factor (TNF) is overproduced in patients with these conditions, and this can lead to inflammation and damage to joints, as well as to other organs and body systems.[14-17]

Several biologics have been developed to block the effects of TNF and control inflammation.[18] These biologics are often referred to as anti-TNFs.[15p1] Erelzi® is an anti-TNF.[1p1&p8]

WHY ERELZI®?

The reference medicines of some biologics have now been available for more than a decade and their manufacturers' patent protection has now expired.[7p12] This means that other pharmaceutical companies are now allowed to produce 'biosimilars' which match the patent-free reference medicines.[19]

ERELZI® IS A BIOSIMILAR CONTAINING THE ACTIVE INGREDIENT ETANERCEPT[1p1]



Erelzi® contains the active ingredient etanercept,[1p1] and it matches the safety profile and clinical effect of the reference medicine.[20-26]

You might have to take Erelzi® on its own or with other medicine(s), as you would with the reference medicine.[1p2,4p2&p25]

TREATMENT WITH ERELZI®

HOW TO ADMINISTER ERELZI®

At the start of your treatment you will be trained on how to administer Erelzi®.[4p12] Erelzi® is injected under your skin (subcutaneous injection), using the device that was provided to you.[1p1] Erelzi® is available either as a pre-filled syringe or SensoReady® pen.[1p1] Your doctor or nurse can help you decide which is best for you.

Rest assured that, throughout your entire treatment with Erelzi®, you will be followed up by your doctor on a regular basis.

HOW TO STORE ERELZI®

Erelzi® should be stored in the refrigerator (2–8°C) and must not be frozen.[4p11] If you have a pack with several syringes or SensoReady® pens, please take one out of the pack for application and return the rest to the refrigerator straight away.[4p11] If you are travelling, please make sure to include a cool pack with your medicine and return the medicine to a refrigerator as soon as possible.[4p11]

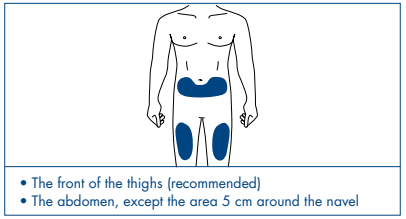
Erelzi® may be stored at temperatures up to a maximum of 25°C for a single period of up to four weeks, after which it should not be refrigerated again.[4p11] Erelzi® should be discarded if not used within four weeks of removal from refrigeration.[4p11]

WHEN TO ADMINISTER ERELZI®

To treat psoriatic arthritis, the recommended dose of Erelzi® is 25 mg twice a week or 50 mg once a week as an injection.[1p3,4p6] Your doctor will confirm the dose before you begin treatment.[4p6] They will also decide how long you should take Erelzi® and whether retreatment is needed.[4p6]

WHERE TO INJECT

Before injection, let Erelzi® reach room temperature (take the blister pack out of the refrigerator and leave unopened for 15 to 30 minutes).[4p11&p14] Erelzi® should be injected in one of these two sites:[4p14]



HOW TO DISPOSE

Dispose of the used syringe in a sharps container (closable, puncture-resistant container).[4p16] Do not throw away the used syringe with your household waste.[4p16]

GETTING READY TO START YOUR TREATMENT

You will be trained on how to administer your medicine, in order to get used to a new injection device.[4p12]

AFTER YOU OR YOUR CARER ARE COMFORTABLE WITH ERELZI® ADMINISTRATION, YOU CAN INJECT YOURSELF OR BE INJECTED AT HOME.[4P12]

Scan the QR code below to watch a self-injection demonstration video, using a pre-filled syringe.

Scan to watch

Scan the QR code below to watch a self-injection demonstration video, using the SensoReady® pen.

Scan to watch

This will give you the flexibility to inject when and where it suits your daily routine, and you may not have to go to the hospital as often.

Your doctor will evaluate your past medical history, as well as any allergies or other conditions you may have and the medications you take, before you can start treatment.[1p6-14,4p8-10]

You will also need to have some initial screening tests, which may include:

- Blood tests to evaluate if you have any ongoing infections[1p4-14]
- Tests for tuberculosis, which may include a chest X-ray, as treatment with biologics may lead to reactivation of latent (inactive) tuberculosis, and must not be initiated in patients with active tuberculosis[4p3]

THE SAFETY PROFILE YOU HAVE COME TO EXPECT

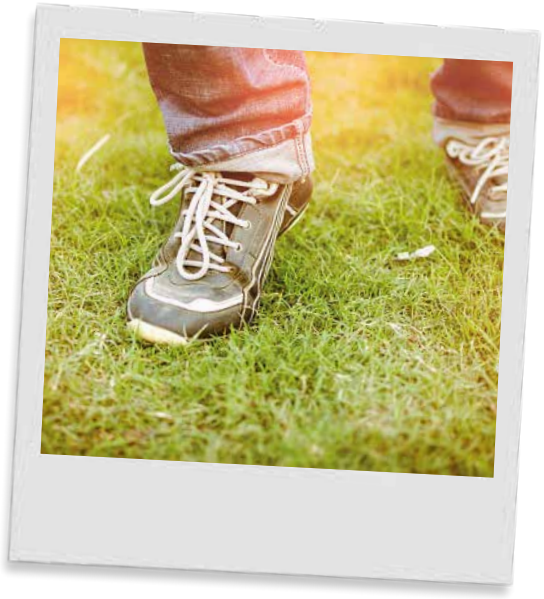
AS ETANERCEPT, ERELZI® HAS A WELL-KNOWN AND WELL-CHARACTERISED SAFETY PROFILE.[20,21]

IF YOU HAVE BEEN PRESCRIBED ERELZI®, AND WERE PREVIOUSLY TAKING ANOTHER ETANERCEPT, THERE ARE SOME THINGS YOU CAN BE REASSURED OF

Erelzi® was developed and proven to work against your disease in the same way that you're used to.[20-26] The diligent manufacturing process, with its high quality standards, delivers a medicine that provides the efficacy and safety that you would expect.[20-26]

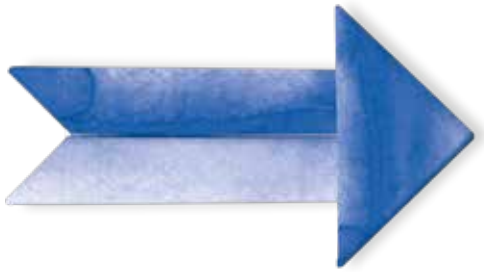
THE EFFECT OF ERELZI® WAS SHOWN IN A CLINICAL TRIAL CALLED EGALITY[21]

WHAT ARE THE NEXT STEPS?



You will receive training on how to use the injection device for Erelzi®.[4p12] Ask your doctor if you have any questions about how to use it, as it is important you are comfortable with it as soon as possible.[4p1&p8] If you are unable to inject yourself, your family or carer may be trained to inject you with Erelzi®.[4p14&p19]

If you feel unwell, contact your doctor immediately.[4,p3&p4&p8]



YOU SHOULD ALWAYS USE ERELZI® EXACTLY AS PRESCRIBED BY YOUR DOCTOR.[4P6] IF YOU FEEL THAT THE TREATMENT IS NOT RIGHT FOR YOU, TALK TO YOUR DOCTOR TO DISCUSS POTENTIAL OPTIONS REGARDING YOUR TREATMENT[4P7-8]

WHAT YOU CAN EXPECT FROM YOUR TREATMENT

If you've been given this leaflet, it is because your doctor thinks Erelzi® may help treat your condition.[4p1-2] However, the benefits and side effects of treatment vary from person to person.[4p8-10]

TALK TO YOUR DOCTOR FOR MORE INFORMATION ABOUT WHAT TO EXPECT FROM YOUR TREATMENT WITH ERELZI®[4P1]

POSSIBLE SIDE EFFECTS

Every medicine can have side effects, and over the course of your treatment, you may experience one or some of them, although not everybody gets them.[4p8] It is not possible to predict which side effects you may have, and they may vary in severity and duration.[1p6-14,4p8-10]

FREQUENT SIDE EFFECTS OF ERELZI® INCLUDE[4P9]

- Infections, including colds, sinusitis, bronchitis, urinary tract infections and skin infections
- Injection site reactions, including bleeding, bruising, redness, itching, pain, and swelling
- Fever
- Itching, rash
- Allergic reactions
- Antibodies against normal tissue

Please see the Patient Information Leaflet for less frequent side effects which might occur when taking Erelzi®.

No studies have been performed on effects on the ability to drive or use machines.[4p6] You should not be treated with Erelzi® if you are pregnant or breastfeeding.[4p5] Safety in pregnancy and lactation has not been established.[4p5]

Your doctor or nurse will be able to provide you with:

- The Erelzi® Patient Information Leaflet, which provides more information about your treatment

If you experience a side effect while taking Erelzi®, please consult your healthcare practitioner.

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 at https://www.report.novartis.com/

NOTES:

YOU ARE NOT ALONE

For more information and support please contact your healthcare provider and/or patient support nurse. You can also email Sandoz at

medical.za@sandoz.com

References: 1. Sandoz SA (Pty) Ltd. ERELZI® (solution for injection). Professional information. 26 January 2022. **2.** National Institute for Health and Care Excellence. Review of TA199; etanercept, infliximab, and adalimumab for the treatment of psoriatic arthritis (includes a review of NICE technology appraisal guidance 104 and 125), and TA220; golimumab for the treatment of psoriatic arthritis. May 29, 2013. Accessed June 13, 2022. https://www.nice.org.uk/guidance/ta199/documents/psoriatic-arthritis-etanercept-infliximab-and-adalimumab-review-proposal-appendix-b-proposal-paper-presented-to-the-institutes-guidance-executive2. **3.** Kamata M, Tada Y. Efficacy and safety of biologics for psoriasis and psoriatic arthritis and their impact on comorbidities: a literature review. IJMS. 2020;21(5):1690. doi:10.3390/ijms21051690. **4.** Sandoz SA (Pty) Ltd. ERELZI® (solution for injection). Patient information leaflet. 26 January 2022. **5.** What are "biologics" questions and answers. FDA. Accessed June 9, 2022. https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers. **6.** Biologics in rheumatoid arthritis (RA). NRAS. Accessed June 3, 2022. https://nras.org.uk/resource/biologics/. **7.** A patient's guide to understanding biosimilars. 2018. Global Healthy Living Foundation. Accessed June 3, 2022. https://creakyjoints.org/wp-content/uploads/2018/12/GHLF_Biosimilars_Patient_Guidelines_2018.pdf. **8.** Morrow T. Defining the difference: what makes biologics unique? Biotechnology Healthcare. Accessed June 2, 2022. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3564302/. **9.** Inflammation: what is it, causes, symptoms & treatment. Cleveland Clinic. Accessed June 6, 2022. https://my.clevelandclinic.org/health/symptoms/21660-inflammation. **10.** Rheumatoid arthritis (RA). CDC. Accessed June 6, 2022. https://www.cdc.gov/arthritis/basics/rheumatoid-arthritis.html. **11.** Psoriatic arthritis - symptoms and causes. Mayo Clinic. Accessed June 6, 2022. https://www.mayoclinic.org/diseases-conditions/psoriatic-arthritis/symptoms-causes/syc-20354076. **12.** Ankylosing spondylitis - symptoms and causes. Mayo Clinic. Accessed June 6, 2022. https://www.mayoclinic.org/diseases-conditions/ankylosing-spondylitis/symptoms-causes/syc-20354808. **13.** Psoriasis - symptoms and causes. Mayo Clinic. Accessed June 6, 2022. https://www.mayoclinic.org/diseases-conditions/psoriasis/symptoms-causes/syc-20355840. **14.** Yost J, Gudjonsson JE. The role of TNF inhibitors in psoriasis therapy: new implications for associated comorbidities. F1000 Med Rep. 2009;1. doi:10.3410/M1-30. **15.** Manara M, Sinigaglia L. Bone and TNF in rheumatoid arthritis: clinical implications. RMD Open. 2015;1(Suppl 1):e000065. doi:10.1136/rmdopen-2015-000065. **16.** Braun J, Sieper J, Breban M, et al. Anti-tumour necrosis factor therapy for ankylosing spondylitis: international experience. Annals of the Rheumatic Diseases. 2002;61(Supplement 3):51iii-60. doi:10.1136/ard.61.suppl_3.iii51. **17.** Mease PJ. Tumour necrosis factor (TNF) in psoriatic arthritis: pathophysiology and treatment with TNF inhibitors. Annals of the Rheumatic Diseases. 2002;61(4):298-304. doi:10.1136/ard.61.4.298. **18.** TNF inhibitors. American College of Rheumatology. Accessed June 6, 2022. https://www.rheumatology.org/I-Am-A/Patient-Caregiver/Treatments/TNF-Inhibitors. **19.** Understanding biosimilars. NPS Medicinewise. Accessed June 2, 2022. https://www.nps.org.au/consumers/understanding-biosimilars#what-is-a-biosimilar? **20.** Hofmann HP, Kronthaler U, Fritsch C, et al. Characterization and non-clinical assessment of the proposed etanercept biosimilar GP2015 with originator etanercept (Enbrel®). Expert Opin Biol Ther. 2016;16(10):1185-1195. doi:10.1080/14712598.2016.1217329. **21.** Griffiths CEM, Thaçi D, Gerdes S, et al. The EGALITY study: a confirmatory, randomized, double-blind study comparing the efficacy, safety and immunogenicity of GP2015, a proposed etanercept biosimilar, vs. the originator product in patients with moderate-to-severe chronic plaque-type psoriasis. Br J Dermatol. 2017;176(4):928-938. doi:10.1111/bjd.15152. **22.** Strand V, Girolomoni G, Schiestl M, et al. The totality-of-the-evidence approach to the development and assessment of GP2015, a proposed etanercept biosimilar. Curr Med Res Opin. 2017;33(6):993-1003. doi:10.1080/03007995.2017.1288612. **23.** Matucci-Cerinic M, Allanore Y, Kavanaugh A, et al. Efficacy, safety and immunogenicity of GP2015, an etanercept biosimilar, compared with the reference etanercept in patients with moderate-to-severe rheumatoid arthritis: 24-week results from the comparative phase III, randomised, double-blind EQUIRA study. RMD Open. 2018;4(2):e000757. doi:10.1136/rmdopen-2018-000757. **24.** Askari A, Sheeran T, Vazquez Coleman J, et al. Patient-reported outcome measures in patients with psoriatic arthritis who switched treatment from etanercept (reference or other biosimilar) to etanercept biosimilar GP2015: interim analysis of real-world data from the COMPACT Study. Paper presented at: EADV 30th Congress; 2021. **25.** Schmalzing M, Askari A, Sheeran T, et al. POS0608: Switching of treatment from reference etanercept to Sandoz etanercept biosimilar in patients with rheumatic diseases: an interim analysis of real-world data from the COMPACT Study. Ann Rheum Dis. 2021;80(Suppl 1):540. **26.** Jaworski J, Matucci-Cerinic M, Schulze-Koops H, et al. Switch from reference etanercept to SDZ ETN, an etanercept biosimilar, does not impact efficacy, safety, and immunogenicity of etanercept in patients with moderate-to-severe rheumatoid arthritis: 48-week results from the phase III, randomized, double-blind EQUIRA study. Arthritis Research & Therapy. 2019;21(1):130. doi:10.1186/s13075-019-1907-x.

S4 ERELZI® 25 mg (solution for injection). Reg. No.: 55/3.1/0392. Composition: Each pre-filled syringe contains 25 mg etanercept. S4 ERELZI® 50 mg (solution for injection). Reg. No.: 55/3.1/0393. Composition: Each pre-filled syringe/pen contains 50 mg etanercept. Pharmacological Classification: A3.1 Anti-rheumatics (anti-inflammatory agents). For full prescribing information refer to the Sandoz Professional Information approved by the South African Health Products Regulatory Authority (SAHPRA).

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