

AMGEN

Inflammation



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Patient information

What you need to know
about treatment with Otezla[®].

With best wishes from AmgenCare

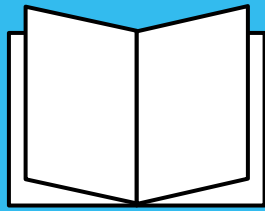
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Would you like to learn more about your diagnosis?

For more information, click here:

Brochures on psoriasis, psoriatic arthritis and Behçet's disease



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Dear patient,

Your doctor has prescribed treatment with Otezla® for you.

This is a medicine containing the active substance apremilast which is used for targeted treatment and alleviation of symptoms in people with chronic inflammatory diseases such as psoriasis, psoriatic arthritis and Behçet's disease.¹

This brochure has been designed to show you what a chronic inflammatory disease is, how the active substance apremilast works, how the medicine is administered and what you need to bear in mind when taking it.

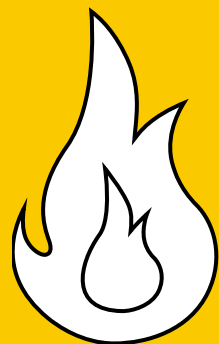
We are there to help you on your new path with your new medicine.

Take your time and read through each chapter. You can use the brochure for reference later on as well.

Of course, your own doctor is still your key point of contact person for any questions that may arise.

The package insert, which you will find in the box your medicine comes in, contains additional important information about Otezla®.

What happens when you have a chronic inflammatory disease?



Inflammation - a vital protective response.

When the immune system detects damaged body cells or intruders in the body it launches an attack. This may be triggered by pathogens or mechanical damage as well as heat, cold or nicotine. The defence response takes the form of inflammation. When the intruders or damaged body cells have been destroyed or degraded the defence response stops and the inflammation subsides.

Chronic inflammatory disease.

In people with a chronic inflammatory disease, this natural defence response does not switch off. The immune system starts to attack healthy body tissue as well. This causes chronic inflammation, which in most cases does not subside without treatment.

Treatment options.

Depending on the precise disease involved, various active substances are used to reduce inflammatory activity, alleviate pain and improve the quality of life of those affected. These include glucocorticoids, conventional therapies, biologics, JAK inhibitors or immunomodulators such as Otezla®.

How messenger substances work.

The body uses various messenger substances (cytokines) to control the immune system's defence response. Some messenger substances trigger inflammation, some maintain inflammation and other cause inflammation to subside. They are activated by specific enzymes such as phosphodiesterase 4 (PDE4). In this case the active substance apremilast in Otezla® goes to work, targeting the enzyme at the inflammation site and inhibiting it. That is why it is also referred to as a selective PDE4 inhibitor.

Otezla®¹ (apremilast): For treatment of chronic inflammatory diseases.

What is Otezla®?

The active substance in Otezla®, apremilast, is an oral immunomodulator which is prescribed for the treatment of chronic inflammatory diseases such as psoriasis, psoriatic arthritis and Behçet's disease.¹

What does an immunomodulator like Otezla® consist of?

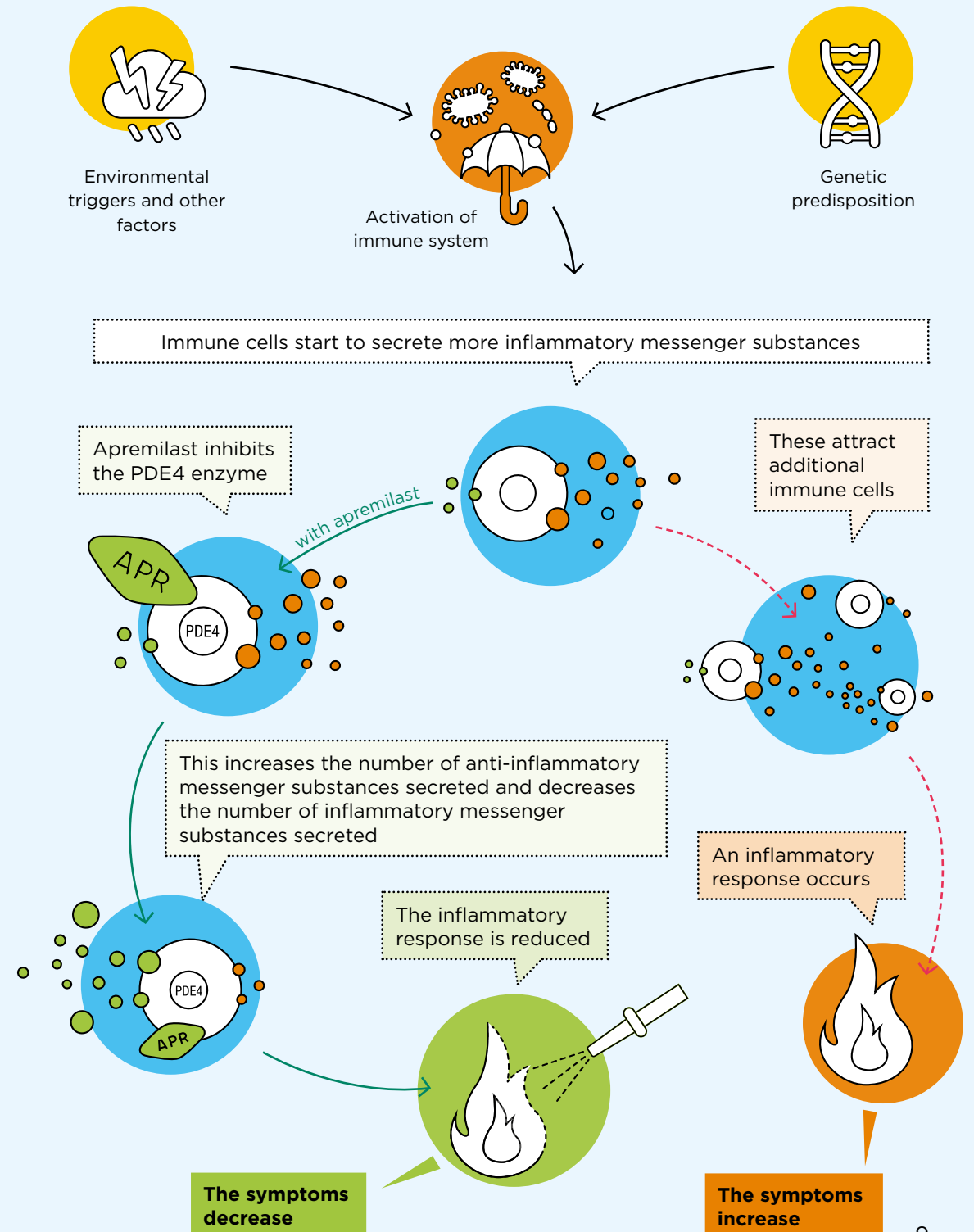
Immunomodulators are complex drugs that selectively target structures that cause disease. The structure targeted by apremilast is a specialised messenger substance in the immune system that causes inflammation, which it blocks at the inflammation site in a targeted manner.

How does apremilast work?

The active substance in Otezla®, apremilast, is a small synthetically manufactured molecule that inhibits the enzyme phosphodiesterase-4 (PDE4). When this special enzyme is blocked, the amount of anti-inflammatory messenger substances produced increases and that of inflammatory messenger substances decreases. This allows the inflammatory processes in the body, which cause the symptoms of the disease, to be reduced.

Otezla® is approved for the treatment of adult patients with active psoriatic arthritis (PsA), moderate to severe chronic plaque psoriasis and mouth ulcers that are associated with Behçet's disease.¹

How does Otezla® work on inflammation?²⁻⁴



Starting to take Otezla®.

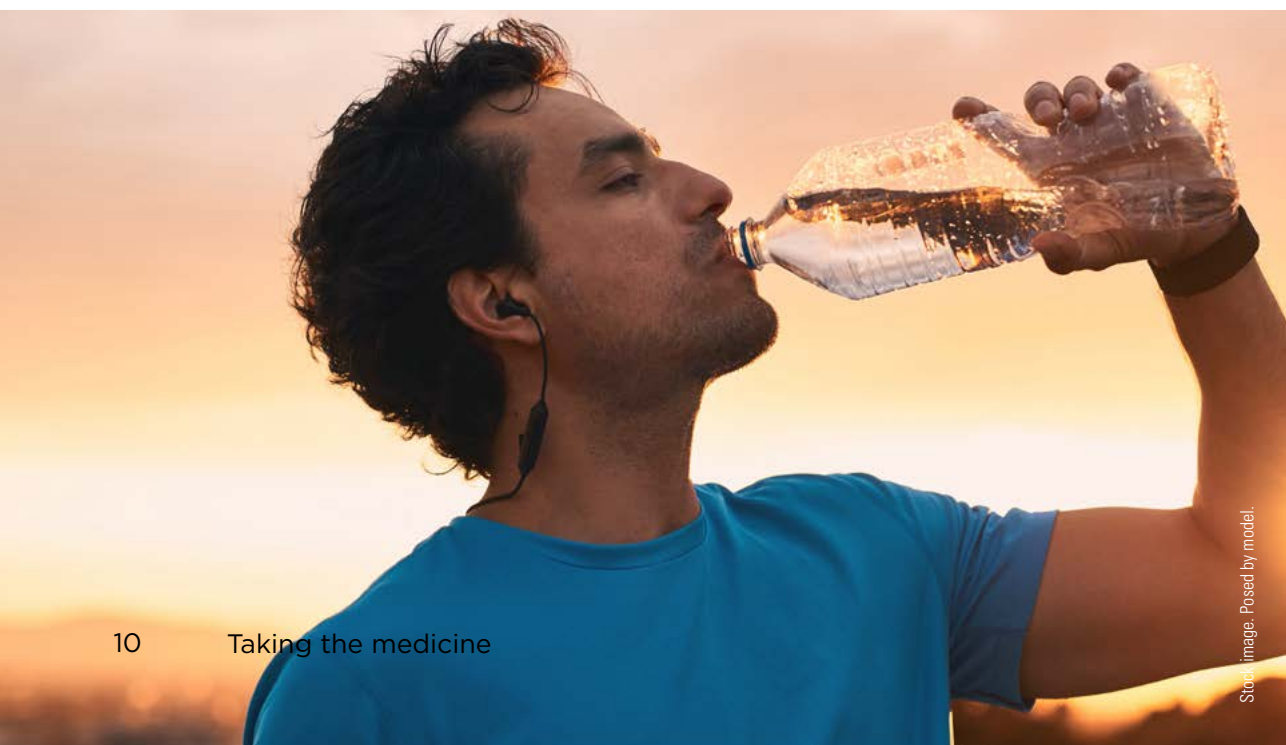
The starter pack contains a total of 27 tablets for the first 14 days. The dosage is increased gradually to allow your body to slowly get used to Otezla® and to alleviate any side effects that may occur: 4 x 10 mg, 4 x 20 mg and 19 x 30 mg.¹

The dosage schedule below is only a guide.

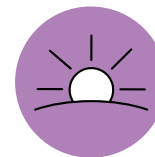
Please stick to the dosage schedule provided by your doctor.

Day 1	Day 2		Day 3		Day 4		Day 5		from day 6 onwards	
10 mg	10 mg	10 mg	10 mg	20 mg	20 mg	20 mg	20 mg	30 mg	30 mg	30 mg

morning evening



General notes on taking the medicine.



Take the tablets whole, with or without food in the morning and evening.

and evening.

Try to maintain a regular 12-hour interval.¹



If you forget to take a tablet

Simply take it later

on, unless it's almost time for the next dose. If you do miss a dose, omit the forgotten tablet and take the next one at the usual time. Don't double up on your dose to make up for a missed tablet.¹



Accidentally taken too high a dose?

Consult your doctor to find out what to do next.¹



If you are taking other medicines

(in particular rifampicin, phenytoin, phenobarbital, carbamazepine and St. John's wort) this can affect how Otezla® works.

If this is the case please talk to your doctor.¹

Please follow the instructions in the package insert.

Course treatment with Otezla®.

The long-term goal of your treatment is to support your immune system without suppressing it entirely. This immunomodulatory effect of Otezla® is also reflected in the course of the treatment. It takes time for your body to adapt to

the changes. The summary below shows the treatment process and roughly when you can expect symptoms to improve. All information is provided as a guide only and may differ from one individual to another.



Month 1:

The dose is gradually increased to allow the body to get used to the active substance. Diarrhoea and nausea may occur temporarily.⁵



Month 2-3:

The immune system is on its way to reaching a balance, some individuals may experience the first alleviation of symptoms.⁵



Month 4-5:

In most cases symptoms improve in the first 24 weeks of treatment.⁵



Month 6+:

You have reached the highest level of active substance you can have without affecting your improved quality of life.⁵

Please note the following safety instructions and always consult your doctor immediately if ...

- ... you are pregnant or breastfeeding.
- ... you have an allergic reaction to apremilast or another ingredient.
- ... you have a rare genetic galactose intolerance, lactase deficit or glucose-galactose malabsorption.
- ... you take medicines regularly or are prescribed new medicines.
- ... you have conditions that might affect the gastrointestinal tract (e.g. allergies or food intolerances).
- ... you have severely impaired renal function (if so the daily dose must not exceed 30 mg - half the usual dose).
- ... symptoms of an existing depression worsen, depression occurs for the first time, or suicidal thoughts occur.

See the package insert for more information and important warnings.

You should continue with the treatment even if you experience a considerable improvement in your symptoms. It's important to continue to take the medicine to ensure that Otezla® works and your condition improves over the long term.¹

Tips on using Otezla®.



What should I do if I have gastrointestinal symptoms?

In the first weeks of taking Otezla® your body first needs to get used to the new medicine. There may be side effects in this period. These side effects may include diarrhoea or vomiting. These symptoms generally occur within the first 2 weeks of

treatment and usually subside within the next 2 to 4 weeks. The symptoms can vary in their severity. Follow the tips below, in combination with advice from your doctor, to ensure you get through this initial phase without too much trouble.⁶



Take Otezla® with food.



Eat foods that bulk up the stool, such as bananas.



Ensure you have sufficient fluid intake (at least 2 litres per day), for example in tea or soup.



Avoid caffeine, sugar (e.g. in lemonade), alcohol and high-fat foods.



Have lighter, more frequent meals.



Cut down on dairy products.

You own personal treatment goals.

When you start your treatment, think about what you are expecting from it and what you want in terms of your symptoms.

For example, you might want to reduce the skin-related symptoms at highly visible sites. Or reduce pain at the sites affected. Or be able to take part in certain social or day-to-day activities you may have avoided recently.

Setting your own goals will make it easier for you to recognise how your treatment is progressing. What are the areas where your life has already improved and where is time still needed? Tell your doctor about the changes you have experienced in relation to your goals.



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AmgenCare is there when you need it

If you have any questions about Otezla® generally or about how to use it, you can call our MedInfo hotline (see reverse page of this brochure). If you'd like to have a long-term contact person to advise you on your treatment please contact our AmgenCare patient programme. Its medically and psychologically trained personnel will be happy to support you with your treatment.

You can also get lots of more detailed patient materials from AmgenCare.

Ask us about it, or visit our website:

www.amgencare.de

Telephone:

0800 264 36 44

Glossary

Arthritis

Inflammatory joint disease

Behçet's disease

Chronic inflammatory disease that can affect the entire body but is in most cases initially associated with ulcers in the mouth and genitals

Biologic (plural: biologics)

Biopharmaceutical products

Cytokines (messenger substances)

The body's signalling substances which are used, for example, to transmit signals between body cells. Some cytokines are involved in the immune response and inflammation processes.

Environmental triggers

Factors in the environment that can cause a condition to develop

Inflammation

The body's defence response to an unwanted stimulus; symptoms: increase in temperature, reddening, swelling, pain and functional impairment. Inflammation can occur almost anywhere in the body and be mild or severe.

Genetic predisposition

Hereditary predisposition

Glucocorticoids

Steroid hormones such as cortisone, which are produced in the adrenal cortex; they have various metabolic tasks and have an immunosuppressant and anti-inflammatory function. They can be applied externally to treat psoriasis and rheumatic conditions.

Immune cells

Cells of the immune system that are produced in greater quantities during inflammation

Messenger substances (cytokines)

The body's signalling substances which are used, for example, to transmit signals between body cells. Some cytokines are involved in the immune response and inflammation processes.

PDE-4 inhibitor (phosphodiesterase-4 inhibitor)

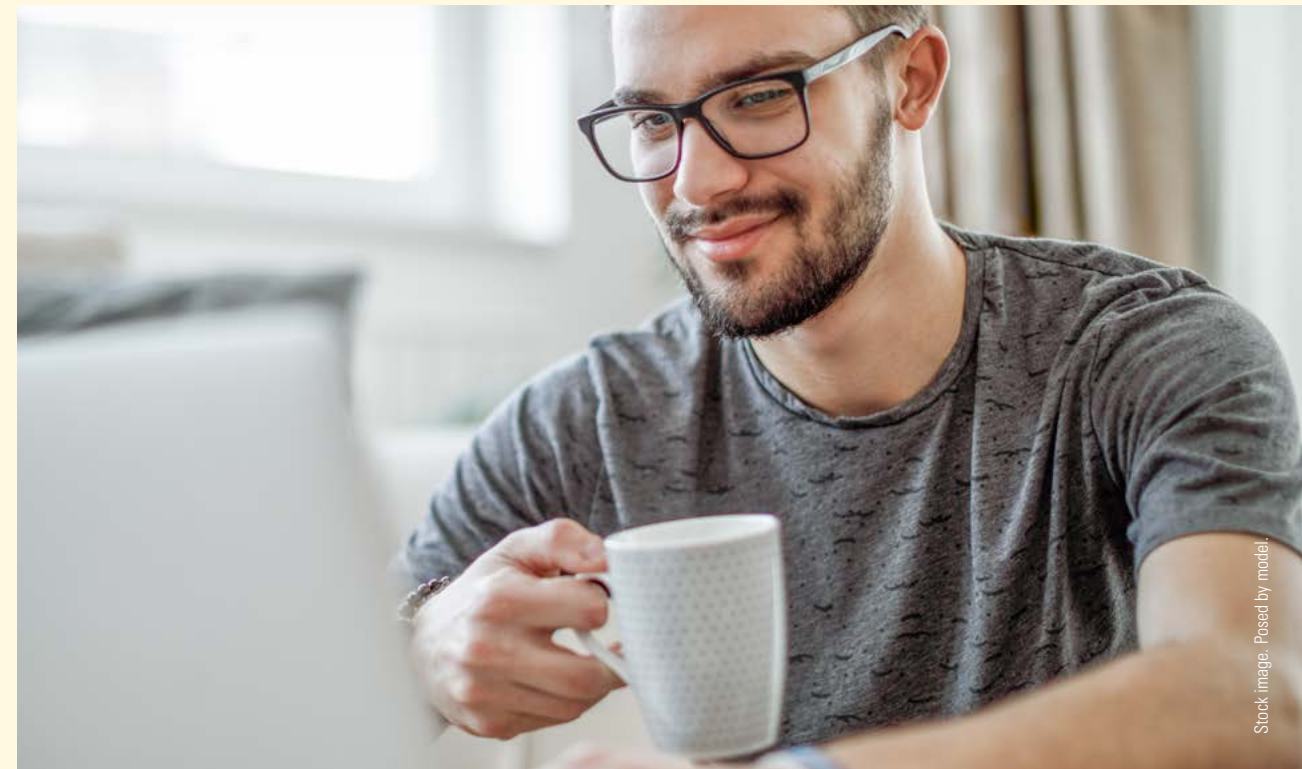
Substance that blocks the phosphodiesterase 4 enzyme, which is involved in the onset of inflammation

Psoriasis

Inflammatory disease of the skin

Therapeutic (plural: therapeutics)

Medicinal product



References:

- 1 Gebrauchsinformation Otezla®, Amgen GmbH.
- 2 Schäfer PH et al. Cell Signal 2014;26(9):2016–2029.
- 3 Schäfer PH et al. J Immunol Res 2015;2015:906349.
- 4 Gottlieb A et al. J Drugs Dermatol 2013;12(8):888–897.
- 5 Fachinformation Otezla®, latest version.
- 6 Pinter A et al. Hautarzt 2019;70(5):354–362.

Personal notes

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online at [medinfo.amgen.de](https://www.medinforamgen.de)



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