



Your guide to OTEZLA® (apremilast)

This booklet is intended for adults with moderate to severe chronic plaque psoriasis or active psoriatic arthritis who have been prescribed OTEZLA.

Please also read the Patient Information Leaflet that comes with your medicine or available at <https://www.medicines.ie/medicines/otezla-10mg-20mg-30mg-33255/patient-info>

Reporting of side effects:

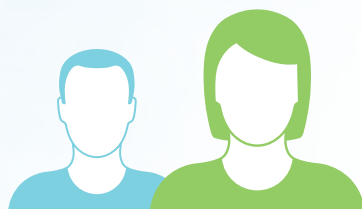
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. Side effects can be reported directly to the Health Products Regulatory Authority (HPRA) using the available methods via www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Amgen Limited on +44 (0) 1223 436441 or Freephone 1800 535 160.

Please report any potential quality issue with the Amgen product you have received, by calling us on +44 (0) 1223 436441 or Freephone 1800 535 160 and providing us with the details. Please ensure that you keep your packaging, so we are able to identify your product more easily.

Your guide to OTEZLA

This booklet has been created to help you understand and manage your treatment.

It contains practical information on how your medicine should be taken and how to get the best out of treatment, as well as information on the benefits of your medicine and the importance of staying on treatment.



This guide will:

- ◆ Provide you with information about taking OTEZLA for psoriasis or psoriatic arthritis
- ◆ Help you manage any side effects that you may experience while you are taking this medicine
- ◆ Help you find further sources of information and support

My personal treatment goals

NAME:

CONTACT NUMBERS:

In addition to using clinical measures, it is important for your doctor to know what treatment success looks and feels like for you. This page is a place for you to capture your personal goals. Try to discuss them during your consultations!

Help setting your goals

Here are some useful things to think about and discuss:

- ◆ Which of your current symptoms are bothering you the most?
- ◆ Are there any specific affected areas that you find particularly troublesome?
- ◆ Have you experienced any difficulty with certain day-to-day tasks?
- ◆ Has there been anything that you feel your symptoms have prevented you from doing or going to?

For example: “To be able to spend an hour gardening” or
“I want to be able to go for a swim”.

1

2

3

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What is OTEZLA, and why has my doctor prescribed it for me?

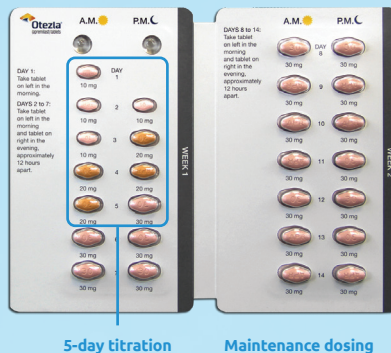
OTEZLA is a medicine for treating moderate to severe plaque psoriasis and psoriatic arthritis in adults. This medicine works in a different way to other medicines used to treat these conditions. It reduces the activity of an enzyme in the body called 'phosphodiesterase 4', which is involved in the process of inflammation.

OTEZLA has been shown to **reduce the inflammation** associated with psoriasis and psoriatic arthritis, and improve the signs and symptoms of these conditions.

It is only given to adults who have:

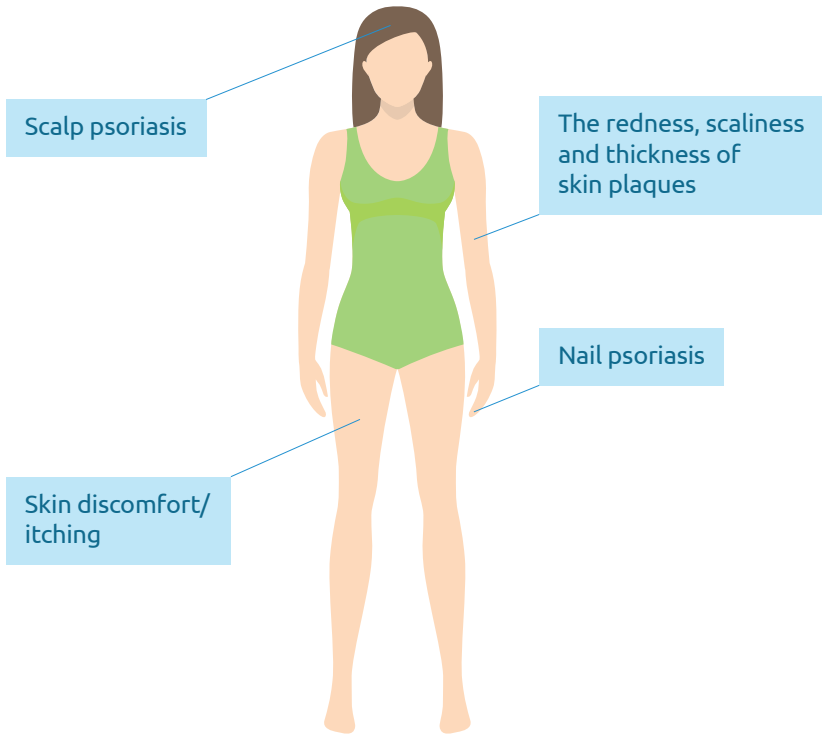
- ◆ Moderate to severe plaque psoriasis, in whom psoralen and ultraviolet-A light (PUVA), or medicines known as systemic therapies (eg. ciclosporin, methotrexate) have been unsuccessful, or in people who cannot use these treatments
- ◆ Psoriatic arthritis, in whom medicines called 'Disease-Modifying Antirheumatic Drugs' (DMARDs) have been unsuccessful, or in people who cannot use these treatments. It can be used alone or in combination with DMARDs.

This medicine comes as a tablet that you take orally (by mouth) at home.



How can OTEZLA help in treating my psoriasis?

Some people who took this medicine for 16 weeks in clinical trials had improvements in:

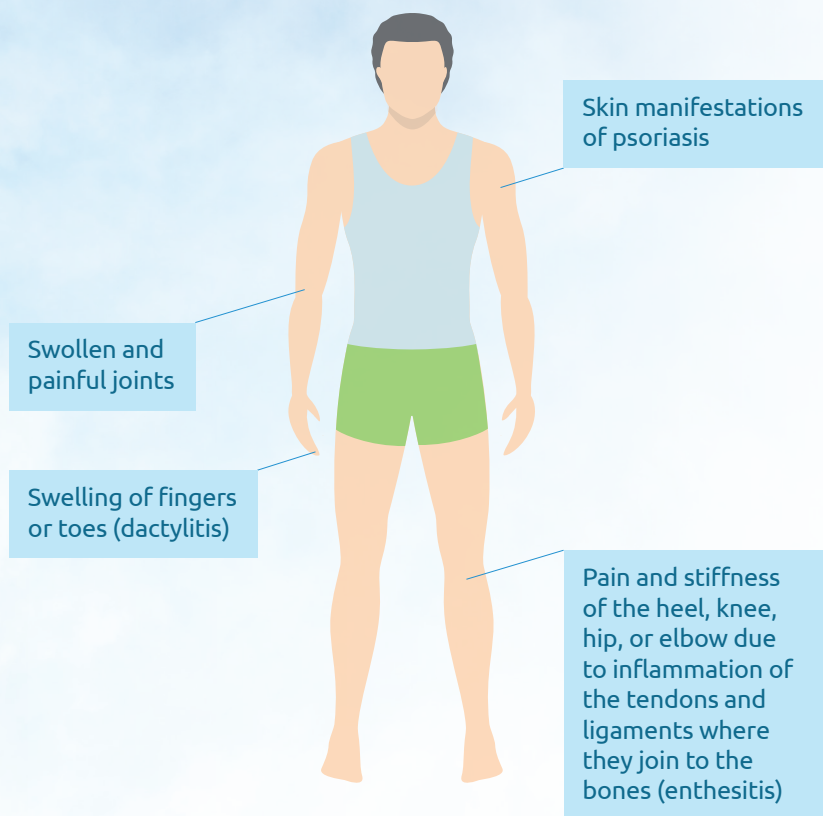


OTEZLA was also shown to improve quality of life in some people with psoriasis.

This means that the impact of your condition on daily activities, relationships and other factors should be less than it was before.

How can OTEZLA help in treating my psoriatic arthritis?

Some people who took this medicine for 16 weeks in clinical trials had improvements in:



OTEZLA can improve your general physical function and has also been shown to improve quality of life in some people with psoriatic arthritis

How could OTEZLA help me in my day-to-day life?

For some patients in clinical trials, this medicine has been shown to improve 'quality of life' in people with psoriasis or psoriatic arthritis.

Your 'quality of life' includes things like:

- ◆ The level of pain you experience
- ◆ Your social life and relationships
- ◆ How able and motivated you are to carry out your daily activities
- ◆ Your emotional wellbeing

For some patients in clinical trials, 'physical function' has been improved in people with psoriatic arthritis.

Your 'physical function' means your physical ability to do things like:

- ◆ Get out of bed
- ◆ Walk and move around
- ◆ Get dressed, comb your hair, put on make-up and other ways in which you maintain your appearance
- ◆ Take a bath or shower
- ◆ Reach and grip objects
- ◆ Carry out common daily activities
- ◆ Eat and drink














What dose of OTEZLA should I take?

Your doctor has given you a starter pack for the first two weeks of your treatment.

This pack contains individually packaged tablets in pop-out blisters with a calendar so that you can see what to take on each day. The amount of active ingredient contained within each tablet

gradually increases (titration) as you progress through the week. This is to help you get the right dose during your **first 6 days of treatment**.

It is therefore very important that you **take the correct tablet, at the correct time, on the correct day**. There is a calendar in the pocket of this booklet to help you keep track.

| | DAY 1 | DAY 2 | DAY 3 | DAY 4 | DAY 5 | DAY 6 AND BEYOND |
|------|---|---|---|---|---|---|
| A.M. |  |  |  |  |  |  |
| P.M. | |  |  |  |  |  |

- ◆ On the **first day** you will take only one tablet
- ◆ **From day two onwards**, you will take one tablet in the morning and then another in the evening, **approximately 12 hours apart**
- ◆ This dosing schedule is not recommended if you have **severe kidney disease**. If you have severe kidney disease you should speak to your doctor

Day 6 and beyond (maintenance dosing)

From day 6 onwards, you will take the same dose every day – one 30 mg tablet taken twice

a day. After the two-week starter pack a monthly maintenance pack will be prescribed.

To help you keep track of your dosing we have provided a calendar for you to fill in at the back of this booklet

How should I take OTEZLA?

OTEZLA tablets are film-coated tablets and should be swallowed whole, preferably with water.

Tips for taking your medicine:



The tablets can be taken with or without food.

You might find that taking your medicine with food may help if you are experiencing nausea (feeling sick)* in the first few weeks.



Take one tablet in the morning and one in the evening, approximately 12 hours apart.



Do not take two tablets at the same time.

What if I make a mistake when taking OTEZLA?

If you take more than you should:

- ◆ Talk to a doctor immediately or go straight to a hospital
- ◆ Take the medicine pack and the Patient Information Leaflet with you

If you miss a tablet:

- ◆ Take it as soon as you remember, but if it is close to the time you are due to take your next tablet, just skip the missed one
- ◆ Take the next tablet at your regular time
- ◆ Do not take two tablets together to make up for a forgotten tablet

*This is discussed in more detail later on in this booklet.

What do you need to know before taking OTEZLA?

Talk to your doctor or pharmacist before taking OTEZLA

Who should not take this medicine?

- ◆ Do not take this medicine if you are allergic to apremilast (the active ingredient in OTEZLA) or any of the following ingredients: cellulose microcrystalline, lactose monohydrate, croscarmellose sodium, magnesium stearate, poly(vinyl alcohol), titanium dioxide (E171), macrogol (3350), talc, iron oxide red (E172), iron oxide yellow (E172) and iron oxide black (E172)
- ◆ Do not take this medicine if you have rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption
- ◆ Do not take this medicine if you are pregnant, think you may be pregnant or are planning a baby*
- ◆ Do not take this medicine while you are breastfeeding

What are the special warnings and precautions when taking OTEZLA?

- ◆ Talk to your doctor if you lose weight without meaning to
- ◆ If you have severe kidney problems then the recommended dose of OTEZLA is 30 mg once a day (morning dose). Your doctor will talk to you about how to increase your dose when you first start taking this medicine
- ◆ Tell your doctor before starting this medicine if you have depression which is getting worse with thoughts of suicide. You or your caregiver should also tell your doctor straight away of any changes in behaviour or mood, feelings of depression and of any suicidal thoughts you may have after taking OTEZLA
- ◆ If you experience severe diarrhoea, nausea or vomiting, you should talk to your doctor

*You should use an effective method of contraception during treatment with OTEZLA.

Can I take OTEZLA with other medicines?

Tell your doctor or pharmacist if you are taking, have recently taken, or might take other medicines. This includes medicines obtained without a prescription and herbal medicines.

This is because OTEZLA can affect the way some other medicines work and vice versa.

In particular, tell your doctor or pharmacist before taking this medicine if you are taking any of the following medicines:

- ◆ **Rifampicin** – an antibiotic used to treat infections
- ◆ **St John's Wort** – a herbal medicine for mild anxiety or depression
- ◆ **Phenytoin, phenobarbital and carbamazepine** – medicines used in the treatment of seizures or epilepsy



What are the possible side effects of OTEZLA?

Like all medicines, this medicine may cause side effects, although not everybody will experience these.

Serious side effects – depression and suicidal thoughts

- ◆ Tell your doctor straight away about any changes in behaviour or mood, feelings of depression, thoughts of suicide or suicidal behaviour (this is uncommon)

Very common side effects (may affect more than 1 in 10 people):

- ◆ Diarrhoea*,**
- ◆ Nausea*,**
- ◆ Headache*
- ◆ Upper respiratory tract infections such as cold, runny nose, sinus infection

Common side effects (may affect up to 1 in 10 people):

- ◆ Cough
- ◆ Back pain*
- ◆ Vomiting*,**
- ◆ Feeling tired
- ◆ Stomach pain*
- ◆ Loss of appetite*
- ◆ Frequent bowel movements
- ◆ Migraine*

- ◆ Tension headache*
- ◆ Difficulty sleeping (insomnia)
- ◆ Indigestion or heartburn
- ◆ Inflammation and swelling of the tubes in your lungs (bronchitis)
- ◆ Common cold (nasopharyngitis)*
- ◆ Depression

Uncommon side effects (may affect up to 1 in 100 people):

- ◆ Rash
- ◆ Hives (urticaria)
- ◆ Weight loss
- ◆ Allergic reaction
- ◆ Bleeding in the bowel or in the stomach
- ◆ Suicidal ideation or behaviour

Not known side effects (frequency cannot be estimated from the available data):

- ◆ Severe allergic reaction (may include swelling of the face, lips, mouth, tongue or throat that may lead to difficulty breathing or swallowing)

*At least one of these side effects was reported as serious

** If you are 65 years of age or older, you might have a higher risk of complications of severe diarrhoea, nausea and vomiting. If your gut problems become severe, you should talk to your doctor

What should I do if I experience any side effects when I take OTEZLA?

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. Please see the front cover for details of how to report side effects.

Managing diarrhoea

Diarrhoea is defined as an increase in the daily number of stools (bowel movements) above your normal level.



Some patients who took this medicine in clinical trials experienced diarrhoea. They were more likely to

have diarrhoea within the first 2 weeks of starting treatment. Usually, the diarrhoea **went away within 4 weeks.**

It is important to manage your diarrhoea early to prevent you from becoming dehydrated and so it does not interfere with your daily routine

Top tips for managing diarrhoea:

If you have diarrhoea it's important to drink plenty of fluids to avoid dehydration, particularly if you are also vomiting.

Here are some tips on what and when to drink:

- ◆ Take small, frequent sips of water
- ◆ Ideally, drink a lot of liquids that contain water, salt and sugar – such as water mixed with juice, flavoured soda and clear soup broth



You can tell that you are drinking enough fluids if your urine is light yellow or almost clear

Managing diarrhoea (continued)

Top tips for managing diarrhoea:

Most experts agree that you should eat solid food as soon as you feel able to. You might find the following suggestions helpful:

- ◆ Eat small, light meals
- ◆ Avoid fatty or spicy foods
- ◆ Good examples of foods to try are:
 - Potatoes
 - Rice
 - Bananas
 - Soup
 - Boiled vegetables
- ◆ Including a few salty foods in your diet may help you as you start to feel better
- ◆ You do not need to eat if you have lost your appetite, but you should continue to drink fluids and eat as soon as you feel able to



Managing nausea (feeling sick) or vomiting

Some people experience nausea or vomiting when they are taking their treatment.



These side effects are more likely to occur within the first 2 weeks of starting treatment. Usually any feelings of sickness or vomiting **go away within 4 weeks**.

You should speak to your doctor if you experience nausea or vomiting

Top tips for managing nausea or vomiting

If you are feeling sick or experiencing vomiting, you may find it helpful to make some changes to your diet:

- ◆ Drink plenty of fluids such as water; sip them little and often
- ◆ Eat small amounts of food often, rather than several large meals in a day
- ◆ Try foods which are high in carbohydrates (such as bread, rice and pasta) and low in fat
- ◆ Savoury foods – such as toast, crackers and crispbread – may be easier for you to manage than sweet or spicy foods
- ◆ The smell of hot foods may make you feel sick – so you may find cold foods preferable
- ◆ Eat foods that appeal to you – avoid foods or smells that make you feel sick
- ◆ Try not to miss meals as having an empty stomach can make nausea worse
- ◆ If you experience vomiting, once it has stopped, take small sips of clear liquid such as water to replace the fluids you have lost

Remember that your tablets can be taken with food – and this may help if you are experiencing nausea

What are the benefits of continuing treatment with OTEZLA?

Psoriasis and psoriatic arthritis are chronic conditions – this means that they may continue for a long time. Therefore, it is important for you to keep on taking your medicine for as long as your doctor recommends.

When you visit your doctor, he or she will ask you questions about your psoriasis or psoriatic arthritis and carry out tests to see what improvements your medicine is making to your condition.

If your symptoms show no evidence of improvement after 24 weeks, then your doctor will consider an alternative treatment for you.



You should continue taking OTEZLA until your doctor tells you to stop. Do not stop taking this medicine without talking to your doctor first.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this booklet.

Tips to help you remember to take your OTEZLA medicine every day

Taking your medicine every day, as recommended by your doctor, will mean that you have the best chance of responding to your treatment and controlling your psoriasis or psoriatic arthritis.

Set up a routine that becomes a habit so you don't miss a tablet

- ◆ You may find it helpful to take your tablet at mealtimes (i.e. at breakfast and dinner) so you don't forget

Use reminders such as:

- ◆ Phone alarms
- ◆ Ask a friend or family member to remind you to take your medication
- ◆ Leave a note on the fridge
- ◆ Set a recurring text message reminder on your phone



What is the OTEZLA treatment diary?

The diary comprises the first 6 weeks of your treatment. If you find it helpful, you can continue to keep the diary for as long as you are taking OTEZLA.

The first column lists the treatment days – on day 1 of your treatment you can fill in the dates of your first 6 weeks of taking this medicine.

Use the other spaces in the diary for noting down details about the signs and symptoms of your condition and how you are feeling.



There is also space for you to note down any questions that you want to ask at your next appointment with the doctor

Treatment diary

Week 1

| Day | Date | Notes about my treatment and condition |
|-----|------|--|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |
| 6 | | |
| 7 | | |

Questions to ask my doctor

Treatment diary

Week 2

| Day | Date | Notes about my treatment and condition |
|-----|------|--|
| 8 | | |
| 9 | | |
| 10 | | |
| 11 | | |
| 12 | | |
| 13 | | |
| 14 | | |

Questions to ask my doctor

Treatment diary

Week 3

| Day | Date | Notes about my treatment and condition |
|-----|------|--|
| 15 | | |
| 16 | | |
| 17 | | |
| 18 | | |
| 19 | | |
| 20 | | |
| 21 | | |

Questions to ask my doctor

Treatment diary

Week 4

| Day | Date | Notes about my treatment and condition |
|-----|------|--|
| 22 | | |
| 23 | | |
| 24 | | |
| 25 | | |
| 26 | | |
| 27 | | |
| 28 | | |

Questions to ask my doctor

Treatment diary

Week 5

| Day | Date | Notes about my treatment and condition |
|-----|------|--|
| 29 | | |
| 30 | | |
| 31 | | |
| 32 | | |
| 33 | | |
| 34 | | |
| 35 | | |

Questions to ask my doctor

Treatment diary

Week 6

| Day | Date | Notes about my treatment and condition |
|-----|------|--|
| 36 | | |
| 37 | | |
| 38 | | |
| 39 | | |
| 40 | | |
| 41 | | |
| 42 | | |

Questions to ask my doctor

Notes

Week 7 and beyond

Notes

Week 7 and beyond

[illegible]

Notes

Week 7 and beyond

PLEASE REFER TO THE PATIENT INFORMATION LEAFLET THAT CAME WITH YOUR MEDICINE, OR AVAILABLE AT <https://www.medicines.ie/medicines/otezla-10mg-20mg-30mg-33255/patient-info>

Visit the patient website www.amgencare.ie for more information (for quick access, scan the below QR code with your phone's camera or QR reader app)



References:

OTEZLA (apremilast). Summary of Product Characteristics. Amgen Europe B.V.

OTEZLA (apremilast). Patient information leaflet. Amgen Europe B.V.

The information on this booklet is not intended as a substitute for consultation with your healthcare professional.

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