

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking Otezla?

Otezla contains the active ingredient apremilast. Otezla is used to treat adults with plaque psoriasis, Psoriatic arthritis, or mouth ulcers associated with Behçet's Disease.

For more information, see Section [1. Why am I taking Otezla?](#) in the full CMI.

2. What should I know before I take Otezla?

Do not use if you have ever had an allergic reaction to apremilast or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take Otezla?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Otezla and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take Otezla?

- Swallow Otezla tablets whole with a glass of water, either with or without food.

More instructions can be found in Section [4. How do I take Otezla?](#) in the full CMI.

5. What should I know while taking Otezla?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking Otezla.• If you have any questions, ask your doctor, pharmacist or nurse• Keep all your doctor's appointments so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine or change the dose without speaking to your doctor.• Do not take Otezla when pregnant or breast feeding.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Otezla affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C.• Keep Otezla in a cool, dry place out of the reach of children.

For more information, see Section [5. What should I know while taking Otezla?](#) in the full CMI.

6. Are there any side effects?

Common side effects: diarrhoea, nausea, vomiting, stomach pain, indigestion, decrease in appetite, cough, cold, runny nose, inflammation/infection of the nose, throat, sinus, or upper respiratory tract, tiredness, difficulty sleeping, headaches, migraines, and back pain.

Serious side effects: shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue, or other parts of the body.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about taking Otezla. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Otezla.**

Where to find information in this leaflet:

- [1. Why am I taking Otezla?](#)
- [2. What should I know before I take Otezla?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Otezla?](#)
- [5. What should I know while taking Otezla?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking Otezla?

Otezla contains the active ingredient apremilast. Otezla is a selective immunosuppressant which helps to reduce inflammation.

Otezla is used to treat adults with the following conditions:

- Plaque psoriasis
- Psoriatic arthritis
- Mouth ulcers associated with Behçet's disease.

Plaque psoriasis

Plaque psoriasis is an inflammatory disease of the skin, which can cause red, scaly, thick, itchy, painful patches on your skin, and can also affect your scalp and nails. Plaque psoriasis can look different depending on skin tone, people with skin of colour may have grey or white scaly patches.

Treatment with Otezla can result in a reduction in psoriasis skin plaques, nail and scalp psoriasis and other signs and symptoms of psoriasis, such as itching, skin pain or discomfort.

Psoriatic arthritis

Psoriatic arthritis is an inflammatory disease of the joints, often accompanied by psoriasis, an inflammatory disease of the skin.

Treatment with Otezla can result in an improvement in swollen and painful joints, swollen and painful fingers / toes, signs and symptoms of psoriasis, and can improve your general physical function.

Behçet's disease

Behçet's disease is a rare type of inflammatory disease which affects many parts of the body. The most common problem is mouth ulcers.

Treatment with Otezla can result in fewer and less painful mouth ulcers.

How Otezla works

Otezla works by reducing the activity of a natural substance in the body's cells called phosphodiesterase 4. This helps regulate the immune response associated with psoriasis,

psoriatic arthritis, and Behçet's disease and helps to control the signs and symptoms of these conditions.

Psoriasis, psoriatic arthritis, and Behçet's disease are usually lifelong conditions. There is currently no cure. Otezla has been shown to improve the quality of life in patients with psoriasis, psoriatic arthritis and Behçet's disease. This means that the impact of your condition on daily activities, relationships and other factors should be less than it was before.

2. What should I know before I take Otezla?

Warnings

Do not take Otezla if:

- You are allergic to apremilast, or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include, rash, itching or hives on the skin, swelling of the face, lips, tongue, mouth or throat that may lead to difficulty breathing or swallowing.
- You are pregnant or breastfeeding.

Check with your doctor if you:

- Have kidney problems
- Experience severe diarrhoea, nausea or vomiting.
- Have experienced depression or have had suicidal thoughts now or in the past.
- Have intolerance to some sugars, Otezla contains lactose (a type of sugar).
- Take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy

Otezla must not be taken during pregnancy. Check with your doctor if you are pregnant or intend to become pregnant.

Breastfeeding

Do not breastfeed whilst taking Otezla. Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Otezla and affect how it works.

Medicines that may reduce the effect of Otezla include:

- rifampicin, an antibiotic used for tuberculosis
- carbamazepine, phenytoin and phenobarbitone, medicines used in the treatment of seizures or epilepsy
- St. John's Wort, a herbal medicine for mild anxiety and depression.

These medicines may affect how well Otezla works. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Otezla.

4. How do I take Otezla?

How much to take

Follow the instructions given to you by your doctor or pharmacist carefully. Take Otezla until your doctor tells you to stop. Your doctor will monitor your progress.

- When you first start taking Otezla, you will receive a 'treatment starter pack' which contains all the doses for the first 14 days of therapy as listed in the table below.
- The 'treatment starter pack' is clearly labelled to help you take the correct tablet at the right time.
- Your treatment will start at a lower dose and will gradually be increased over the first 6 days of treatment.
- The starter pack also contains enough tablets for a further 8 days at the daily recommended dose (days 7 to 14).
- After the titration phase is complete the recommended dose of Otezla is 30 mg twice a day - one 30 mg tablet in the morning and one 30 mg tablet in the evening. This is a total daily dose of 60 mg.
- Once the recommended dose has been reached, you will only get the 30 mg tablet strength in your prescribed packs.
- You will only ever need to go through this stage of gradually increasing your dose once, even if you re-start treatment following a (longer) break.

Day	Morning dose	Evening dose	Total Daily dose
Day 1	10 mg (pink)	No dose	10 mg
Day 2	10 mg (pink)	10 mg (pink)	20 mg
Day 3	10 mg (pink)	20 mg (brown)	30 mg
Day 4	20 mg (brown)	20 mg (brown)	40 mg
Day 5	20 mg (brown)	30 mg (beige)	50 mg
Day 6 onward	30 mg (beige)	30 mg (beige)	60 mg

If you have severe kidney problems, the recommended daily dose 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 Otezla.

When to take Otezla

- Take Otezla at about the same time each day, following the instructions provided.
- Most people should take one tablet in the morning and one tablet in the evening each day, approximately 12 hours apart.
- Take Otezla until your doctor tells you to stop.

How to take Otezla

- Swallow the tablets whole, preferably with water, either with or without food, as directed by your doctor.
- Do not crush, break or chew the tablets.

- Take Otezla at about the same time each day, one tablet in the morning and one tablet in the evening.

If you forget to take Otezla

If you miss a dose of Otezla, take it as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much Otezla

If you think that you have taken too much Otezla, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking Otezla?

Things you should do

Your doctor will monitor your progress while you are taking Otezla. Keep all your doctor's appointments so that your progress can be checked.

Tell your doctor if you have experienced depression or have had suicidal thoughts in the past.

During treatment with Otezla, tell your doctor or nurse if you experience severe diarrhoea, nausea or vomiting. These side effects are usually noticed at the start of treatment. Inform your doctor, nurse or pharmacist if you experience these side effects.

Call your doctor straight away if during treatment you:

- Feel depressed, have suicidal thoughts, experience other mood changes or notice that these events have worsened.
- Experience any serious side effects listed in the table below.

Remind any doctor, dentist or pharmacist you visit that you are taking Otezla.

Things you should not do

- Do not take Otezla when pregnant or breastfeeding.
- Do not take Otezla if you are under the age of 18 years. Safety and effectiveness in children have not been established.
- Do not take Otezla after the expiry date printed on the pack or if the packaging shows signs of tampering.
- Do not stop taking this medicine suddenly or change the dose without speaking to your doctor.
- Do not give Otezla to anyone else, even if they have the same condition as you.
- Do not take Otezla to treat any other complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Otezla affects you.

Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly.

Store Otezla below 30°C.

Store it in a cool dry place away from moisture, heat, or sunlight; for example, do not store it in:

- the bathroom or near a sink, or
- the car or on windowsills.

Keep it where children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gut and digestion:</p> <ul style="list-style-type: none">• diarrhoea; nausea; vomiting; stomach pain; indigestion• decrease in appetite• weight loss <p>Lungs and upper airway:</p> <ul style="list-style-type: none">• cough; cold; runny nose• inflammation/infection of the nose, throat, sinus, or upper respiratory tract <p>Other:</p> <ul style="list-style-type: none">• tiredness; trouble or difficulty sleeping• headaches or migraine headaches• back pain• skin rash	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• shortness of breath• wheezing or difficulty breathing• swelling of the face, lips, tongue or other parts of the body.	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of</p>

Serious side effects	What to do
	<p>these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Otezla contains

Active ingredient (main ingredient)	apremilast
Other ingredients (inactive ingredients)	microcrystalline cellulose lactose monohydrate croscarmellose sodium magnesium stearate (vegetable grade) polyvinyl alcohol titanium dioxide polyethylene glycol talc iron oxide red iron oxide yellow (20 mg and 30 mg tablets only) iron oxide black (30 mg tablets only)
Potential allergens	Contains lactose

Do not take this medicine if you are allergic to any of these ingredients.

What Otezla looks like

Otezla 10 mg - Pink, diamond shaped film-coated tablet with "APR" engraved on one side and "10" on the opposite side.

Otezla 20 mg - Brown, diamond shaped film-coated tablet with "APR" engraved on one side and "20" on the opposite side.

Otezla 30 mg - Beige, diamond shaped film-coated tablet with "APR" engraved on one side and "30" on the opposite side.

The tablets are provided in blister packs as follows.

- Otezla titration starter pack, a folding wallet containing 27 film-coated tablets: 4 × 10 mg tablets, 4 × 20 mg tablets and 19 × 30 mg tablets (AUST R 220424)

- Otezla 30 mg standard trade pack contains 56 x 30mg film-coated tablets. (Aust R 220423).

Sponsor

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