PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

OTEZLA 10 mg (film-coated tablet)

OTEZLA 20 mg (film-coated tablet)

OTEZLA 30 mg (film-coated tablet)

Apremalist, 10mg, 20 mg & 30 mg

Contains sugar (lactose monohydrate)

Each 10 mg film-coated tablet contains 57 mg of lactose (as lactose monohydrate).

Each 20 mg film-coated tablet contains 114 mg of lactose (as lactose monohydrate).

Each 30 mg film-coated tablet contains 171 mg of lactose (as lactose monohydrate).

Read all of this leaflet carefully before you start taking OTEZLA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- OTEZLA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What OTEZLA is and what it is used for

What Otezla is

Otezla contains the active substance ‘apremilast’. This belongs to a group of medicines called phosphodiesterase 4 inhibitors, which help to reduce inflammation

What Otezla is used for

OTEZLA is used alone or in combination with other medicines to treatadults with the following conditions:

- Psoriatic arthritis.
- Moderate to severe plaque psoriasis.

What psoriatic arthritis is

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

What plaque psoriasis is

Psoriasis is an inflammatory disease of the skin, which can causered, scaly, thick, itchy, painful patches on your skin and can also affect your scalp and nails.

2. What you need to know before you take OTEZLA

Do not take OTEZLA :

- If you are allergic (hypersensitive) to apremilast or any of the ingredients of this medicine.
- if you are pregnant or think you may be pregnant.
- If you are breastfeeding your baby.

Warnings and precautions

Take special care with OTEZLA:

- If your doctor considers you to be underweight, and you observe an unintentional loss of body weight while being treated with OTEZLA;
- If you have severe kidney problems – your doctor will then determine the correct dosage for you;
- Before starting treatment with Otezla, inform your doctor if you are suffering from symptoms of

worsening depression with suicidal thinking or behaviour, especially if you take any additional medicines since some of those could increase the probability of these side effects. You should also immediately inform your doctor of any changes in behaviour or mood and of any suicidal thoughts you mayhave. You may also experience sleeplessness, or depressive mood (see Possible side effects').

- If you suffer from depression;
- If you suffer from diarrhoea, nausea and vomiting.
- If you are 65 years or older as you are at higher risk to experience complications such as diarrhoea, nausea and vomiting (see 'Possible side effects') .
- If you have a history of irregular heart rhythm

Children/ and adolescents

- If you are under the age of 17 years, as OTEZLA has not been studied in children and adolescents.

Other medicines with OTEZLA:

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

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

OTEZLA with food and drink and alcohol

You can take the tablets either with or without food, preferably with water.

Pregnancy and breastfeeding and fertility:

You should not take OTEZLA if you are pregnant.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before

taking OTEZLA.

You should not become pregnant while taking Otezla and should use an effective method of contraception during treatment with Otezla. It is not known if this medicine passes into human milk. You should not use Otezla while breastfeeding your infant.

Driving and using machinery:

It is not always possible to predict to what extent OTEZLA may interfere with your daily activities of a patient. You should ensure that you do not engage in the above activities until you are aware of the measure to which OTEZLA affects you

OTEZLA contains lactose

Otezla contains lactose (a type of sugar) which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, talk to contact your doctor before taking this medicinal product. Patients with the rare hereditary conditions of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take OTEZLA

3. How to take OTEZLA:

Do not share medicines prescribed for you with any other person.

Always take OTEZLA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

- When you first start taking OTEZLA, you will receive a ‘treatment initiation pack’ which contains all the doses as listed in the table below.
- The ‘treatment initiation pack’ is clearly labelled to make sure you take the correct tablet at the correct time.
- Your treatment will start at a lower dose and will gradually be increased over the first 6 days of treatment.
- The ‘treatment initiation pack’ will also contain enough tablets for another 8 days at the recommended dose (Days 7 to 14).

- The recommended dose of OTEZLA is 30 mg twice a day after the titration phase is complete - one 30 mg dose in the morning and one 30 mg dose in the evening, approximately 12 hours apart, with or without food.
- This is a total daily dose of 60 mg. By the end of Day 6 you will have reached this recommended dose.
- 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.

Day	**Morning Dose**	**Evening Dose**	**Total Daily Dose**
Day 1	10 mg (pink)	**Do not take a 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 onwards	30 mg (beige)	30 mg (beige)	60 mg

People with severe kidney problems

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 OTEZLA.

How and when to take OTEZLA

- OTEZLA is for oral use
- Swallow the tablets whole, preferably with water.
- You can take the tablets either with or without food.
- Take OTEZLA at about the same time each day, one tablet in the morning and one tablet in the evening.
- If your condition has not improved after six months of treatment, you should talk to your doctor.

Your doctor will tell you how long your treatment with OTEZLA will last.

If you have the impression that the effect of OTEZLA is too strong or too weak, talk to your doctor or pharmacist.

If you take more OTEZLA than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of Otezla:

- Do not take a double dose to make up for forgotten individual doses.
- If you miss a dose of OTEZLA, take it as soon as you remember. If it is less than 6 hours to the time for your next dose, just skip the missed dose. Take the next dose at your regular time.

If you stop taking Otezla

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

4. Possible side effects

OTEZLA can cause side effects.

Not all side effects reported for OTEZLA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking OTEZLA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash(hives) or itching;
- fainting

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Otezla. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Bleeding in the bowel or in the stomach;
- Inflammation and swelling of the air tubes in your lungs (bronchitis);
- Upper respiratory tract infections such as cold, runny nose, sinus infection.
- Uncommon instances of suicidal thinking and behaviour (including suicide) were reported. Please notify your doctor immediately of any feelings of depression, suicidal thoughts or suicidal behaviour you may have. You may also experience sleeplessness (common), or depressive mood (common) (see 'Warnings and Precautions').

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Headaches, migraines or tension headaches;
- Diarrhoea;
- Nausea;
- Cough;
- Back pain;
- Vomiting;
- Feeling tired;
- Stomach pain;
- Loss of appetite;
- Frequent bowel movements;
- Difficulty sleeping (insomnia);
- Indigestion or heartburn;
- Common cold (nasopharyngitis).

The following side effects have been reported less frequently:

- Weight loss
- Bleeding of the stomach (gastrointestinal haemorrhage).

The following side effects have been reported but the requency is unknown:

If you are 65 years of age or older, you might have a higher risk of complications of severe diarrhoea, nausea and vomiting.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of OTEZLA.

5. How to store OTEZLA

Store at or below 30 °C

Keep in the blister and carton until required for use.

Store in the original package / container.

Do not store in bathrooms.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems. (e.g. toilets).

Store all medicines out of reach of children.

6. Contents of the pack and other information

What OTEZLA contains

Active ingredient:

Each OTEZLA 10 mg tablet contains 10 mg apremilast.

Each OTEZLA 20 mg tablet contains 20 mg apremilast.

Each OTEZLA 30 mg tablet contains 30 mg apremilast.

Contains sugar (lactose monohydrate):

Each 10 mg film-coated tablet contains 57 mg of lactose (as lactose monohydrate).

Each 20 mg film-coated tablet contains 114 mg of lactose (as lactose monohydrate).

Each 30 mg film-coated tablet contains 171 mg of lactose (as lactose monohydrate).

The inactive ingredients are:

Microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate.

OTEZLA 10 mg tablets contain Opadry II Complete Film Coating System Pink, which contains iron oxide red, polyethylene glycol, polyvinyl alcohol, talc and titanium dioxide.

OTEZLA 20 mg tablets contain Opadry II Complete Film Coating System Brown, which contains iron oxide red, iron oxide yellow, polyethylene glycol, polyvinyl alcohol, talc and titanium dioxide.

OTEZLA 30 mg tablets contain Opadry II Complete Film Coating System Beige, which contains iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, polyvinyl alcohol, talc and titanium dioxide.

What OTEZLA looks like and contents of the pack

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

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

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

Otezla 10 mg, 20 mg, 30 mg film-coated tablets (initiation pack)

PVC/ aluminium foil blisters containing 27 film-coated tablets (4 x 10 mg, 4 x 20 mg, 19 x 30 mg).

Otezla 30 mg film-coated tablets

PVC/ aluminium foil blisters containing 14 film-coated tablets, in pack sizes of

56 tablets and 168 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration and Manufacturer

Amgen South Africa (Pty) Ltd.

Building D, Ballyoaks Office Park,

Ballyclare Drive

Bryanston Ext. 7

2021

South Africa

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Registration numbers

Otezla 10 mg: 51/32/0864

Otezla 20 mg: 51/32/0865

Otezla 30 mg: 51/32/0866

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website