

PART III: CONSUMER INFORMATION

Pr OTEZLA[®]
apremilast tablets

This leaflet is part III of a three-part "Product Monograph" published when OTEZLA[®] (apremilast) was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about OTEZLA[®]. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

OTEZLA[®] is used in adults to treat:

- moderate to severe plaque psoriasis, and
- psoriatic arthritis alone or in combination with methotrexate if you cannot use another type of medicine called 'Disease-Modifying Antirheumatic Drugs' (DMARDs) or if you have tried one of these medicines and it did not work.

OTEZLA[®] is not approved for use in combination with any other medicines taken by mouth used to treat psoriasis, biological therapies (such as TNF antagonists and anti-IL-12/23 p40 antibodies) or with phototherapy (light therapy using UV light).

What it does:

OTEZLA[®] belongs to a class of drugs called phosphodiesterase 4 (PDE4) inhibitors. It contains the active ingredient apremilast which works by reducing the activity of PDE4. This results in less inflammation in the skin and joints.

When it should not be used:

Do not take OTEZLA[®] if you:

- are allergic to apremilast or to any non-medicinal ingredient in the formulation.
- have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorptionbecause lactose is a non-medicinal ingredient in OTEZLA[®].
- are breastfeeding. It is not known if OTEZLA[®] passes into your breast milk. OTEZLA[®] should not be used if you are breastfeeding.
- are younger than 18 years old.

- are pregnant or intend to become pregnant. It is not known if OTEZLA[®] will harm your unborn baby. If you take OTEZLA[®] while you are pregnant, talk to your doctor about how you can be included in the OTEZLA[®] Pregnancy Registry.

What the medicinal ingredient is:

apremilast

What the nonmedicinal ingredients are:

croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, iron oxide red, iron oxide yellow (20 and 30 mg only) and iron oxide black (30 mg only).

What dosage forms it comes in:

Tablets: 10 mg, 20 mg and 30 mg.

WARNINGS AND PRECAUTIONS

BEFORE you use OTEZLA[®] talk to your doctor or pharmacist if you:

- have kidney problems.
- have a history of the heart condition, tachyarrhythmia (fast heartbeat or heart palpitations).
- have heart disease or congestive heart failure.
- have tuberculosis or a viral infection such as viral hepatitis, herpes infection or shingles.
- are using immunosuppressive drugs (such as cyclosporine).
- have a history of depression and/or suicidal thoughts or behaviours.
- have low blood pressure
- have any other medical conditions.
- 65 years of age or older.

OTEZLA[®] can cause weight loss. Your doctor will need to regularly monitor your weight.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with OTEZLA[®]:

- Rifampin, used to treat tuberculosis.

- Medicines used to control seizures such as phenobarbital, carbamazepine and phenytoin.
- Medicines that suppress your immune system such as cyclosporine and tacrolimus.
- Methotrexate to treat your psoriasis
- Biological therapies, such as TNF antagonists and anti-IL-12/23 p40 antibodies.
- The botanical medicine St. John's Wort.

PROPER USE OF THIS MEDICATION

Take OTEZLA[®] exactly as your healthcare provider tells you to take it. OTEZLA[®] should be taken by mouth and swallowed whole, with or without food. The tablets should not be crushed, split, or chewed.

Usual adult dose:

The recommended dose is 30 mg twice a day. When you first start taking OTEZLA[®], the dose needs to be increased gradually; therefore, you must follow the instructions below.

Dose titration schedule:

Day 1		Day 2		Day 3	
AM		AM	PM	AM	PM
10 mg		10 mg	10 mg	10 mg	20 mg
Day 4		Day 5		Day 6	
AM	PM	AM	PM	AM	PM
20 mg	20 mg	20 mg	30 mg	30 mg	30 mg

Overdose:

If you think you have taken too much OTEZLA[®], contact your doctor, nurse or pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of OTEZLA[®], take it as soon as you remember. If it is close to the time for your next dose, just skip the missed dose. Take the next dose at your regular time. Do not double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- diarrhea
- nausea
- vomiting
- headache
- upper respiratory tract infection (e.g. common cold)
- flu (body aches and pains, tiredness, fever)

- decreased appetite
- abdominal discomfort, indigestion
- fatigue, trouble sleeping
- back pain
- dizziness.

If any of these affect you severely, tell your doctor, nurse or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common (occurring in 1 to 9 patients per 100)	Migraine	✓		
	Depression		✓	
	Weight loss		✓	
Uncommon (occurring in 1 to 9 patients per 1000)	Fast heartbeat and/or heart palpitations	✓		
	Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
	Infection of the lungs: shortness of breath, difficult and painful breathing, cough, wheezing and fever		✓	
	Severe diarrhea, nausea or vomiting			✓

This is not a complete list of side effects. For any unexpected effects while taking OTEZLA[®], contact your doctor or pharmacist.

HOW TO STORE IT

Store OTEZLA[®] at 15 to 30 °C.

Keep OTEZLA[®] tablets and all medicines out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
 - **Fax toll-free to 1-866-678-6789, or**
 - **Mail to: Canada Vigilance Program
 Health Canada
 Postal Locator 0701E
 Ottawa, Ontario
 K1A 0K9**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.celgenecanada.net>

or by contacting the sponsor, Celgene Inc., at:

1-877-923-5436

This leaflet was prepared by Celgene Inc.

The information in this document is current as of the last revision date shown below. For the most current information, please visit the website or call the number above.

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