Package leaflet:
Information for the patient

Otezla®

Otezla 10 mg film-coated tablets

Otezla 20 mg film-coated tablets

Otezla 30 mg film-coated tablets
Apremilast

Read all of this leaflet carefully before you start taking this medicine - because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or nurse.

What is in this leaflet

1. What Otezla is and what it is used for
2. Before you take Otezla
3. How to take Otezla
4. Possible side effects
5. How to store Otezla
6. Contents of the pack and other information

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 to treat adults with the following conditions:
- **Psoriatic arthritis -** if you cannot use another type of medicine called 'Disease-Modifying Antirheumatic Drugs' (DMARDs) or when you have tried one of these medicines and it did not work.
- **Moderate to severe plaque psoriasis -** if you cannot use one of the following treatments or when you have tried one of these treatments and it did not work:
  - phototherapy - a treatment where certain areas of skin are exposed to ultraviolet light
  - systemic therapy - a treatment that affects the entire body rather than just one local area, such as 'ciclosporin' or 'methotrexate'.

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 cause red, scaly, thick, itchy, painful patches on your skin and can also affect your scalp and nails.

How Otezla works
Psoriatic arthritis and psoriasis are usually lifelong conditions and there is currently no cure. Otezla works by reducing the activity of an enzyme in the body called 'phosphodiesterase 4', which is involved in the process of inflammation. By reducing the activity of this enzyme, Otezla can help to control the inflammation associated with psoriatic arthritis and psoriasis, and thereby reduce the signs and symptoms of these conditions.

In psoriatic arthritis, treatment with Otezla results in an improvement in swollen and painful joints, and can improve your general physical function.

In psoriasis, treatment with Otezla results in a reduction in psoriatic skin plaques and other signs and symptoms of the disease.

Otezla has also been shown to improve the quality of life in patients with psoriasis or psoriatic arthritis. This means that the impact of your condition on daily activities, relationships and other factors should be less than it was before.

2. Before you take Otezla

Do not take Otezla:
- if you are allergic to apremilast or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or think you may be pregnant.

Warnings and precautions
Talk to your doctor or pharmacist before taking Otezla.

If your doctor considers you to be underweight, and you observe an unintentional loss of body weight while being treated with Otezla, you should talk to your doctor.
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.

Children and adolescents
Otezla has not been studied in children and adolescents, therefore it is not recommended for use in children and adolescents aged 17 years and under.

Other medicines and Otezla
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Otezla can affect the way some other medicines work. Also some other medicines can affect the way Otezla works.

In particular, tell your doctor or pharmacist before taking Otezla if you are taking any of the following medicines:
- rifampicin – an antibiotic used for tuberculosis
- phenytoin, phenobarbital and carbamazepine - medicines used in the treatment of seizures or epilepsy
- St John's Wort – a herbal medicine for mild anxiety and depression.

Pregnancy and breast-feeding
There is little information about the effects of Otezla in pregnancy. You should not become pregnant while taking this medicine 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 breast-feeding.

Tell your doctor if you think you may be pregnant or are planning to have a baby, or if you are breast-feeding or intend to breast-feed.

Driving and using machines
Otezla has no effect on the ability to drive and use machines.

Otezla contains lactose
Otezla contains lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

3. How to take Otezla

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

How much to take
- 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.

APRX600ABPLX083V01H02

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النشرة المرفقة بالعبوة:
معلومات للمريض

- 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 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
- 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.

If you take more Otezla than you should
If you take more Otezla than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack and this leaflet with you.

If you forget to take Otezla
- 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 take two doses at the same 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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effects (may affect more than 1 in 10 people)
- diarrhoea
- nausea

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
- difficulty sleeping (insomnia)
- indigestion or heartburn
- headaches, migraines or tension headaches
- upper respiratory tract infections such as cold, runny nose, sinus infection.
- inflammation and swelling of the tubes in your lungs (bronchitis).
- common cold (nasopharyngitis)

Uncommon side effects (may affect up to 1 in 100 people)
- rash
- weight loss
- allergic reaction

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 this leaflet. You can also report side effects directly via the reporting system listed at the end of this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Otezla

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Do not use Otezla if you notice any damage or signs of tampering to the medicine packaging.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Otezla contains

- The active substance is apremilast.
- Each film-coated tablet contains 10 mg of apremilast.
- Each film-coated tablet contains 20 mg of apremilast.
- Each film-coated tablet contains 30 mg of apremilast.

- The other ingredients in the tablet core are microcrystalline cellulose, lactose monohydrate, croscarmellose sodium and magnesium stearate.
- The film-coating contains polyvinyl alcohol, titanium dioxide (E171), - macrogol, talc, iron oxide red (E172).
- The 20 mg film-coated tablet also contains iron oxide yellow (E172).
- The 30 mg film-coated tablet also contains iron oxide yellow (E172) and iron oxide black (E172).

What Otezla looks like and contents of the pack

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

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

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

Pack sizes
- The treatment initiation pack is a folding wallet containing 27 tablets: 4 x 10 mg tablets, 4 x 20 mg tablets and 19 x 30 mg tablets.
- The one-month standard pack contains 56 x 30 mg tablets.

Manufacturer:
Celgene International Sarl,
Boudry, Switzerland.

Marketing Authorization Holder:
Celgene Europe Ltd, Uxbridge, UK

This leaflet was last revised in 01/2015

To Report Any Side Effect(s):

Saudi Arabia:

The National Pharmacovigilance and Drug Safety Centre (NPC)
- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sfda.gov.sa
- Website: www.sfda.gov.sa/npc

United Arab Emirates:

Pharmacovigilance and Medical Device Section
Drug Department
UAE MOH
- Phone: 0097142301448
- Hotline: 8001111
- Email: pv@moh.gov.ae
- P.O. Box: 1853 Dubai UAE

· ***Other Countries:***

- Please contact the relevant competent authority.

This is a medicament
– A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
– Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament to you
– The doctor and the pharmacist are experts in medicine, its benefits and risks.
– Do not, by yourself, interrupt the period of treatment prescribed for you.
– Do not repeat the same prescription without consulting your doctor.

Keep Medicament out of the reach and sight of children and any other person not directly involved in the treatment

Council of Arab Health Ministers
Union of Arab Pharmacists

Celgene