Package leaflet: Information for the patient

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 you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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 to treat adults with the following conditions:
- **Active 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 chronic 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', 'methotrexate' or 'psoralen '.
- **Behçet's disease (BD)** - to treat the mouth ulcers which is a common problem for people with this illness.

Otezla is used to treat children and adolescents 6 years of age and older and weighing at least 20 kg with the following condition:
- **Moderate to severe plaque psoriasis –** if your doctor determines that it is appropriate for you to take a systemic therapy like Otezla.

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.

What Behçet's disease is

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

How Otezla works

Psoriatic arthritis, psoriasis and Behçet's disease 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, psoriasis and Behçet's disease, and thereby reduce the signs and symptoms of these conditions.

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

In adults and in children and adolescents from the age of 6 years and weighing at least 20 kg with psoriasis, treatment with Otezla results in a reduction in psoriatic skin plaques and other signs and symptoms of the disease.

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In adults with Behçet's disease, treatment with Otezla reduces the number of mouth ulcers and can stop them completely. It can also reduce the associated pain.

Otezla has also been shown to improve the quality of life in adult and paediatric patients with psoriasis, adult patients with psoriatic arthritis and adult patients with 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 you need to know 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.

Depression and suicidal thoughts

Tell your doctor before starting Otezla 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.

Severe kidney problems

If you have severe kidney problems, your dose will be different – see section 3.

If you are underweight

Talk to your doctor while taking Otezla if you lose weight without meaning to.

Gut problems

If you experience severe diarrhoea, nausea, or vomiting, you should talk to your doctor.

Children and adolescents

Otezla is not recommended for use in children who have moderate to severe plaque psoriasis and are below 6 years of age or weigh less than 20 kg, because it has not been studied in these age and weight groups.

Otezla is not recommend for use in children and adolescents below 18 years of age in other indications, because safety and efficacy have not been established in this age group.

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

Do not take Otezla if you are pregnant or think you may be pregnant.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
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.

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 have an intolerance to some sugars, contact 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 enough tablets for a total of two weeks of treatment.
- 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 during the first week of treatment (titration phase).
- The 'treatment initiation pack' will also contain enough tablets for another week at the recommended dose.
- Once the recommended dose has been reached, you will only get a single tablet strength in your prescribed packs.
- You will only ever need to go through the stage of gradually increasing your dose once even if you re-start treatment.

Adults
- The recommended dose of Otezla for adult patients is 30 mg twice a day after the titration phase is completed, as shown in the table below - 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.

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

<u>Children and adolescents 6 years of age and older</u>
- The Otezla dose will be based on body weight.

For patients who weigh from 20 kg to less than 50 kg: The recommended dose of Otezla is 20 mg twice a day, after the titration phase is completed, as shown in the table below - one 20 mg dose in the morning and one 20 mg dose in the evening, approximately 12 hours apart, with or without food. This is a total daily dose of 40 mg.

	Weight of 20 kg to less than 50 kg		
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)	20 mg (brown)	40 mg
Day 6 onwards	20 mg (brown)	20 mg (brown)	40 mg

For patients who weigh at least 50 kg: The recommended dose of Otezla is 30 mg twice a day after the titration phase is completed (the same as the adult dose), as shown in the table below –

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.

	Weight of 50 kg or more		
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

Patients with severe kidney problems

If you are an adult with severe kidney problems then the recommended dose of Otezla is 30 mg **once a day (morning dose)**.

In children and adolescents 6 years of age and older with severe renal impairment, the recommended dose of Otezla is 30 mg **once a day (morning dose)** for patients who weigh at least 50 kg, and 20 mg **once a day (morning dose)** for children who weigh 20 kg to less than 50 kg**.**

Your doctor will talk to you about how to increase your dose when you first start taking Otezla. Your doctor may advise that you only take the morning dose shown in the table above that applies to you (for adults or for children/adolescents) and that you skip the evening dose.

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.

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 a double dose to make up for a forgotten dose.

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.

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
- headaches
- 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
- difficulty sleeping (insomnia)
- indigestion or heartburn
- inflammation and swelling of the tubes in your lungs (bronchitis)
- common cold (nasopharyngitis)
- depression
- migraine
- tension headache

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
- anxiety
- mood changes

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)

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.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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 or on the wallet or on the carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Do not use this medicine 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.
- Otezla 10 mg film-coated tablets: each film-coated tablet contains 10 mg of apremilast.
- Otezla 20 mg film-coated tablets: each film-coated tablet contains 20 mg of apremilast.
- Otezla 30 mg film-coated tablets: each film-coated tablet contains 30 mg of apremilast.

The other ingredients in the tablet core are cellulose microcrystalline, lactose monohydrate, croscarmellose sodium and magnesium stearate.
- The film-coating contains poly (vinyl alcohol), titanium dioxide (E171), macrogol (3350), 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 for treatment initiation

The treatment initiation packs are folding wallets containing:

- 27 film-coated tablets: 4 × 10 mg tablets and 23 × 20 mg tablets
- 27 film-coated tablets: 4 × 10 mg tablets, 4 × 20 mg tablets and 19 × 30 mg tablets

Pack sizes with Otezla 20 mg tablets

- The one-month standard pack contains 56 × 20 mg film-coated tablets.

Pack sizes with Otezla 30 mg tablets

- The one-month standard pack contains 56 × 30 mg film-coated tablets.
- The three-month standard pack contains 168 × 30 mg film-coated tablets.

Marketing Authorisation Holder
Amgen Limited
216 Cambridge Science Park
Milton Road
Cambridge
CB4 0WA
United Kingdom

Manufacturer
Amgen Europe B.V.
Minervum 7061
4817 ZK Breda
The Netherlands

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

Amgen Limited
Tel: +44 (0)1223 420305

This leaflet was last revised in December 2025.

Other sources of information

Detailed and updated information on this medicine is available by scanning the QR code on the outer packaging with a smartphone. The same information is also available on the following URL: www.medicines.org.uk.

Package leaflet: Information for the patient

Otezla 10 mg film-coated tablets
Otezla 20 mg film-coated tablets
Otezla 30 mg film-coated tablets
apremilast

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- 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 you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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 to treat adults with the following conditions:
- **Active 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 chronic 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', 'methotrexate' or 'psoralen '.
- **Behçet's disease (BD)** - to treat the mouth ulcers which is a common problem for people with this illness.

Otezla is used to treat children and adolescents 6 years of age and older and weighing at least 20 kg with the following condition:
- **Moderate to severe plaque psoriasis –** if your doctor determines that it is appropriate for you to take a systemic therapy like Otezla.

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.

What Behçet's disease is

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

How Otezla works

Psoriatic arthritis, psoriasis and Behçet's disease 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, psoriasis and Behçet's disease, and thereby reduce the signs and symptoms of these conditions.

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

In adults and in children and adolescents from the age of 6 years and weighing at least 20 kg with psoriasis, treatment with Otezla results in a reduction in psoriatic skin plaques and other signs and symptoms of the disease.

In adults with Behçet's disease, treatment with Otezla reduces the number of mouth ulcers and can stop them completely. It can also reduce the associated pain.

Otezla has also been shown to improve the quality of life in adult and paediatric patients with psoriasis, adult patients with psoriatic arthritis and adult patients with 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 you need to know 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.

Depression and suicidal thoughts

Tell your doctor before starting Otezla 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.

Severe kidney problems

If you have severe kidney problems, your dose will be different – see section 3.

If you are underweight

Talk to your doctor while taking Otezla if you lose weight without meaning to.

Gut problems

If you experience severe diarrhoea, nausea, or vomiting, you should talk to your doctor.

Children and adolescents

Otezla is not recommended for use in children who have moderate to severe plaque psoriasis and are below 6 years of age or weigh less than 20 kg, because it has not been studied in these age and weight groups.

Otezla is not recommend for use in children and adolescents below 18 years of age in other indications, because safety and efficacy have not been established in this age group.

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

Do not take Otezla if you are pregnant or think you may be pregnant.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
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.

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 have an intolerance to some sugars, contact 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 enough tablets for a total of two weeks of treatment.
- 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 during the first week of treatment (titration phase).
- The 'treatment initiation pack' will also contain enough tablets for another week at the recommended dose.
- Once the recommended dose has been reached, you will only get a single tablet strength in your prescribed packs.
- You will only ever need to go through the stage of gradually increasing your dose once even if you re-start treatment.

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Adults
- The recommended dose of Otezla for adult patients is 30 mg twice a day after the titration phase is completed, as shown in the table below - 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.

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

Children and adolescents 6 years of age and older
- The Otezla dose will be based on body weight.

For patients who weigh from 20 kg to less than 50 kg: The recommended dose of Otezla is 20 mg twice a day, after the titration phase is completed, as shown in the table below - one 20 mg dose in the morning and one 20 mg dose in the evening, approximately 12 hours apart, with or without food. This is a total daily dose of 40 mg.

	Weight of 20 kg to less than 50 kg		
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)	20 mg (brown)	40 mg
Day 6 onwards	20 mg (brown)	20 mg (brown)	40 mg

For patients who weigh at least 50 kg: The recommended dose of Otezla is 30 mg twice a day after the titration phase is completed (the same as the adult dose), as shown in the table below –

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.

	Weight of 50 kg or more		
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

Patients with severe kidney problems

If you are an adult with severe kidney problems then the recommended dose of Otezla is 30 mg **once a day (morning dose)**.

In children and adolescents 6 years of age and older with severe renal impairment, the recommended dose of Otezla is 30 mg **once a day (morning dose)** for patients who weigh at least 50 kg, and 20 mg **once a day (morning dose)** for children who weigh 20 kg to less than 50 kg**.**

Your doctor will talk to you about how to increase your dose when you first start taking Otezla. Your doctor may advise that you only take the morning dose shown in the table above that applies to you (for adults or for children/adolescents) and that you skip the evening dose.

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.

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 a double dose to make up for a forgotten dose.

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.

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
- headaches
- 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
- difficulty sleeping (insomnia)
- indigestion or heartburn
- inflammation and swelling of the tubes in your lungs (bronchitis)
- common cold (nasopharyngitis)
- depression
- migraine
- tension headache

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
- anxiety
- mood changes

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)

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.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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 or on the wallet or on the carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Do not use this medicine 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.
- Otezla 10 mg film-coated tablets: each film-coated tablet contains 10 mg of apremilast.
- Otezla 20 mg film-coated tablets: each film-coated tablet contains 20 mg of apremilast.
- Otezla 30 mg film-coated tablets: each film-coated tablet contains 30 mg of apremilast.

The other ingredients in the tablet core are cellulose microcrystalline, lactose monohydrate, croscarmellose sodium and magnesium stearate.
- The film-coating contains poly (vinyl alcohol), titanium dioxide (E171), macrogol (3350), 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 for treatment initiation

The treatment initiation packs are folding wallets containing:

- 27 film-coated tablets: 4 × 10 mg tablets and 23 × 20 mg tablets
- 27 film-coated tablets: 4 × 10 mg tablets, 4 × 20 mg tablets and 19 × 30 mg tablets

Pack sizes with Otezla 20 mg tablets

- The one-month standard pack contains 56 × 20 mg film-coated tablets.

Pack sizes with Otezla 30 mg tablets

- The one-month standard pack contains 56 × 30 mg film-coated tablets.
- The three-month standard pack contains 168 × 30 mg film-coated tablets.

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Other sources of information

Detailed and updated information on this medicine is available by scanning the QR code on the outer packaging with a smartphone. The same information is also available on the following URL: www.medicines.org.uk.