

Apriva® 10 mg, 20 mg and 30 mg Film-coated Tablets

Apremilast

Read all of this leaflet carefully before you start using 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. 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 "Possible side effects".

The product is known by the name above but will be referred to as Apriva throughout the rest of this leaflet.

In this leaflet:

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

1. What Apriva is and what it is used for

What Apriva is

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

What Apriva is used for

Apriva is used to treat adults with the following conditions:

- **Active psoriatic arthritis** - if you cannot use another type of medicine called 'Disease-Modifying Anti-rheumatic 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 'cyclosporin', 'methotrexate' or 'psoralen'.
- **Behçet's disease (BD)** - to treat the mouth ulcers which is a common problem for people with this illness.

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 Apriva works

Psoriatic arthritis, psoriasis and Behçet's disease are usually lifelong conditions and there is currently no cure. Apriva 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, Apriva 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 psoriatic arthritis, treatment with Apriva results in an improvement in swollen and painful joints and can improve your general physical function.

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

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

Apremilast has also been shown to improve the quality of life in patients with psoriasis, psoriatic arthritis or 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 Apriva

Do not take Apriva

- 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 Apriva.

Depression and suicidal thoughts

Tell your doctor before starting Apriva if you have depression which is getting worse with thoughts of suicide.

You or your caregiver should also tell your doctor straight away if any changes in behaviour or mood, feelings of depression and of any suicidal thoughts you may have after taking Apriva.

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 Apriva 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

Apremilast has not been studied in children and adolescents, therefore it is not recommended for use in children and adolescents aged 7 years and under.

Other medicines and Apriva

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 Apriva can affect the way some other medicines work. Also some other medicines can affect the way Apriva works.

In particular, tell your doctor or pharmacist before taking Apriva 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

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 Apriva in pregnancy. You should not become pregnant while taking this medicine and should use an effective method of contraception during treatment with Apriva.

It is not known if this medicine passes into human milk. You should not use apremilast while breast-feeding.

Driving and using machines

Apriva has no effect on the ability to drive and use machines.

Apriva contains lactose monohydrate and sodium

Apriva contains lactose monohydrate (a type of sugar). Each film-coated tablet of Apriva 10 mg, 20 mg and 30 mg Film-coated Tablet contains 43.7 mg, 87.3 mg or 131 mg lactose monohydrate; respectively. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Apriva contains sodium. Each film-coated tablet of Apriva 10 mg, 20 mg and 30 mg Film-coated Tablet contains 0.28 mg, 0.56 mg or 0.84 mg sodium; respectively, which is less than 1 mmol (23 mg), that is to say essentially 'sodium-free'.

3. How to take Apriva

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 Apriva, you will receive a 'starter pack' which contains all the doses as listed in the table below.
- The 'starter 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 'starter pack' will also contain enough tablets for another 9 days at the recommended dose (days 7 to 15).
- The recommended dose of Apriva 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.
- Apriva 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 (Red)	Do not take a dose	10 mg
Day 2	10 mg (Red)	10 mg (Red)	20 mg
Day 3	10 mg (Red)	20 mg (White)	30 mg
Day 4	20 mg (White)	20 mg (White)	40 mg
Day 5	20 mg (White)	30 mg (Pink)	50 mg
Day 6 onwards	30 mg (Pink)	30 mg (Pink)	60 mg

People with severe kidney problems

If you have severe kidney problems, then the recommended dose of Apriva 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 Apriva.

How and when to take Apriva

- Apriva is for oral use.
- Swallow the tablets whole, preferably with water.
- You can take the tablets either with or without food.
- Take Apriva 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 Apriva than you should

If you take more Apriva 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 Apriva

- If you miss a dose of Apriva, 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 Apriva

- You should continue taking Apriva until your doctor tells you to stop.
- Do not stop taking Apriva 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, migraines or tension 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

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 behavior

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.

5. How to store Apriva

Keep this medicine out of the sight and reach of children.

Store below 30°C.

Store in the original package.

Do not use this medicine after the expiry date which is stated on the package after "EXP". The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of deterioration.

Do not throw away 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 Apriva contains

The active substance is apremilast. Each film-coated tablet of Apriva 10 mg, 20 mg and 30 mg Film-coated Tablet contains 10 mg, 20 mg or 30 mg apremilast; respectively.

The other ingredients are microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, magnesium stearate, colloidal silicon dioxide, Opadry red (in 10 mg tablets only), Opadry white (in 20 mg tablets only) and Opadry pink (in 30 mg tablets only).

What Apriva looks like and contents of the pack

Apriva 10 mg Film-coated Tablets are red elliptical shaped film-coated tablets embossed with "H01" from one side in PVC/PVDC-aluminum blisters.

Apriva 20 mg Film-coated Tablets are white elliptical shaped film-coated tablets embossed with "H02" from one side in PVC/PVDC-aluminum blisters.

Apriva 30 mg Film-coated Tablets are pink oval shaped film-coated tablets embossed with "H221" from one side in PVC/PVDC-aluminum blisters.

Pack sizes:

- Starter pack: 29 film-coated tablets: 4 (10 mg) film-coated tablets, 4 (20 mg) film-coated tablets and 21 (30 mg) film-coated tablets.
- Standard pack: 60 (30 mg) film-coated tablets.

Marketing Authorization Holder and Manufacturer

Hikma Pharmaceuticals
 Bayader Wadi El Seer
 Industrial Area
 P.O. Box 182400
 Amman 11118, Jordan
 Tel: + (962-6) 5802900
 Fax: + (962-6) 5817102
 Website: www.hikma.com

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

This leaflet was last revised in 01/2021; version number JO3.0.

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 also help provide more information on the safety of this medicine.

- Jordan

Jordan Food and Drug Administration- Rational Drug Use and Pharmacovigilance department
 Tel: + (962-6) 5632000
 e-mail: jpc@jfda.jo
 Website: www.jfda.jo
 Smart phones application: JFDA
 Paper reporting form: Yellow card

Council of Arab Health Ministers, Union of Arab Pharmacists

This is a Medicament

- 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.
- The doctor and the pharmacist are the experts in medicines, their 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 all medicaments out of reach of children.