

Package leaflet: Information for the patient

Pevanti 2.5 mg Tablets
Pevanti 5 mg Tablets
Pevanti 10 mg Tablets
Pevanti 20 mg Tablets
Pevanti 25 mg Tablets
Prednisolone

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.
- Your doctor may have given you this medicine before from another company. It may have looked slightly different. However, either brand will have the same effect.

The name of your medicine is Pevanti 2.5 mg Tablets, Pevanti 5 mg Tablets, Pevanti 10 mg Tablets, Pevanti 20 mg Tablets, Pevanti 25 mg Tablets. It will be referred to as Pevanti Tablets for ease hereafter.

Important things you need to know about Pevanti Tablets

- **Pevanti is a steroid medicine.** This can be prescribed for many different conditions, including serious illnesses.
- **You need to take it regularly** to get the maximum benefit.
- **Do not stop taking this medicine** without talking to your doctor - you may need to reduce the dose gradually.
- **Pevanti can cause side effects in some people** (read section 4 for more information). Some side effects such as mood changes (feeling depressed, or 'high'), or stomach problems can happen straight away. If you feel unwell in any way, keep taking your tablets, but **see your doctor straight away.**
- **Some side effects only happen after weeks or months.** These include weakness of arms and legs, or developing a rounder face (read section 4 for more information).
- **If you take this medicine for more than 3 weeks, you will be given a blue 'steroid card':** always keep it with you and show it to any doctor or nurse treating you.
- **Keep away from people who have chickenpox or shingles,** if you have never had them. They could affect you severely. If you do come into contact with chickenpox or shingles, **see your doctor straight away.**

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important for you.

What is in this leaflet

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

1. What Pevanti Tablets are and what they are used for

Pevanti Tablets contain the active ingredient prednisolone. Prednisolone belongs to a group of medicines called steroids. Their full name is corticosteroids. These corticosteroids occur naturally in the body and help to maintain health and well-being. Boosting your body with extra corticosteroid (such as Prednisolone) is an effective way to treat various illnesses such as allergic reactions (for example asthma, eczema) and inflammatory conditions (for example arthritis).

Prednisolone acts by reducing the inflammation caused by these illnesses, which could otherwise go on making your condition worse.

You must take this medicine regularly to get maximum benefit from it.

2. What you need to know before you take Pevanti Tablets

Do not take Pevanti Tablets:

- if you are **allergic** to prednisolone or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- if you have an **infection** that affects your whole body (systemic infection), which is not already being treated (such as measles, chickenpox or shingles).
- if you are suffering from a **herpes** infection of the eye.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Pevanti Tablets.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Pevanti Tablets, especially if:

- you have or have ever had **severe depression** or manic-depression (bipolar disorder). This includes having had depression before while taking steroid medicines like Pevanti Tablets or any of your close family has had these illnesses.
- you have or have ever had **mental problems** such as ‘depression’ or ‘psychoses’.
- you have **epilepsy** (fits).
- you or anyone in your family has **diabetes**.
- you have **high blood** pressure.
- you have **kidney, liver** or **heart** problems.
- you have brittle or weak bones called **osteoporosis**.
- you are receiving treatment for a condition called myasthenia gravis (**a rare muscular disorder**)
- you have ever had **blood clots** (deep vein thrombosis or thromboembolism)
- you or anyone in your family has an eye problem called **glaucoma**.
- you have or have ever had a **stomach ulcer**.
- you have or have ever had a bad reaction such as muscle weakness to any **steroid**.
- you have been in contact with anyone who has chickenpox, shingles or measles. **Contact your doctor immediately for advice.**
- you have or have ever had ‘**tuberculosis**’ (TB).
- you are receiving any **vaccines** (please see below, “Vaccinations”).
- you have **Scleroderma** (also known as **systemic sclerosis**, an autoimmune disorder) because daily doses of 15 mg or more may increase the risk of a serious complication called **scleroderma renal crisis**. Signs of scleroderma renal crisis include **increased blood pressure** and **decreased urine production**. The doctor may advise that you have your blood pressure and urine regularly checked.

If any of the above apply to you, your doctor may want to see you more often during your treatment.

If any of the above applies to you, or if you are not sure, talk to your doctor before taking this medicine.

Contact your doctor if you experience blurred vision or other visual disturbances.

Mental problems while taking Pevanti Tablets

Mental health problems can happen while taking steroids like Pevanti Tablets (see also section 4, Possible side effects)

- These illnesses can be serious.
- Usually they start within a few days or weeks of starting the medicine.
- They are more likely to happen at high doses.
- Most of these problems go away if the dose is lowered or the medicine is stopped. However, if problems do happen, they might need treatment.

Talk to your doctor if you (or someone taking this medicine), show any signs of mental problems. This is particularly important if you are depressed or might be thinking about suicide. In a few cases, mental problems have happened when doses are being lowered or stopped.

Other medicines and Pevanti Tablets

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines may increase the effects of Pevanti Tablets and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat) Pevanti Tablets and some other medicines can affect the way each other work. In particular, tell your doctor if you are taking any of the following:

- medicines for thinning your blood (such as warfarin)
- medicines for **diabetes** (such as insulin)
- medicines for **epilepsy** (such as carbamazepine and phenytoin)
- medicines for **high blood pressure** (such as furosemide and bendroflumethazide)
- medicines which contain **oestrogens** including oral contraceptives
- medicines to treat **infections** (such as rifampicin, erythromycin and ketoconazole – used in fungal infections)
- medicines to treat **asthma** (such as salbutamol and salmeterol)
- **anti-inflammatory** medicines (such as aspirin and ibuprofen)
- ciclosporin – used to suppress the immune system
- methotrexate – used to treat a variety of illnesses such as arthritis
- mifepristone – used for abortion
- oral contraceptives (the ‘pill’)

Vaccinations

If you have just had any injections or vaccinations, tell your doctor before you take Pevanti Tablets. If you are going to have any injections or vaccinations, tell your doctor or nurse that you are taking Pevanti Tablets. This includes those needed for a foreign holiday. Some vaccines should not be given to patients taking Pevanti Tablets. This is because Pevanti Tablets can affect the way some vaccines work. Talk to your doctor if you are not sure.

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.

Pevanti Tablets contain lactose

This medicine contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

3. How to take Pevanti Tablets

If you have been given this medicine for more than three weeks, you will be given a blue ‘steroid card’ by your doctor or pharmacist. It contains information about your medicine, including dose instructions. This is important if you fall ill or are in an accident. You should carry the card with you at all times.

Always take this medicine exactly as your doctor or pharmacist has told you, especially if you are elderly.

Check with your doctor or pharmacist if you are not sure.

Swallow the tablets whole with a glass of water in the morning after breakfast. It is important to take your medicine at the right times.

The recommended doses are

Adults - 20-60 mg daily initially (higher doses may be required for specific conditions), reducing to a maintenance dose of 5-20 mg daily.

Elderly – doses may be adjusted by the doctor depending of the severity of the side effects.

Use in children and adolescents

Children do not take as many tablets as adults. Your doctor will tell you what is the right number of tablets for your child.

Your doctor may change your dose in order to use the lowest effective dose, depending on your response to the medicine.

Your doctor should check your progress at regular visits. Also, your doctor may have to check your progress after you have stopped using this medicine, since some of the effects may continue.

If you take more Pevanti Tablets than you should

If you (or someone else) take more tablets than prescribed, or you think a child may have taken any tablets, contact your nearest hospital emergency department or tell your doctor immediately.

If you forget to take Pevanti Tablets

If you forget to take a dose, take it as soon as you remember and then take your next dose at the usual time. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Pevanti Tablets

If you have been given Pevanti Tablets for more than 3 weeks your doctor will ensure that your dose is gradually reduced so as to avoid any withdrawal symptoms. **It is important that you complete the course of treatment as per your doctor’s instructions.**

If you suddenly stop taking your medicine the following side effects can occur: lack of appetite, feeling sick, being sick, tiredness, skin peeling, inflammation of the inside of the nose, inflammation (swelling and redness) of the conjunctiva (the outermost layer of the eye and the inner surface of the eyelids), muscle or joint pain, fever, headache, weight loss, painful itch skin lumps or low blood pressure. If you notice any of these symptoms please contact your doctor as soon as possible.

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

4. Possible side effects

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

You may experience side effects particularly when you first start taking this medicine. Talk to your doctor or pharmacist if you notice any of the following effects or any effects not listed in this leaflet.

Stop taking Pevanti Tablets and contact your doctor straight away if the following allergic reaction happens: puffy, swollen face, tongue or body, which may cause shortness of breath, shock and collapse.

Tell your doctor straight away if you experience any of the following:

- inflammation of the pancreas (very severe abdominal pains)
- steroids including Pevanti Tablets can cause **serious mental health problems**. These are common in both adults and children. They can affect about 5 in every 100 people taking medicines like Pevanti Tablets. These side effects include:
 - feeling depressed, including thinking about suicide
 - feeling high (mania) or moods that go up and down
 - feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing your memory
 - feeling, seeing or hearing things which do not exist (hallucinations). Having strange and frightening thoughts, changing how you act or having feelings of being alone
 - feeling dependant or addicted to this product.

The following side effects have been reported. **Tell your doctor** if you experience any of the following:

Not known: frequency cannot be estimated from the available data

Heart – high blood pressure, congestive heart failure in those already at risk

Stomach and intestines – increased appetite, indigestion, feeling sick, feeling bloated, weight gain, stomach ulcers which may burst and cause bleeding, diarrhoea, very sore throat and white areas inside your mouth (oral thrush)

Muscles or bones – brittle bones (osteoporosis), muscle weakness and pain

Nervous system – dizziness, headache, difficulty in sleeping, worsening of epilepsy, raised pressure in the skull (causing pain behind the eyes)

Skin – difficult healing of wounds, unusual increase in hair growth on body or face, skin rashes, unusual bruising, thinning of the skin, acne, appearance of reddish purple lines

Hormones – filling or rounding of the face (Cushing's syndrome), periods become irregular or stop completely, changes in blood glucose levels, weight gain, reduced growth in infancy, childhood and adolescence.

Kidney – water and salt retention, loss of potassium in the urine. Scleroderma renal crisis in patients already suffering from scleroderma (an autoimmune disorder). Signs of scleroderma renal crisis include increased blood pressure and decreased urine production.

Blood – blood clots, increase in the number of white blood cells

Eyes – increase pressure in the eye, cataracts, thinning of the tissue of the eye, bulging of the eye, blurred vision

Other – increased risk to infections, previous infections such as tuberculosis (TB) may reoccur more easily.

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 HPRA

Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2 Tel: +353 1 6764971: Fax: +353 1 6762517
Website: www.hpra.ie, E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pevanti Tablets

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 label and carton. The expiry date refers to the last day of that month.

This medicinal product stored in HDPE bottles does not require any special storage precautions. Do not store above 25°C for tablets stored in blisters.

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

6. Contents of the pack and other information

What Pevanti Tablets contain

- The active substance is prednisolone. Each tablet contains either 2.5 mg, 5 mg, 10 mg, 20 mg or 25 mg of prednisolone.
- The other ingredients are: potato starch, lactose, talc, gelatine and magnesium stearate.

What Pevanti Tablets look like and contents of the pack

Pevanti Tablets are plain white, circular tablets with a score-line on one side. Pevanti 2.5 mg and 5 mg are biplane tablets. Pevanti 10 mg tablets are biconvex with a break line on one side and “1” added on one side of the break line. Pevanti 20 mg and 25 mg are biconvex tablets.

Pevanti 2.5 mg, 5 mg, 10 mg and 20 mg Tablets come in packs of 30 tablets each in blisters or in packs of 25, 50, 100, 200 and 300 tablets in HDPE bottles

Pevanti 25 mg Tablets come in packs of 56 or 60 tablets each in blisters or in packs of 10, 56 and 100 tablets in HDPE bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Mercury Pharmaceuticals Ltd,
Capital House
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Manufacturer

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