

## **Package leaflet: Information for the user**

### **Prednisolone 5mg Suppositories**

Prednisolone Sodium Phosphate

- **Prednisolone 5mg Suppositories is a steroid medicine**, prescribed for many different conditions, including serious illnesses.
- **You need to use it regularly** to get the maximum benefit.
- **Don't stop using this medicine** without talking to your doctor – you may need to reduce the dose gradually.
- **Prednisolone 5mg Suppositories can cause side effects in some people** (read section 4 on side effects below). Some problems such as mood changes (feeling depressed or 'high') or stomach problems can happen straight away. If you feel unwell in any way, keep using your medicine, 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 on side effects for more information).
- **If you use it for more than 3 weeks, you will get 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.

**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 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 Prednisolone 5mg Suppositories are and what they are used for
2. What you need to know before you use Prednisolone 5mg Suppositories
3. How to use Prednisolone 5mg Suppositories
4. Possible side effects
5. How to store Prednisolone 5mg Suppositories
6. Contents of the pack and other information

#### **1. What Prednisolone 5mg Suppositories are and what they are used for**

Prednisolone 5mg Suppositories (called Prednisolone Suppositories throughout the rest of this leaflet) 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 corticosteroids (such as Prednisolone Suppositories) is an effective way to treat various illnesses involving inflammation in the body. Prednisolone Suppositories reduces this inflammation, which could otherwise go on making your condition worse. You must use this medicine regularly to get the maximum benefit.

Prednisolone Suppositories are used to reduce tenderness, heat and swelling in the following conditions where the bowel becomes inflamed:

- haemorrhagic and granular proctitis
- Crohn's disease.

## **2. What you need to know before you use Prednisolone 5mg Suppositories**

### **Do not use Prednisolone Suppositories:**

- if you are allergic to Prednisolone sodium phosphate or any of the other ingredients of this medicine (listed in section 6).

If any of the above applies to you talk to your doctor or pharmacist.

### **Check with your doctor first:**

- **If you have ever had severe depression** or manic depression (bipolar disorder). This includes having had depression before while using steroid medicines like Prednisolone Suppositories
- **If any of your close family** has had these illnesses.

### **Warnings and precautions**

#### **Talk to your doctor, pharmacist or nurse before using Prednisolone Suppositories.**

#### **Talk to your doctor if:**

- You have or have ever had tuberculosis (TB)
- You have epilepsy (fits), severe mental illness, hypertension (high blood pressure), osteoporosis (thinning of the bones), stomach or duodenal ulcers
- You or any of your family have ever had glaucoma (raised eye pressure)
- You have recently had a heart attack
- You have recently been in contact with someone who has chickenpox, shingles or measles or recently had chickenpox, shingles or measles yourself. This product may make chickenpox, shingles or measles much worse
- You are diabetic
- You have an underactive thyroid gland
- You have ever suffered from muscle wasting due to corticosteroids
- You have liver, kidney or heart disease
- You have just been or are about to be immunised
- You have myasthenia gravis (an illness that causes you to have weak muscles)
- You have a bowel disease where you have bloody diarrhoea
- You have diverticulitis (a digestive disease)
- You have stomach problems
- You have an infection.

- You experience blurred vision or other visual disturbances.

If any of the above applies to you, talk to your doctor before using Prednisolone Suppositories.

### **Other medicines and Prednisolone Suppositories**

**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 Prednisolone Suppositories and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat)
- Medicines to thin your blood (e.g. Warfarin or Aspirin)
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) (e.g. Ibuprofen or Aspirin)
- Antibiotics (e.g. fluoroquinolones, rifabutin or erythromycin)
- Medicines to treat diabetes (e.g. insulin)
- Medicines to treat epilepsy (e.g. carbamazepine, phenytoin, primidone or phenobarbital)
- Medicines to treat a fungal infection (e.g. amphotericin or ketoconazole)
- Medicines to lower your blood pressure (e.g. hydralazine)
- Water tablets (e.g. bendrofluazide)
- Medication that contains oestrogen (e.g. contraceptives, hormone replacements)
- Medicines for your heart (e.g. digoxin)
- Medicines to treat cancer (e.g. methotrexate or aminoglutethimide)
- Medicines to suppress your immune system (e.g. ciclosporin)
- Mifepristone (used for termination of pregnancy)
- Medicines to treat myasthenia gravis (e.g. anticholinesterases)
- Medicines that contain liquorice
- Medicines used to cause paralysis during operations (e.g. neuromuscular blockers)
- Human growth hormone called somatropin
- Medicines for asthma (e.g. bambuterol, salbutamol, salmeterol or theophylline)
- Medicines to treat ulcers (e.g. carbenoxolone)
- Any other medicine, including medicines obtained without a prescription

If any of the above applies to you, talk to your doctor or pharmacist.

### **Mental problems while using Prednisolone Suppositories**

Mental health problems can happen while using steroids like Prednisolone Suppositories (see also section 4).

- 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 a doctor if you (or someone who is using this medicine), shows 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.

### **Chickenpox, shingles or measles**

You should avoid contact with anyone who has either chickenpox, shingles or measles as it could be extremely serious if you caught it from them.

**Tell your doctor immediately if you suspect you may have come into contact with a person who has chickenpox, shingles or measles.**

### **Pregnancy, breast-feeding and fertility**

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 using this medicine.

## **3. How to use Prednisolone 5mg Suppositories**

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

### **Important:**

**Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not or you are not sure, ask your doctor or pharmacist.**

- When using this medicine you should follow the instructions given by your doctor. The usual dose is outlined below
- One suppository should be used each night and one in the morning after emptying your bowels
- Treatment usually continues for some months and may be restarted if symptoms flare up again after stopping, if your doctor thinks it appropriate.

### **Instructions on how to use Prednisolone Suppositories**

1. Empty your bowels and wash your hands.
2. Unwrap a suppository.
3. Gently insert the suppository into your back passage and allow it to dissolve.
4. Wash your hands.

While you are using this medicine, your doctor may ask you to have check-ups. These are to make sure that your medicine is working properly and that the dose you are using is right for you.

### **If you use more Prednisolone Suppositories than you should**

Do not use more Prednisolone Suppositories than you should. If you accidentally use two suppositories within a shorter period of time than prescribed by your doctor, let your doctor know.

### **If you forget to use Prednisolone Suppositories**

If you forget to use your suppository, contact your doctor who will tell you what to do. If you only remember at the time of your next suppository, use a single suppository and continue as usual. Do not use a double dose to make up for a forgotten dose.

### **If you stop using Prednisolone Suppositories**

**Do not stop using Prednisolone Suppositories without first talking to your doctor.**

**It is very important that you do not suddenly stop using Prednisolone Suppositories even if you feel better, unless your doctor tells you to.** If you stop using your medicine too suddenly, you may suffer from some of the following: Fever, joint and muscle pain, itching eyes, nose or skin, mood changes, loss of weight, low hormone levels and low blood pressure, symptoms of which may include dizziness, headaches or fainting. In extreme cases this can be fatal. Your doctor will tell you how to stop using Prednisolone Suppositories.

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.

##### **Serious effects: Tell a doctor straight away**

Steroids including Prednisolone can cause serious mental health problems. These are common in both adults and children. They can affect about 5 in every 100 people using medicines like Prednisolone.

- **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. Having strange and frightening thoughts, changing how you act or having feelings of being alone.**

In addition, if you experience any of the following side effects whilst using your medicine, **tell your doctor or pharmacist immediately:**

- **Severe allergic reaction** which may include a red and lumpy skin rash, difficulty breathing, swelling of face, mouth, lips or eyelids, unexplained high temperature (fever), shock and feeling faint. **If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away**
- **Serious skin reactions** involving severe blistering and peeling of the skin
- Symptoms of fever, bruising, bleeding, feeling dizzy, sweating, trouble breathing, thinking, or tingling in your arms, legs or gut. These could be signs of a condition known as **leucocytosis**
- Symptoms of nausea, diarrhoea, indigestion, high temperature, yellowing of skin or swelling around your stomach. This could be a sign of **acute pancreatitis**.

Other side effects are:

Not known: frequency cannot be estimated from the available data

- Worsening of tuberculosis (TB), epilepsy or schizophrenia if you already have any of these problems
- Thinning of the bones (osteoporosis)
- Prominent veins or thinning of the skin
- Higher blood pressure

- Increased pressure in the eye (glaucoma)
- Cataracts
- Worsening of viral or fungal eye diseases
- Thinning of the cornea or sclera (the outer wall of the eye)
- Detachment of the retina
- Headaches or blurred vision
- Wasting of muscles
- Breaking of tendons. Symptoms can include hearing or feeling a pop or a snap, severe pain, immediate bruising and an inability to put weight on or use the affected area
- If you have recently had a heart attack, prednisolone can cause the tissues of the heart to tear
- Severe stomach pain
- Stomach ulcers which may bleed
- Irregular menstrual periods
- Acne or extra hair growth
- Weight gain or increased appetite
- Increased risk of infection
- Water retention
- Low levels of potassium in your blood
- Bruising or poor wound healing
- Inflammation of the skin, abscesses or changes in skin colour
- Separation of the top layer of the skin from the lower skin layers
- Blood clots
- Changes in blood test results for lipids (e.g. cholesterol)
- Thrush in the mouth or throat
- Feeling sick, hiccups, heartburn or indigestion
- Fungal infection (candidiasis)
- Loss of blood to your bones (avascular osteonecrosis)
- Bone fractures.

Additional care should be taken if this medicine is given to elderly patients, as side effects may be more serious.

#### **Additional side effects in children and adolescents**

- slowed growth in adolescence
- symptoms of blurred vision, seizures, lethargy, vomiting or behavioral changes. These could be signs of condition known as increased intracranial pressure.

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

## **5. How to store Prednisolone 5mg Suppositories**

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

Store below 25°C and keep the suppositories in the outer carton to protect from light.

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 Prednisolone Suppositories contains**

- The active substance is prednisolone sodium phosphate (5mg). One suppository contains 5mg prednisolone as the sodium phosphate ester
- The other ingredient is Witepsol H15 (hard fat).

### **What Prednisolone Suppositories look like and contents of the pack**

Prednisolone Suppositories are cream coloured, large oval shaped suppositories. They come in packs of 10.

### **Marketing Authorisation Holder**

RPH Pharmaceuticals AB, Box 603, 101 32 Stockholm, Sweden.

### **Manufacturer**

Haupt Pharma Livron, 1, rue Comte de Sinard, F-26 250 Livron, France.

### **Carrying your steroid card**

- If your doctor asks you to carry a steroid card, be sure to keep it with you always.
- Show it to any doctor, dentist, nurse, midwife or anyone else who is giving you treatment.
- Even after your treatment has finished tell any doctor, dentist, nurse, midwife or anyone else who is giving you treatment that you have had steroid treatment.
- A steroid card may be obtained from your doctor, pharmacist or local Family Health Service Authority. In Scotland, steroid cards are available from the Scottish Office of Home and Health.

**This leaflet was last revised in 11/2020.**