

- **Prednisolone Rectal Solution 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 Rectal Solution 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 chicken pox 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Prednisolone Rectal Solution is and what it is used for

Prednisolone 20mg/100ml Rectal Solution (referred to as Prednisolone Rectal Solution in this leaflet) contains 20mg of the active substance prednisolone as the sodium phosphate ester.

Prednisolone Rectal Solution 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 Rectal Solution) is an effective way to treat various illnesses involving inflammation in the body. Prednisolone Rectal Solution reduces this inflammation, which could otherwise go on making your condition worse. You must use this medicine

regularly to get the maximum benefit.

Prednisolone Rectal Solution is used to reduce tenderness, heat and swelling in ulcerative colitis and Crohn's disease, where the bowel becomes inflamed.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you use Prednisolone Rectal Solution

Do not use Prednisolone Rectal Solution:

- if you are allergic to Prednisolone Sodium Phosphate or any of the other ingredients of this medicine (listed in section 6).
- if you are a child.

Warnings and precautions

Talk to your doctor or pharmacist before using Prednisolone Rectal Solution

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

If either of the above applies to you, talk to your doctor before using Prednisolone Rectal Solution.

- if 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.
- if you have myasthenia gravis (an illness that causes you to have weak muscles)
- if you have a bowel disease where you have bloody diarrhoea

- if you have diverticulitis (a digestive disease)
- if you have osteoporosis (thinning of the bones), as post-menopausal females are particularly at risk
- if you have hypertension (high blood pressure)
- if you have a weakening of the heart (caused by an underlying heart or blood vessel problem)
- if you have severe mental illness
- if you are diabetic or have a family history of diabetes
- if you have, or have ever had tuberculosis (TB)
- if you or any of your family have ever had glaucoma (raised eye pressure)
- if you have ever suffered from muscle wasting due to corticosteroids
- if you have liver, kidney or heart disease
- if you have epilepsy (fits)
- if you have stomach or duodenal ulcers
- if you have stomach problems
- if you have an under-active thyroid gland
- if you have recently had a heart attack
- if you have just been or are about to be immunised
- if you have an infection
- if you have undergone intestinal surgery

If any of the above applies to you, talk to your doctor before using Prednisolone Rectal Solution

Mental problems while using Prednisolone Rectal Solution;

Mental health problems can happen while taking steroids like Prednisolone Rectal Solution (see also section 4 on 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 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.

Children

The size of the Prednisolone Rectal Solution bottle means that this product is not suitable for children.

Other medicines and Prednisolone Rectal Solution

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

- Medicines to thin your blood (e.g. Warfarin or Aspirin)
- Non-Steroidal Anti-Inflammatory Drugs (NSAID) e.g. Ibuprofen or Aspirin
- Antibiotics (e.g. fluoroquinolones, rifampicin, 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)

- Medicines to treat a viral infection (e.g. ritonavir)
- Water tablets (e.g. bendroflumazide)
- Medication that contains oestrogen (e.g. contraceptives, hormone replacements, as may become ineffective)
- 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, formoterol, salbutamol, salmeterol, terbutaline or theophylline)
- Medicines to treat ulcers (e.g. carbenoxolone)
- Live vaccines should not be taken by individuals with a damaged immune system

Some medicines may increase the effects of Prednisolone Rectal Solution and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat)

Pregnancy

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 a small risk of cleft palate or retarded growth in the foetus. Also, underactivity of the adrenal glands may occur in a newborn child.

When steroids are essential, patients with normal pregnancies may be treated as though they are not pregnant. Patients with high blood pressure or fluid retention require close monitoring.

Breast-feeding

Small amounts of this medicine pass into breast milk. Infants of mothers taking steroids should be monitored carefully for signs of adrenal suppression.

Driving and using machines.

There are no known effects on driving or using machines.

Warnings about visual problems when using Prednisolone Rectal Solution

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

Prednisolone Rectal Solution contains parahydroxybenzoates which may cause allergic reactions.

3. How to use Prednisolone Rectal Solution

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

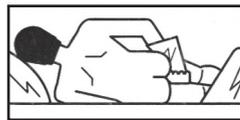
Important:

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.

The recommended dose is one enema used each night for two to four weeks. After this, treatment depends on how your body has responded to the medicine.

Some people prefer a warm enema. If you do, put the bottle in warm water for a few minutes before use.

1. Hold the bottle upwards and remove the cap.
2. Attach the nozzle.
3. Place your hand in the protective plastic bag.
4. Grease the nozzle with petroleum jelly.
5. Lie in bed on the left side with knees drawn up (semi-prone position). Gently insert about half the length of the nozzle into your rectum (back passage). Squeeze the bottle until all the liquid goes into your back passage, taking a minute or so to do it. Slowly remove the nozzle from your back passage making sure that no liquid goes back into the bottle.



6. Invert the plastic bag around the bottle and discard the whole unit without getting up from the semi-prone position.
7. Roll over and lie face down for 3 to 5 minutes. You can then go to sleep in any comfortable position.

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 Rectal Solution than you should

Do not use more Prednisolone Rectal Solution than you should.

If you accidentally use two enemas within a shorter period of time than prescribed by your doctor, let your doctor know. Treatment is unlikely to be needed in cases of serious overdose.

If you forget to use Prednisolone Rectal Solution

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

If you stop using Prednisolone Rectal Solution

Do not stop using Prednisolone Rectal Solution without first talking to your doctor.

It is very important that you do not suddenly stop using Prednisolone Rectal Solution 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 Rectal Solution.

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.

Steroids including prednisolone can cause serious mental health problems, and the following very serious effects may occur.

- Breaking and rupture of tendons
- Allergic reactions (which can include rashes, breathing difficulties or shock)
- Anaphylaxis (which is a severe, potentially life threatening allergic reaction caused by nuts, shellfish, dairy products and insect stings that can develop rapidly)
- Obstruction of a blood vessel by a blood clot (thromboembolism)
- Inflammation of the pancreas which develops quickly, symptoms include severe upper stomach pain, often with nausea and vomiting (acute pancreatitis)
- Toxic epidermal necrolysis - a severe skin reaction which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell
- Headaches, blurred vision, enlargement of blind spot, dimming or blackout of vision, and ultimate loss of vision
- Becoming dependent on something to help alleviate specific emotions (psychological dependence).

These are common in both adults and children. **Common:** may affect up to 1 in 10 people

- Feeling irritable.
- Having delusions.
- Having behaviour problems.
- 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.

- **Worsening of schizophrenia if you already have this problem**

If you notice any of these problems **talk to a doctor straight away.**

Not known: frequency cannot be estimated from the available data.

- Worsening of tuberculosis (TB) if you already have this problem
- Increased risk of infection
- Higher blood pressure
- Changes in blood test results for lipids (e.g. cholesterol)
- Symptoms resembling leukaemia, white blood cell count is raised in response to an allergy, infection or severe physical stress (leukemoid reactions)
- Suppression of growth in infants, children and adolescents
- Irregular periods, or your periods may stop altogether
- A round, usually red face (Cushingoid facies)
- Acne or extra hair growth
- Weight gain or increased appetite
- Intolerance to carbohydrates which might result in a requirement for anti-diabetic treatment
- Loss of protein and calcium balance
- Worsening of epilepsy if you already have this problem
- 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
- 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
- Thrush in the mouth or throat
- Feeling sick, hiccups, heartburn or indigestion
- Prominent veins or thinning of the skin
- Bruising or poor wound healing
- Appearance of stretch marks
- Inflammation of the skin, abscesses or changes in skin colour
- Separation of the top layer of the skin from the lower skin layers
- Thinning of the bones (osteoporosis)
- Spine, arm and leg fractures
- Wasting of muscles
- Salt and water retention in the body
- Lack of, or extreme loss of, the normal amount of potassium
- Abnormal increase in the number of white blood cells (leucocytosis)
- Blurred vision.

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme on the MHRA website: 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 Rectal Solution

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 carton and bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the bottle in the outer carton in order 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 Rectal Solution contains

The active substance is Prednisolone Sodium Phosphate. Each 100ml bottle contains 20mg Prednisolone (as Prednisolone Sodium Phosphate).

The other ingredients are Novapreserve B5, Disodium edetate, Sodium acid phosphate, Disodium phosphate anhydrous, Sodium hydroxide and purified water.

What Prednisolone Rectal Solution looks like and contents of the pack

Prednisolone Rectal Solution is a clear liquid in a 100ml plastic bottle with a separate nozzle and a separate plastic bag. Each bottle, nozzle and plastic bag is only used once. A pack contains seven bottles, seven nozzles and seven plastic bags.

Marketing Authorisation Holder

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Manufacturer

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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 or 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 January 2024.

If this leaflet is difficult to see or read or you would like it in a different format, please contact

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