

## Package leaflet: Information for the user

# Prednisolone 20 mg/dose Rectal Foam (prednisolone metasulphobenzoate sodium)

Your medicine is known by the above name but will be referred to as Prednisolone throughout this leaflet.

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

## 1. What Prednisolone is and what it is used for

Prednisolone is a foam enema which is inserted into the rectum. Prednisolone belongs to a group of medicines called corticosteroids which are used to reduce inflammation. This medicine is used to treat ulcerative colitis (inflammation of the bowels) and may be used to treat proctitis (inflammation of the rectum).

## 2. What you need to know before you use Prednisolone

### Do not use Prednisolone:

- If you are allergic to prednisolone or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from peritonitis (inflammation of the peritoneum – (abdominal lining)).
- If you suffer from bowel problems such as obstruction, perforation or rectal/colonic fistulae (abnormal connection between internal organs) or if you have a possible infection.

If you think this may apply to you speak to your doctor.

### Warnings and precautions

Talk to your doctor before using Prednisolone:

- If 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 you suffer from severe ulcerative colitis this medicine may not be suitable for you and you should talk to your doctor before using it.
- The use of Prednisolone may make diagnosing an infection more difficult, but your doctor should be aware of this.

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

This medicine is for application in the rectum only.

It is not advisable to use Prednisolone for a long period of time, but your doctor will be aware of this.

### Children and adolescents

This medicine is not recommended for use in children (i.e. those under 18 years old).

### Other medicines and Prednisolone

You can use Prednisolone whilst taking other medicines.

Tell your doctor if you are taking, have recently taken or might take any other medicines.

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

### 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.

### Prednisolone contains cetostearyl alcohol and sorbic acid

This may cause local skin reactions (e.g. contact dermatitis).

### Prednisolone contains polysorbates

Polysorbates can cause allergic reactions.

## 3. How to use Prednisolone

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

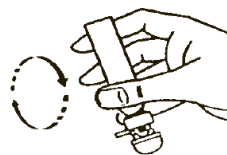
### The recommended dose is:

One metered-dose of Prednisolone should be inserted rectally, using one of the applicator nozzles provided, once or twice daily for 2 weeks. Your doctor may decide to extend the treatment for a further 2 weeks.

### Administration

This medicine has been designed for your maximum comfort and ease of use. Read these instructions carefully before using Prednisolone for the first time.

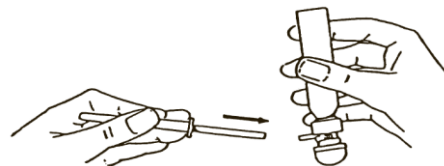
If you find it difficult to use Prednisolone in a standing position an alternative is to administer while lying on your side with both legs bent up.



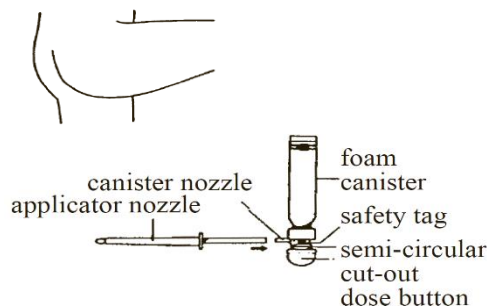
1. Shake before use.

2. When using for the first time remove and discard the small plastic safety tag from under the button.

3. Carefully push an applicator nozzle onto the side arm of the canister. Line up semi-circular cut-out on cap with nozzle.



4. The easiest way to use Prednisolone is to stand with one foot raised on a chair and gently insert the nozzle tip into your rectum. It may help if you smear the nozzle with lubricating jelly before insertion.



5. Important: Holding the canister with the dose button pointing down, press the button on the canister firmly and release. Only press the button once otherwise you will exceed the recommended dose. Note: the canister will only work when held with the dose button pointing down. Foam is expelled when the button is released. Dispose of the used nozzle in the plastic bag provided - the nozzles will not flush down toilets.



## Disposal

The used nozzles should be disposed of in the plastic bag provided.

## If you forget to use Prednisolone

Do not worry if you miss a dose of Prednisolone. Administer it as soon as you remember and then use your next dose at the usual time. Do not use more than 2 doses in one day.

## If you use more Prednisolone than you should

Overdosage by this route is unlikely, but if someone else takes your medicine or it is used incorrectly take the canister to your doctor and ask for advice.

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

## 4. Possible side effects

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

Side effects where the frequency is not known:

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.

Slow heart rate.

Blurred vision.

## 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 at: [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

- **Keep out of the sight and reach of children.**
- Do not use this medicine after the expiry date stated on the carton and canister. The expiry date refers to the last day of that month.
- Pressurised container containing a flammable propellant.
- Do not store above 25°C. Do not refrigerate.
- Protect from sunlight and do not expose to temperatures above 50°C. Do not pierce or burn even after use. Do not spray on naked flame or any incandescent material.
- Discard after 14 doses have been used.

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.

If your medicine becomes discoloured or shows signs of deterioration seek the advice of your pharmacist who will tell you what to do.

## 6. Contents of the pack and other information

### What Prednisolone contains

- Each dose contains 20mg of prednisolone (as prednisolone metasulphobenzoate sodium).
- Also includes cetomacrogol emulsifying wax, cetostearyl alcohol, oleyl alcohol, light liquid paraffin, phenoxyethanol, sorbic acid, polysorbate 20, disodium edetate, sodium hydroxide and purified water. The propellant in Prednisolone contains butane 48.

### What Prednisolone looks like and contents of the pack

Aluminium aerosol with a metering valve containing a white to pale cream coloured foam. Pack containing 1 aerosol, 14 disposable applicators and 14 disposable plastic bags.

Manufactured by PNR Pharma Services Ltd, Building No. 2, The Green, Dublin Airport Central, Dublin Airport, Swords, Co. Dublin, K67 E2H3, Ireland.

or  
PNR Pharma Services Ltd, Skybridge House, Corballis Road North, Dublin Airport, Swords, Co. Dublin, K67 P6K2, Ireland.

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