

Package leaflet: Information for the user

Prednisolone 20 mg Rectal Foam

Prednisolone as Prednisolone Metasulphobenzoate Sodium

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

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1. What Prednisolone 20 mg Rectal Foam is and what it is used for

Prednisolone 20 mg Rectal Foam is a foam enema which is inserted into the rectum. Prednisolone 20 mg Rectal Foam 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 20 mg Rectal Foam

Do not use Prednisolone 20 mg Rectal Foam:

- 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 20 mg Rectal Foam:

- 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 20 mg Rectal Foam may make diagnosing an infection more difficult, but your doctor should be aware of this.
- It is not advisable to use Prednisolone 20 mg Rectal Foam for a long period of time, but your doctor will be aware of this.

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

Children and adolescents

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

Other medicines and Prednisolone 20 mg Rectal Foam

Interactions have been reported between corticosteroids and non-steroidal anti-inflammatory drugs, barbiturates, diuretics, phenytoin, rifampicin, amphotericin, anticoagulants, cyclophosphamide, hypoglycaemic agents and vaccines. These are all documented interactions and are well known to healthcare professionals.

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

Some medicines may increase the effects of Prednisolone 20 mg Rectal Foam 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 for advice before taking this medicine.

Prednisolone 20 mg Rectal Foam contains cetostearyl alcohol and sorbic acid

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

Prednisolone 20 mg/dose Rectal Foam contains polysorbates

Polysorbates can cause allergic reactions.

3. How to use Prednisolone 20 mg Rectal Foam

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

The recommended dose is:

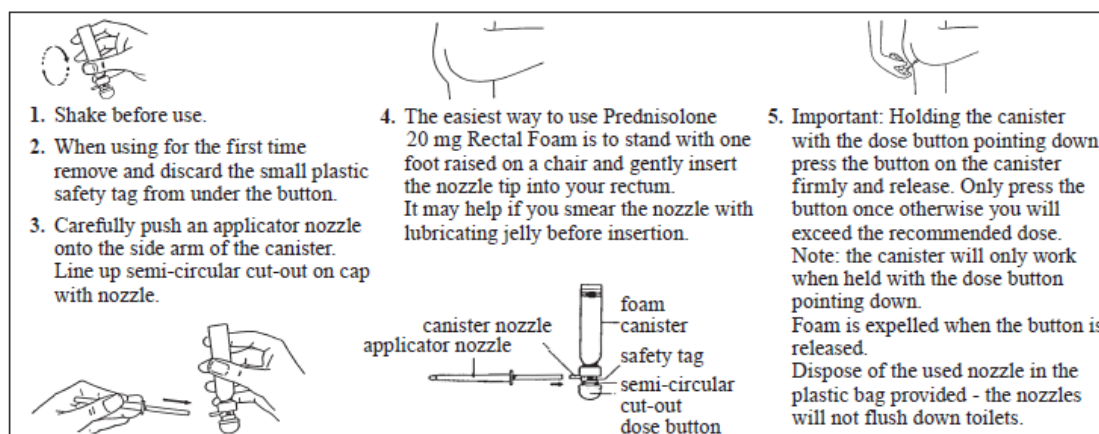
One metered-dose of Prednisolone 20 mg Rectal Foam should be inserted rectally, using one of the applicator nozzles provided, once or twice daily for 2 weeks. Your doctor may decide to extend the treatment for a further 2 weeks.

Administration

This medicine has been designed for your maximum comfort and ease of use. Read these instructions carefully before using Prednisolone 20 mg Rectal Foam for the first time.

This medicine is for application in the rectum only.

If you find it difficult to use Prednisolone 20 mg Rectal Foam in a standing position an alternative is to administer while lying on your side with both legs bent up.



Disposal

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

If you forget to use Prednisolone 20 mg Rectal Foam

Do not worry if you miss a dose of Prednisolone 20 mg Rectal Foam. 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 20 mg Rectal Foam 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.

Normally, there are no side effects associated with the use of Prednisolone 20 mg Rectal Foam.

Side effects where the frequency is not known:

- Blurred vision.
- 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.

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 help provide more information on the safety of this medicine.

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5. How to store Prednisolone 20 mg Rectal Foam

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IR3-1/L/s/8

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 canister after 'EXP'. The expiry date refers to the last day of that month.

Prednisolone 20 mg Rectal Foam is supplied in a pressurised container containing a flammable propellant. Do not store above 25°C. 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. Do not store in a refrigerator.

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 to protect the environment.

6. Contents of the pack and other information

What Prednisolone 20 mg Rectal Foam contains

- The active substance is prednisolone metasulphobenzoate sodium. Each metered dose contains 31.4 mg of the active ingredient (equivalent to 20.0 mg of prednisolone).
- The other ingredients are cetomacrogol emulsifying wax, cetostearyl alcohol, oleyl alcohol, light liquid paraffin, phenoxyethanol, sorbic acid, polysorbate 20, disodium edetate, sodium hydroxide and purified water. (See end of Section 2 for further information on cetostearyl alcohol, sorbic acid, and polysorbate 20). The propellant in Prednisolone 20 mg Rectal Foam is Butane 48.

What Prednisolone 20 mg Rectal Foam looks like and contents of the pack

Prednisolone 20 mg Rectal Foam is a white to pale cream coloured, metered-dose rectal foam supplied in a canister. Each canister contains enough product for 14 doses and comes supplied with disposable applicators and disposal bags.

Marketing Authorisation Holder

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