

PREDFOAM
Prednisolone

as Prednisolone Metasulphobenzoate Sodium

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you notice any side effects please tell your doctor.

In this leaflet:

1. What Predfoam is and what it is used for
2. Before you use Predfoam
3. How to use Predfoam
4. Possible side effects
5. How to store Predfoam
6. Further information

1. What Predfoam is and what it is used for

Predfoam is a foam enema which is inserted into the rectum. Predfoam belongs to a group of medicines called corticosteroids which are used to reduce inflammation.

Predfoam is used to treat ulcerative colitis (inflammation of the bowels) and may be used to treat proctitis (inflammation of the rectum).

2. Before you use Predfoam

Do not use Predfoam:

- If you are allergic (hypersensitive) to prednisolone or any of the other ingredients of Predfoam (see Section 6 for full list of ingredients).
- 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.

Take special care with Predfoam:

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

Predfoam is for application in the rectum only.

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

Using other medicines

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.

Please tell your doctor if you are taking any other medicines, including medicines obtained without prescription.

Pregnancy and breast-feeding

Ask your doctor for advice before using Predfoam if you are pregnant or breast-feeding.

3. How to use Predfoam

Dosage

Always use Predfoam exactly as your doctor has told you. You should check with your doctor if you are not sure.

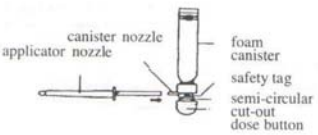
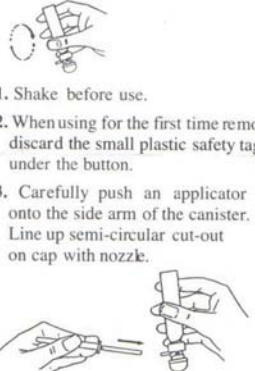

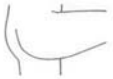
Predfoam is not recommended for use in children (i.e. those under 18 years old).

One metered-dose of Predfoam 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

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

If you find it difficult to use Predfoam 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 Predfoam 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 Predfoam

Do not worry if you miss a dose of Predfoam. Administer Predfoam 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 Predfoam 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 product, ask your doctor.

4. Side effects

Normally, there are no side effects associated with the use of Predfoam. However, if you think that Predfoam is causing you any unusual discomfort or problems, please contact your doctor or pharmacist.

5. How to store Predfoam

Keep out of the reach and sight of children.

Do not use Predfoam after the expiry date stated on the carton and canister after 'Use By End'. The expiry date refers to the last day of that month.

Predfoam 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Predfoam contains

The active substance is prednisolone metasulphobenzoate sodium. Each metered dose contains 31.4mg of the active ingredient (equivalent to 20.0mg of prednisolone).

The other ingredients are non-ionic emulsifying wax, cetostearyl alcohol, oleyl alcohol, technical white oil, phenoxyethanol, sorbic acid, polysorbate 20, disodium edetate, sodium hydroxide and purified water. The propellant in Predfoam is Butane 48.

What Predfoam looks like and contents of the pack

Predfoam is supplied in a canister. Each canister contains enough product for 14 doses and comes supplied with disposable applicators and disposal bags.

Marketing Authorisation Holder

Forest Laboratories UK Limited
Bourne Road, Bexley,
Kent DA5 1NX, UK.

Manufacturer

Pharmaserve (North West) Limited
Astmoor Industrial Estate
Runcorn, Cheshire WA7 1NU.

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Other formats:

To listen to or to request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product Name	Reference Number
Predfoam	0108/0101

This is a service provided by the Royal National Institute of the Blind.



Forest Laboratories UK Limited

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