package leaflet: information for the user

Predfoam® 20 mg Rectal Foam
(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.
• The name of this medicine is Predfoam® 20 mg Rectal Foam but will be referred to as Predfoam throughout the remainder of the leaflet.

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
You can use Predfoam whilst taking other medicines.

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 up.

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. Possible side effects

Normally, there are no side effects associated with the use of PREDFOAM.

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store PREDFOAM

- Keep out of the sight and reach of children.
- Do not use PREDFOAM after the expiry date stated on the carton and canister after ‘EXP’. 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 refrigerate.
- Discard after 14 doses have been used.
- If your medicine becomes discoloured or shows any signs of deterioration, return them to your pharmacist.
- 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 31.4 mg, equivalent to prednisolone 20.0 mg.

Also contains: cetomacrogol emulsifying wax, cetostearyl alcohol, oleyl alcohol, sodium hydroxide, technical white oil, phenoxyethanol, sorbic acid, polysorbate 20, disodium edetate, purified water and butane 48.

What PREDFOAM looks like and contents of the pack

Aluminium aerosol with a metering valve containing a white to pale cream coloured foam. Aerosol contained in a printed carton, together with 14 disposable applicators and 14 disposable plastic bags.

Manufactured by Pharmaserve (North West) Limited, Astmoor Industrial Estate, Runcorn, Cheshire, WA7 1NU, UK

Procured from within the EU by the Product Licence holder: MPT Pharma Ltd, Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall WS9 8ER, UK.

Repackaged by MPT Pharma Ltd.

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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 Prednisolone 20 mg/dose Rectal Foam is and what it is used for
2. Before you use Prednisolone 20 mg/dose Rectal Foam
3. How to use Prednisolone 20 mg/dose Rectal Foam
4. Possible side effects
5. How to store Prednisolone 20 mg/dose Rectal Foam
6. Further information

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

Prednisolone 20 mg/dose Rectal Foam is a foam enema which is inserted into the rectum. Prednisolone 20 mg/dose Rectal Foam belongs to a group of medicines called corticosteroids which are used to reduce inflammation.

Prednisolone 20 mg/dose Rectal Foam 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 Prednisolone 20 mg/dose Rectal Foam

Do not use Prednisolone 20 mg/dose Rectal Foam:
- If you are allergic (hypersensitive) to prednisolone or any of the other ingredients of Prednisolone 20 mg/dose Rectal Foam (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 Prednisolone 20 mg/dose Rectal Foam:
- If you suffer from severe ulcerative colitis Prednisolone 20 mg/dose Rectal Foam may not be suitable for you and you should talk to your doctor before using it.
- The use of Prednisolone 20 mg/dose Rectal Foam may make diagnosing an infection more difficult but your doctor should be aware of this.

Prednisolone 20 mg/dose Rectal Foam is for application in the rectum only. It is not advisable to use Prednisolone 20 mg/dose Rectal Foam for a long period of time, but your doctor will be aware of this.

Using other medicines
You can use Prednisolone 20 mg/dose Rectal Foam whilst taking other medicines.

Pregnancy and breast-feeding
Ask your doctor for advice before using Prednisolone 20 mg/dose Rectal Foam if you are pregnant or breast-feeding.

3. How to use Prednisolone 20 mg/dose Rectal Foam

Dosage
Always use Prednisolone 20 mg/dose Rectal Foam exactly as your doctor has told you. You should check with your doctor if you are not sure.

Prednisolone 20 mg/dose Rectal Foam is not recommended for use in children (i.e. those under 18 years old).

One metered-dose of Prednisolone 20 mg/dose 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
Prednisolone 20 mg/dose Rectal Foam has been designed for your maximum comfort and ease of use. Read these instructions carefully before using Prednisolone 20 mg/dose Rectal Foam for the first time.

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 20 mg/dose Rectal Foam 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.

Dispense is expelled when the button is released.

Dispense 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 20 mg/dose Rectal Foam
Do not worry if you miss a dose of Prednisolone 20 mg/dose Rectal Foam. Administer Prednisolone 20 mg/dose Rectal Foam 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/dose Rectal Foam than you should
Overdose by this route is unlikely, but if someone else takes your medicine 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. Possible side effects

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

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Prednisolone 20 mg/dose Rectal Foam

- Keep out of the sight and reach of children.
- Do not use Prednisolone 20 mg/dose Rectal Foam after the expiry date stated on the carton and canister after ‘EXP’. The expiry date refers to the last day of that month.
- Prednisolone 20 mg/dose 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 refrigerate.
- Discard after 14 doses have been used.
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6. Further information

What Prednisolone 20 mg/dose Rectal Foam contains

The active substance is prednisolone metasulphobenzoate sodium 31.4 mg, equivalent to prednisolone 20.0 mg.

Also contains: cetomacrogol emulsifying wax, cetostearyl alcohol, oleyl alcohol, sodium hydroxide, technical white oil, phenoxyethanol, sorbic acid, polysorbate 20, disodium edetate, purified water and butane 48.

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

Aluminium aerosol with a metering valve containing a white to pale cream coloured foam. Aerosol contained in a printed carton, together with 14 disposable applicators and 14 disposable plastic bags.

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