

Package leaflet: Information for the user

Prednisolon Unimedic 31.25 mg rectal solution prednisolone sodium phosphate

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Prednisolon Unimedic is and what it is used for
2. What you need to know before you use Prednisolon Unimedic
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1. What Prednisolon Unimedic is and what it is used for

Prednisolon Unimedic is a cortisone preparation used for moderate or severe ulcerative proctosigmoiditis (ulcerative inflammation of the large intestine), particularly for the treatment of acute exacerbations in the lower part of the large intestine or rectum.

2. What you need to know before you use Prednisolon Unimedic

Do not use Prednisolon Unimedic

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).
- if you have any local viral, fungal or bacterial infections (such as tuberculosis or gonorrhoea).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Prednisolon Unimedic.

Contact a doctor if you experience blurred vision or other visual impairment.

Other medicines and Prednisolon Unimedic

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines because Prednisolon Unimedic may influence the dosage of certain medicines.

Tell your doctor or pharmacist in particular if you are using any of the following:

Medicine (active substance)	Purpose of use
phenobarbital, phenytoin and carbamazepine	prevention of convulsive seizures
rifampicin	treatment of infections such as tuberculosis
itraconazole	treatment of fungal infections
ketoconazole (excluding shampoo)	treatment of Cushing's syndrome (when the body produces too much cortisol)

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.

There is only limited experience of the use of Prednisolon Unimedic during pregnancy.

Prednisolon Unimedic passes into breast milk but is unlikely to have an effect on breastfed children.

3. How to use Prednisolon Unimedic

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

Your doctor will determine what is the best dosage for you.

The doctor's dosage instructions should always be followed but the recommended dose for adults is usually 125 ml rectal solution into the rectum every evening before going to bed.

Instructions for use

- Prednisolon Unimedic rectal solution is applied at bedtime. Use a plastic bag to protect your hand (see images).
- Press the protective cap as far down as possible against the upper side of the lid (NOTE: do not twist).
- Remove the pressed down protective cap.
- Lie on your left side, possibly with a pillow under your hip, and insert the nozzle of the bottle into your rectum. You can make the insertion easier by greasing the nozzle with a little bit of petroleum jelly.
- Start by squeezing out some solution, so that the rectum gets used to it, and then empty the contents of the bottle into the rectum slowly over a few minutes.
- Remove the nozzle from the rectum when the bottle is empty but keep squeezing the bottle to avoid the solution being drawn back into the bottle.
- If you need to take a break during the use of the rectal solution, remove the nozzle of the bottle from the rectum but keep squeezing the bottle to avoid the solution being drawn back into the bottle. Then continue by applying the rest of the medicine. Discard the bottle after use.
- Roll over and lie still on your stomach for 3 to 5 minutes.
- The rectal solution should stay in the rectum as long as possible, preferably overnight.

Pull the plastic bag over your hand and grab the bottle. Do not release the bottle after it has been emptied. Invert the bag around the bottle and discard it.



If you use more Prednisolon Unimedic than you should

If you use more Prednisolon Unimedic than you should, please contact your doctor or a hospital.

If you forget to use Prednisolon Unimedic

Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

Prednisolon Unimedic is given into the rectum. When prednisolone is given into the rectum, the amount of prednisolone absorbed by the body is not that high, and adverse effects are therefore few. In connection with long-term use, the concentrations of certain hormones produced in the adrenal cortex (part of the adrenal glands) may decrease. (Decrease in plasma cortisol.)

Common (may affect up to 1 in 10 people): Nausea

Rare (may affect up to 1 in 1000 people): Decrease in plasma cortisol

Not known (frequency cannot be estimated from the available data): 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 national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Prednisolon Unimedic

Keep this medicine out of the sight and reach of children.

Keep in the outer carton to protect from light.

Do not store above 25 °C.

Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

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 Prednisolon Unimedic contains

- The active substance is prednisolone sodium phosphate. 125 ml rectal solution contains 31.25 mg prednisolone sodium phosphate equivalent to 23.25 mg prednisolone.
- The other ingredient(s) are purified water, sodium chloride, ethanol (96 %), nicotinamide, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium citrate, disodium phosphate dihydrate, sodium hydroxide and citric acid.

What Prednisolon Unimedic looks like and contents of the pack

Each pack contains 6 soft plastic bottles à 125 ml with a nozzle and a protective cap.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This leaflet was last revised in 2020-02-04