

PERINAL™

CUTANEOUS SPRAY

hydrocortisone/lidocaine hydrochloride

Read all of this leaflet carefully before using this product.

Keep this leaflet. You may need to read it again. Ask your doctor or pharmacist if you need more information or advice. You must contact a doctor if your symptoms worsen or do not improve.

If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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

1. WHAT PERINAL CUTANEOUS SPRAY IS AND WHAT IT IS USED FOR

- Perinal Cutaneous Spray is a treatment to spray on and around your bottom (anus) to relieve painful and itchy symptoms caused, for example, by haemorrhoids (piles).
- Haemorrhoids are swollen or enlarged blood vessels that can be either internal (inside the anus) or external (outside the anus). They can cause varying degrees of pain, itch and irritation, particularly after going to the toilet.
- Perinal Cutaneous Spray is suitable for use by **adults, the elderly and children over the age of 14**. Children under the age of 14 may also use it if recommended by their doctor.
- The **active ingredients** are hydrocortisone and lidocaine hydrochloride. These work by:
 - Reducing itching and inflammation (hydrocortisone), and;
 - Relieving pain and discomfort (lidocaine hydrochloride).

2. BEFORE YOU USE PERINAL CUTANEOUS SPRAY

It is very important that you tell your doctor if:

- you have bleeding or persistent pain from your bottom (anus), especially if associated with having to go to the toilet more or less often than you have done in the past;
- if your stomach is unusually swollen or bloated, or;
- if you are losing weight.

Do not delay telling your doctor if you have any of the symptoms above, because you may need urgent treatment.

Do not use Perinal Cutaneous Spray:

- if you are **allergic (hypersensitive)** to hydrocortisone, lidocaine hydrochloride or any of the other ingredients of Perinal Cutaneous Spray listed in Section 6;
- internally (inside the anus);
- anywhere other than over and around the anal area;
- on broken or infected skin.

Take special care when using this spray:

- Avoid using the spray continuously for more than 7 days, unless advised by your doctor.
- Keep the spray away from the eyes, nose and mouth.
- **For children under the age of 14**, only use Perinal Cutaneous Spray if recommended by a doctor.

Using other medicines

Perinal Cutaneous Spray is not known to affect, or to be affected by, any other medicines. However, tell your doctor or pharmacist if you are using other medicines containing corticosteroids because the risks of side effects (see Section 4) may be additive.

Pregnancy and breast-feeding

It is unclear whether this product is safe for use during pregnancy and breast-feeding. Animal birth defects have occurred with similar medicines containing corticosteroids, so there may be a very small risk of these problems in humans.

You should therefore not normally use this product if you are pregnant or breast-feeding unless your doctor has recommended you to do so.

Driving and using machinery

Using this product is not known to affect your ability to drive or use machinery.

3. HOW TO USE PERINAL CUTANEOUS SPRAY

Use Perinal Cutaneous Spray only on and around your bottom (anus).

Prime the pump before use by pressing down on the top of the pump once or twice.

For adults, the elderly and children over 14 years of age:

- Parting your buttocks, if necessary, spray once over the affected area (the spray will operate in any orientation, even upside down).
- Repeat up to three times a day if you need to.
- Replace the cap after use.
- Always wash your hands after use.

Stop using the spray after 7 days unless your doctor advises you to carry on with it.

If the spray gets into the eyes it may cause irritation. If it gets into the eyes, rinse the eyes with plenty of water. If rinsing one eye, take care to avoid washing product into the other eye. If irritation persists seek medical attention.

If you occasionally forget to use Perinal Cutaneous Spray, do not worry, just carry on using it when you remember.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Perinal Cutaneous Spray can cause side effects, although not everybody gets them.

- You may feel a local tingling sensation after initial application. This is normal and only temporary.
- Rarely, individuals may experience more persistent discomfort and irritation, in which case they may be allergic to the spray's ingredients and should stop using it.
- Topical corticosteroids are usually well tolerated when used in the right amount and for the correct length of time. However, **prolonged, excessive use, particularly in children**, can cause local skin thinning (making the skin damage easily) and adrenal suppression (a type of hormone imbalance that causes generalised effects on the body). Stopping treatment normally corrects these side effects. If any of the side effects get serious, or you notice any other side effects not mentioned in this leaflet, **stop using** this product and **tell** your doctor or pharmacist.

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.

United Kingdom

Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

5. HOW TO STORE PERINAL CUTANEOUS SPRAY

- Keep it out of the reach and sight of children.
- Always replace the cap tightly after use.
- Do not store the product above 25°C.
- Do not use after the expiry date shown on the tube and carton. The expiry date refers to the last day of that month.
- 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 Perinal Cutaneous Spray contains:

The **active ingredients** are **hydrocortisone** (0.2% w/w) and **lidocaine hydrochloride** (1.0% w/w). The **other ingredients** are macrogol cetostearyl ether (cetomacrogol 1000), citric acid monohydrate, sodium citrate, propyl gallate, phenoxyethanol and purified water.

What Perinal Cutaneous Spray looks like and contents of the pack

- The spray is a colourless to pale yellow solution.
- It is available in 30 ml collapsible tubes fitted with metered dose spray pumps and caps.

The Marketing Authorisation holder is

Dermal Laboratories, Hitchin, Herts, SG4 7QR, UK.

The Manufacturer is

Fleet Laboratories Ltd, 94 Rickmansworth Road, Watford, Herts, WD18 7JJ, UK.

To listen to or 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: Perinal Cutaneous Spray, PL 00173/0049.

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