SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Uniroid-HC Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of ointment contains
hydrocortisone 5 mg and cinchocaine hydrochloride 5 mg

Excipient(s) with known effect:
Each gram of ointment contains 5 mg cetostearyl alcohol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment.
An off-white, odourless, smooth, translucent ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Uniroid-HC Ointment is indicated primarily for the treatment of external haemorrhoids for the short term relief of pain, irritation and associated pruritus ani. Uniroid-HC Ointment can also be used for internal haemorrhoids.

4.2 Posology and method of administration

Posology

Adults
Treatment with Uniroid-HC Ointment should be limited to seven days. Patients should be advised to return to their doctor if the condition persists beyond this time.

Directions for use and dosage schedule:
First wash the anal area gently with water and pat dry with cotton wool. With the finger, spread a small quantity of the ointment on the painful area without rubbing. Do not use toilet paper.

Apply the ointment twice a day (morning and evening) and after each bowel movement, or as prescribed by the doctor.

The ointment can be used internally by means of the nozzle applicator which is supplied. Insert the nozzle applicator to full extent and squeeze the tube gently from the lower end whilst withdrawing.

The nozzle applicator must be cleaned thoroughly in warm, soapy water before and after each use.

The ointment may be used separately or concurrently with the suppositories.

Elderly

Dosage modifications are not required in the elderly.

Paediatric population
Uniroid-HC Ointment is not recommended for use in children under 12 years of age unless directed by a doctor.

Method of administration
For rectal use only

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

This product is contraindicated in tuberculosis, anal thrush and most viral lesions of the skin including herpes simplex, vaccinia and varicella.

4.4 Special warnings and precautions for use

Apply only to the region of the rectum and anus and surrounding skin.
Hydrocortisone can cause thinning and damage to the skin.

Recurrent or prolonged application may increase the risk of contact sensitisation particularly to cinchocaine.

As with all preparations containing topical steroids, the possibility of systemic absorption should be considered. In particular, long-term continuous therapy should be avoided in infants. Adrenal suppression can occur even without occlusion.

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR).

Excipients
This medicinal product contains cetostearyl alcohol. This may cause local skin reactions, such as contact dermatitis.

4.5 Interaction with other medicinal products and other forms of interaction

Co-treatment with CYP3A inhibitors, including cobicistat-containing medicinal products, is expected to increase the risk of systemic side-effects.
The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

4.6 Fertility, pregnancy and lactation

Pregnancy
In pregnant animals, administration of corticosteroids can cause abnormalities of foetal development. The relevance of this finding to human beings has not been established. However, topical steroids should not be used extensively in pregnancy, i.e. in large amounts or for long periods.

Breastfeeding
Hydrocortisone may pass into human breast milk. Given the possible maternal systemic absorption and lack of data, Uniroid-HC Ointment should preferably not be used during lactation unless the potential benefits to the mother outweigh the potential risks, including those to the breastfed child.

4.7 Effects on ability to drive and use machines

Uniroid-HC Ointment has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The frequencies of adverse events are ranked according to the following convention: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), not known (cannot be estimated from the available data).

Endocrine disorders
Not known: Adrenal suppression (see section 4.4).
When applied topically and to a large enough area, especially of damaged skin for long enough, or if under occlusive dressing, hydrocortisone may have this adverse effect.

Eye disorders
Not known: Chorioretinopathy, vision blurred (see section 4.4).

Skin and subcutaneous disorders
Not known: Urticaria, rash (see section 4.4).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Not applicable to a product with this route of administration.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Agents for treatment of haemorrhoids and anal fissures for topical use - corticosteroids
ATC code: C 05 AA 01.

Hydrocortisone
The principle pharmacological actions of hydrocortisone are on gluconeogensis, glycogen deposition, protein and calcium metabolism and inhibition of corticotrophin secretion and anti-inflammatory activity (glucocorticoid actions). When applied topically hydrocortisone causes reduction of inflammation, pruritus and exudation in disorders of the skin and perianal region.

Cinchocaine hydrochloride
Cinchocaine hydrochloride is a local anaesthetic agent and is suitable for surface or spinal anaesthesia and for relaxing sphincteric spasms. It is an anaesthetic of the amide type. It is more toxic than cocaine by local application, but its local anaesthetic action is greater, so it can be used in lower concentrations. Its action is more prolonged than lignocaine.

Surface or topical anaesthetics such as cinchocaine block the sensory nerve endings in the skin preventing transmissions of impulses along the nerve fibres and inhibiting depolarisation and ion-exchange. These effects are reversible. Before this blocking action can occur the lipid, soluble anaesthetic base must penetrate the lipoprotein nerve sheath and the effectiveness of the anaesthetic depends on the concentration attained in the nerve fibre. The onset of action varies depending on the anaesthetic used. Cinchocaine has a rapid onset of action and is also long lasting.

5.2 Pharmacokinetic properties

Hydrocortisone

Hydrocortisone is passed through the skin, particularly in denuded areas. About 90% of plasma hydrocortisone is bound to plasma proteins, mainly to globulin, less so to albumin. In the liver and most body tissues it is metabolised to hydrogenated and degraded forms such as tetrahydrocortisone and tetrahydrocortisol. These degraded forms are excreted in the urine. They are mainly conjugated as glucuronides. A very small proportion of unchanged hydrocortisone is excreted in the urine.

Cinchocaine hydrochloride

Most local anaesthetics such as cinchocaine hydrochloride are absorbed through damaged skin. Cinchocaine hydrochloride is an ester-type local anaesthetic. Following absorption, it is hydrolysed by esterases in the plasma and liver.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl alcohol
White soft paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

Externally white enamelled and printed; internally lacquered aluminium tube with medium density polyethylene nozzle applicator and white plug seal cap.

The product is available in tubes of 30g and 15g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 17736/0001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

3 November 2000/ 25 April 2003

10 DATE OF REVISION OF THE TEXT

15/02/2025