

# Peitel cream

*Prednicarbate (D.O.E.) [Spanish non-proprietary name]*

## Composition

Per 100 g of cream:

Prednicarbate (D.O.E.) 0.250 g in an oil/aqueous emollient (O/A), containing the following excipients: Octyldodecanol, Liquid paraffin, Stearyl alcohol, Cetyl alcohol, Myristyl alcohol, Sorbitan monostearate, Polysorbate 60, Benzyl alcohol, Edetate disodium and Purified water.

## Pharmaceutical Form and content of recipient

Cream. Tubes containing 30 g and 60 g.

## Activity

Prednicarbate, the active substance in *Peitel*, is a topical corticosteroid characterised by its marked anti-inflammatory, anti-allergic, anti-exudative and anti-pruritic properties.

## Marketing authorisation holder and manufacturer

Marketing authorisation holder: Laboratorios Novag S.A. Gran Via Carlos III, 94 08028 Barcelona (Spain)

Manufacturer: Ferrer Internacional, S.A. Joan Buscallà 1-9 08190 Sant Cugat del Vallès Barcelona (Spain)

## Indications

*Peitel cream* is indicated for all inflammatory skin disorders that require topical corticosteroid therapy, such as dermatitis, eczema and psoriasis.

*Peitel cream* is suitable for treating particularly sensitive skin regions, large areas and those that require repetitive long-term treatment (maximum 4 weeks). *Peitel cream* can be used in children and the elderly.

## Contraindications

*Peitel cream* should not be used in patients with hypersensitivity to Prednicarbate or any of the excipients.

*Peitel cream* should not be administered to your eyes. Also, *Peitel cream* should not be used to treat acne rosacea, perioral dermatitis, skin reactions caused by vaccinations, or skin manifestations of tuberculosis, syphilis or viral infections (e.g. chickenpox).

Avoid contact between *Peitel Cream* and rubber condoms because they may leak or tear.

## Precautions

Avoid contact with eyes.

## Interactions

None described.

## Warnings

In the event of simultaneous local bacterial or fungal infections, use additional antibacterial or antimycotic treatment.

No damage should occur if you have too high a dose (by applying too much, to very large areas or too frequently), or if you miss an application. However, you are advised to inform your doctor if you do not apply the cream as indicated.

## Pregnancy and breastfeeding:

Its harmlessness has not been demonstrated in pregnancy, and therefore prolonged treatment should be avoided (for longer than four weeks) in extensive areas (more than one third of the body) during the first trimester of pregnancy. There is not sufficient clinical experience during breastfeeding, and therefore it is not recommended during this period.

## Effects on driving capacity

None reported.

## Use in children:

See dosage.

## Dosage

Follow your doctor's instructions exactly with regard to length and frequency of treatment.

Unless otherwise indicated by your doctor, apply a thin layer once or twice daily to the affected skin, rubbing in gently if possible. Normally, 2 or 3 weeks of treatment are sufficient. As with other steroids, it is not advisable to continue treatment for more than 4 weeks.

Administration in children should be limited to the lowest dosage compatible with effective treatment.

*Peitel cream* is a galenic formulation that is appropriate for acute dry or exudative skin disorders.

## Overdose

If the recommended dosage is significantly exceeded, adverse effects from corticosteroids cannot be ruled out.

In this form of presentation the possibility of intoxication following application is unlikely.

In the event of overdosage or accidental swallowing, ring the Toxicology Information Service on 91 562 04 20.

## Adverse reactions

Experience shows that if the product is used as instructed, no side effects are expected such as cutaneous atrophy (thinning of the skin), telangiectasia (dilated small superficial vessels) or distended striae (maximum length of continuous treatment: 4 weeks).

Rarely, there may be itchiness, local skin irritation (stinging, redness, exudate, burning feeling) as a sign of allergic skin reaction, and folliculitis.

Inform your doctor or pharmacist if you have any other reactions apart from those described above.

## Storage

Store at a temperature of less than +25° C.

## Expiry

This medicine should not be used after the expiry date indicated on the package

## Other presentations

*Peitel cream*, 30 and 60 g tubes.

*Peitel ointment*, 30 and 60 g tubes.

*Peitel solution with applicator*, 60 ml bottle.

*Peitel solution*, 60 ml bottle.

## Keep medicines out of reach and out of the sight of children

Text revised: September 1998