PACKAGE LEAFLET

PEITEL 0.25% cream

Prednicarbate

COMPOSITION
Per 100 g of cream:
Prednicarbate 0.250 g in an oil/water emulsion (O/W) which contains as excipients: octyldodecanol, light liquid paraffin, stearyl alcohol, cetyl alcohol, myristyl alcohol, sorbitan monostearate, polysorbate 60, benzyl alcohol, disodium edetate and purified water.

PHARMACEUTICAL FORM AND PACKAGE CONTENT
Cream. Tube containing 30 g.

ACTIVITY
Prednicarbate, the active substance of PEITEL is a topical corticosteroid characterised by its marked anti-inflammatory, antiallergic, antiexudative and antipruritic properties.

MARKETING AUTHORIZATION HOLDER

FERRER INTERNACIONAL, S.A.
Gran Vía Carlos III, 94
08028-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 and large areas where a repetitive long-term treatment is required (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 the eyes. PEITEL cream should neither be used to treat acne rosacea, perioral dermatitis, skin reactions caused by vaccinations, nor skin manifestations of tuberculosis, syphilis or viral infections (e.g. chickenpox).
Contact between PEITEL cream and latex condoms should be avoided as it may cause leaks or tears in them.

PRECAUTIONS
Avoid contact with eyes

INTERACTIONS
None described

WARNINGS
In the event of simultaneous local bacterial or fungal infections, additional antimycotic or antibacterial treatment should be used.
Contact your doctor if you experience blurred vision or other visual disturbances.
The application of too high a dose (application of an excessive amount, on large areas or too-frequent applications) or forgetting a dose once is not expected to cause harmful effects. However, patients are

advised to inform their doctor of any deviation from the prescribed treatment.

This medicine contains cetyl alcohol and stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).
This medicine contains 300 mg benzyl alcohol in each tube of 30 g, which is equivalent to 10 mg/g. Benzyl alcohol may cause allergic reactions and mild local irritation.

Pregnancy and lactation:
It has not been demonstrated that it is harmless in pregnancy; therefore, a long treatment (more than four weeks) on large areas (more than one third of the body surface) should be avoided during the first quarter of pregnancy. There is not sufficient clinical experience during lactation; therefore its use during this period is nor recommended.

Effects on ability to drive:
None described.

Pediatric use:
See Dosage.

DOSAGE
The indications given by the doctor on the duration and frequency of treatment should be followed exactly. Unless prescribed otherwise by your doctor, apply a thin layer of cream on the affected skin area, once or twice daily, rubbing gently if possible. A treatment of 2 or 3 weeks will usually suffice. As with other corticosteroids, the continuous treatment for more than 4 weeks is not advisable.
Administration in children should be limited to the lowest dose compatible with an effective treatment.
PEITEL cream is a galenic form appropriate for acute dry or exudative skin diseases.

OVERDOSE
If the recommended dosage is significantly exceeded, the adverse events related to corticosteroids cannot be eliminated.
With the dosage form of PEITEL cream, the possibility of intoxication following application is unlikely.

ADVERSE EVENTS
The experience shows that, when properly used, no adverse effects as cutaneous atrophy (thinning of the skin), telangiectasia (small dilated superficial blood vessels) or stretch marks can be expected (maximum length of continuous treatment: 4 weeks).
Occasionally, itchiness, local skin irritation as a sign of allergic skin reaction (stinging, redness, exudate, burning feeling) and folliculitis may appear.
With not known frequency (cannot be estimated from the available data), blurred vision may occur.
Tell your doctor or pharmacist if you experience any other reaction different from those described.

STORAGE
Store below 30ºC

EXPIRY
Do not use this medicine after the expiry date shown on the pack.

KEEP MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN