PEITEL DATA SHEET

1. NAME OF THE MEDICINAL PRODUCT

PEITEL Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Pharmacologically Active Components

1 g of cream contains:
2.5 mg of prednicarbate (INN) in an oil-in-water emollient (O/A).

3. PHARMACEUTICAL FORM

Cream.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

PEITEL cream is indicated in all inflammatory skin conditions in which treatment with topical corticosteroids is indicated, such as dermatitis, eczemas and psoriasis.

PEITEL cream is suitable for treatment of particularly sensitive skin regions, large surfaces and conditions where repeated long-term treatment is required (maximum 4 weeks). PEITEL cream may be used in children and the elderly.

4.2. Dosage and Method of Administration

The doctor's indications on the length and frequency of treatment should be followed exactly.

Unless prescribed otherwise by a doctor, apply a thin layer of PEITEL cream once or twice daily to the affected skin, rubbing in gently if possible. Two or three weeks of treatment are normally sufficient. As with other corticosteroids, it is not advisable to continue treatment for more than four weeks.

PEITEL Cream is a galenic formulation suitable for acute dry or exudative skin conditions.

4.3. Contraindications

PEITEL should not be used:

- in patients with hypersensitivity to prednicarbate or any of the excipients (see section 6.1),

- on the eyes. Even application of PEITEL, if prolonged, in the area immediately around the eyes should be preceded by a careful risk-benefit assessment and should only be performed under medical supervision, as small amounts of topical corticosteroids coming repeatedly into contact with the conjunctiva can lead to an increase in intraocular pressure over time.

PEITEL should not be used for the treatment of:

- skin reactions due to vaccinations,
- skin manifestations of tuberculosis, syphilis or viral infections (e.g. chicken pox),
- acne rosacea,
- perioral dermatitis,

as there is a risk of exacerbating the condition.

PEITEL cream contain paraffin which can cause latex condoms to leak or tear, so contact with PEITEL should be avoided.

4.4. Special Warnings and Precautions for Use

Avoid contact with the eyes.
In the event of local bacterial or fungal superinfections, additional antibacterial or antifungal treatment should be administered.

With children, PEITEL should be administered with caution, limited to the lowest dose compatible with effective treatment.

No adverse effects are expected with short-term application of excessive doses (the use of excessive amounts of PEITEL, application over too large an area or overly frequent applications) or with forgetting to apply the treatment on a single occasion. Patients are advised to inform their doctor of any such deviations from the scheduled 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.
Visual disturbance
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) which have been reported after use of systemic and topical corticosteroids.

4.5. Interaction with Other Medicinal Products and Other Forms of Interaction

None have been described.

4.6. Pregnancy and Breastfeeding

Its harmlessness in pregnancy has not been demonstrated; therefore prolonged continuous treatment (more than four weeks) should be avoided in the first trimester of pregnancy.

Extensive application (more than 30% of body surface) of PEITEL cream should not be used during the first trimester of pregnancy.

There is not sufficient clinical experience with use of PEITEL cream during breastfeeding, and therefore its use during this period is not recommended.

4.7. Effects on the Ability to Drive Vehicles and Operate Machinery

None have been described.

4.8. Adverse Reactions

Experience indicates that if the product is used as indicated, no secondary effects, such as skin atrophy, telangiectasia or striae distensae, are expected (maximum length of continuous treatment: 4 weeks).

On rare occasions, itching and local skin irritations (stinging, redness, exudation) as a sign of allergic skin reaction; folliculitis.
With not known frequency, blurred vision may occur (see also section 4.4).
May occasionally produce a burning sensation.

These or any other clinical signs must be reported to the doctor.

4.9. Overdose

If the recommended dose is significantly exceeded, adverse effects specific to corticosteroids cannot be ruled out.

With the PEITEL cream, intoxication after application is unlikely to occur.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Prednicarbate, the active ingredient in PEITEL, is a non-halogenated topical corticosteroid esterified in positions 17 and 21 by the ethyl carbonate and propionate groups, respectively, characterised by its marked antiphlogistic, antiallergic, antiexudative and antipruriginous properties.

Double-blind trials have shown that prednicarbate, despite being a non-halogenated corticosteroids, is equivalent in its clinical effectiveness to halogenated corticosteroids such as betamethasone valerate, desoxymetasone or fluocortolone. If the product is used properly, none of the local adverse effects specific to corticosteroids, such as atrophy or telangiectasia, are to be expected (maximum length of continuous treatment: 4 weeks).

The extremely low influence of prednicarbate on collagen synthesis and the growth of human skin fibroblasts reflects the scant atrophogenic potency of the active ingredient. Following extensive application of prednicarbate on diseased skin (psoriasis, neurodermatitis) no suppression of natural cortisol synthesis has been observed.

5.2. Pharmacokinetic Properties

Healthy skin only absorbs PEITEL at a proportion of 0.1%. Histo-autoradiographic studies show that prednicarbate accumulates in the dermis and there is a clear concentration gradient for the surface, the stratum corneum, towards the stratum basale. After subcutaneous application of 1 to 10 mg of (radio-labelled) prednicarbate per kg of bodyweight in rats, 29% of the dose was eliminated in the urine and 65% in the faeces. Sixty eight per cent of prednicarbate is metabolised into the two main metabolites: 20-dihydroprednisolone and 6-beta-hydroxy-20-dihydroprednisolone.
Comparative studies with prednisolone show that the metabolism of prednicarbate is substantially analogous to that of prednisolone.

Biotransformation of prednicarbate into prednisolone-17-ethyl carbonate, with a milder action, and a half-life of approximately 3 hours, has been identified for the skin compartment.

Neither prednicarbate nor any of its metabolites have been systematically detected after percutaneous administration. This low systemic bioavailability after application to the skin is also reflected in an unaltered cortisol secretion pattern.

5.3. Preclinical Safety Data

The 24-hour epicutaneous test performed with preparations of PEITEL cream on intact and damaged guinea pig and rabbit skin enabled them to be rated as “non-irritant for the skin” in accordance with FDA guidelines.

The contact phototoxicity and photosensitisation tests with prednicarbate showed no indication of a possible appearance of this skin reaction.

The teratogenesis, fertility, embryotoxicity and peri- and post-natal tolerance tests were performed on rats and other embryotoxic tests on rabbits. Just one single high dose of prednicarbate, which produced a systemic effect, caused the known teratogenic effects common to all corticosteroids. If the therapeutic dose and topical application of prednicarbate is observed, these findings are not transferable.

Prednicarbate showed no mutagenic effect in the Ames test or the micronuclei test.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

2-octyl-dodecanol, low-viscosity paraffin, stearyl alcohol, cetyl alcohol, myristyl alcohol, sorbitan monostrearate, polysorbate 60, benzyl alcohol and edetate disodium.

6.2. Incompatibilities

None have been described.

6.3. Shelf-life

3 years

6.4. Special Precautions for Storage

Must be stored at temperatures below 30 ºC.

6.5. Nature and Contents of Container

Flexible aluminium tubes with 30 g of cream.

6.6. Instructions for Use/Handling

Not necessary.

6.7. Name and Permanent Address of the Marketing Authorisation Holder

Ferrer Internacional, S.A.
Gran Vía Carlos III, 94.
08028-Barcelona

With prescription.

KEEP ALL MEDICATION OUT OF THE REACH AND SIGHT OF CHILDREN

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

FERRER INTERNACIONAL, S.A.
Gran Vía de Carlos III, 94
08028 – Barcelona
SPAIN

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

10. DATE OF REVISION OF THE TEXT

September 2017