

PERSKINDOL® COOL (GEL)

1. PRODUCT NAME

PERSKINDOL COOL (GEL)

2. NAME AND STRENGTH OF ACTIVE INGREDIENT

Gel contain the following active ingredients:

Gel: Levomenthol 7%

3. PRODUCT DESCRIPTION

Perskindol Cool (Gel) contains essential oils which when applied to the affected area provides a refreshing cooling sensation.

4. PHARMACODYNAMICS / PHARMACOKINETICS

No pharmacodynamic and pharmacokinetic studies of menthol and active essential oils have been conducted until now. Systemic exposure to menthol under normal conditions of use, is low.

5. INDICATIONS

For the temporary relief from minor aches and pains in muscles and joints, Sprains, bruise and muscle strains from sporting injuries.

6. RECOMMENDED DOSE

Apply in thin layers to the affected area 3 times a day. Can be used on the arms, elbows, wrists, hands, neck, back, shoulders, legs, knees, ankles and feet.

7. MODE OF ADMINISTRATION

Apply a thin layer of Perskindol Cool (gel) without pressure on painful areas 3 times. Wash your hands after use.

8. CONTRAINDICATION

Should not be apply to the face of infants or small children, particularly not in the nasal area (glottal spasm or bronchial spasm up to asthma-like attacks or even possible respiratory failure).

9. WARNING AND PRECAUTION

Do not apply topical peppermint to open the skin areas.

10. INTERACTIONS WITH OTHER MEDICAMENTS

No studies on possible interactions have been conducted to date.

11. PREGNANCY AND LACTATION

Excess use contraindicated in early pregnancy due to its emmenagogue effect.

12. UNDESIRABLE EFFECTS

Hypersensitivity reactions may include skin rash and perianal burning.

13. OVERDOSE AND TREATMENT

Excess use contraindicated in early pregnancy due to its emmenagogue effect.

14. STORAGE CONDITION AND SHELF-LIFE

Store below 30°C.

Shelf-life: 2 years

15. DOSAGE FORM AND PACKAGE AVAILABLE

Gel: 100 ml tubes, and 4 ml sachets

16. NAME OF MANUFACTURER

Vifor SA, Switzerland

17. NAME OF MARKETING AUTHORIZATION HOLDER

Vifor Consumer Health SA, Switzerland

18. NAME OF IMPORTER AND DISTRIBUTOR

Zuellig Pharma Limited., Bangkok, Thailand

19. DATE OF REVISION OF PACKAGE INSERT

August 2017.