PACKAGE INSERT

SCHEDULING STATUS: S2

PROPRIETARY NAME (and dosage form): PHENERGAN® CREAM

COMPOSITION:

PHENERGAN cream contains

Promethazine base	2 g/100 g
Dibromopropamidine isethionate	0,15 g/100 g
Methyl hydroxybenzoate (preservative)	0,2 % m/m

PHARMACOLOGICAL CLASSIFICATION:
A 13.4.2 – Dermatological Preparations - Other

PHARMACOLOGICAL ACTION:
PHENERGAN cream combines the potent long-acting antihistaminic activity and local analgesic properties of the promethazine base with the antiseptic properties of dibromopropamidine isethionate.

INDICATIONS:
PHENERGAN cream is of value in the early treatment of first and second degree burns and scalds, in which it prevents infection, limits erythema, blistering and oedema, relieves pain, minimises the formation of scar tissue and often shortens the period of treatment.

It is useful for early application to insect bites and stings, particularly where there is a risk of secondary infection.

CONTRA-INDICATIONS:
Prolonged treatment of burned or scalded areas with PHENERGAN cream is inadvisable because the antihistaminic and local analgesic effects are only useful for the first days: moreover, prolonged local antihistamine treatment may interfere with healing.

Sensitivity to any of the ingredients.

Do not use for acute vesicular and exudative dermatoses.

DOSAGE AND DIRECTION FOR USE:

In burns and scalds the cream is applied directly to the affected area. Minor lesions and those on exposed parts may require no covering or only such as is necessary for their protection; for those on other parts of the body a gauze dressing and bandage may be indicated and these should not be disturbed more often than is necessary.

In solar or other ultraviolet light burns, the cream may be applied lightly. For insect and other stings the cream should be applied immediately and repeated two or three times a day, or more often if necessary.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

In a few instances promethazine topically has caused photosensitisation and application should be stopped immediately if any such adverse reaction arises or if there is no improvement within 3 days. The cream should be applied sparingly, and with caution on skin which is broken or eczematous.

If very large areas are involved the amount used should be restricted as far as possible, to limit any general effects such as drowsiness, which might result from systemic absorption of the promethazine; this is not likely to occur unless at least several tubes have been used.

Skin sensitisation may occur.

Antihistamines may suppress positive skin test results and should be stopped several days before the test.

PHENERGAN cream may stain clothing, bed linen, etc., such stains often only becoming evident when the material is laundered. Care should therefore be taken to prevent the cream from coming into contact with such articles.

IDENTIFICATION:
A clean, smooth, white or cream-coloured cream.

PRESENTATION:
25 g tubes.

STORAGE INSTRUCTIONS:
Store below 25 ºC.
Protect from light.
Keep out of reach of children.

APPLICATION NUMBER:
G1334 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT:
sanofi-aventis south africa (pty) ltd
2 Bond Street, Midrand, 1685
South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
September 1974