

Deca-Peptide Solution

MELBILD



1. NAME OF THE MEDICINAL PRODUCT

Basic Fibroblast Growth Factor derived Decapeptide Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Decapeptide Solution 5ml where each 5ml contains:

Deca-peptide.....5mg

Excipients

(Tween 80, Brij S2-SO-SG, Isopropyl Myristate, Sodium acetate, Glacial acetic acid, Isopropyl alcohol, purified water)

3. PHARMACEUTICAL FORM

Solution

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the management of vitiligo patches. Topical application of Decapeptide solution induces migratory behaviour and proliferation of melanin producing cells, melanocytes in white depigmented patches of skin and roots of hair.

Decapeptide Solution can effectively be used alone or in combination with other treatments.

4.2 Method of Administration

To begin with remove the plug of the Decapeptide solution container & replace it with a roller. Gently shake the bottle and then apply. Before applying Decapeptide solution clean and dry the affected area thoroughly and then apply as very thin film. It is best to apply Decapeptide solution some 2 hours before retiring for the night. Every morning the treated patches may be exposed to sunlight for 10-15 minutes or commercially available ultraviolet lamps.

4.3 **Contraindications**

Hypersensitivity to any ingredients/components in the formulation

4.4 **Special Warnings and Special Precautions for Use**

For external use only

4.6 **Fertility, Pregnancy and Lactation**

The safety of Decapeptide solution during pregnancy and lactation has not been established but use during these periods is not considered to constitute a hazard.

4.7 **Undesirable Effects**

No side effects or contraindications have been reported.

5. **PHARMACOLOGICAL PROPERTIES**

5.1 **Pharmacodynamic Properties**

Decapeptide Solution which works in similar fashion like bFGF. It is known to modulate cell growth, cell differentiation and motility. bFGF binds to low affinity receptors on the cell surface and in the extracellular matrix and activate melanocytes.

Decapeptide Solution also stimulates the regrowth of melanocytes in depigmented hair roots in the vitiligo patch and surrounding skin and results in re-pigmentation.

Decapeptide Solution increases melanocyte / keratinocyte ratio thus its topical application increases melanocytes in hypopigmented lesions. It acts as a chemotactic agent, helps healthy melanocytes migrate to affected area and restores natural skin complexion.

6. **PHARMACEUTICAL PARTICULARS**

6.1 **Shelf-life:** 18 months

6.2 **Special Precautions for Storage:** Store below 25°C

6.3 **Nature and contents of container:** Glass bottle

Marketed by:

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