

## **Abridged Rx Information : Soframycin Skin Cream**

**For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory**

### **SOFRAMYCIN<sup>®</sup> SKIN CREAM**

**Composition** : Framycetin Sulphate IP 1%w/w, Preservatives (Methyl Paraben IP 0.08%w/w and Propyl Paraben IP 0.04%w/w), Excipients q.s. Available as a tube of 20g/30g/100g. Framycetin is an aminoglycoside antibiotic. **Indications** : Burns, scalds, wounds, ulcers, boils, impetigo, fungulosis, sycosis barbae, otitis externa, paronychia and secondary infections in scabies and lice. **Dosage and Administration** : Apply to affected area two or three times daily. **FOR EXTERNAL USE ONLY.** **Contraindications** : Hypersensitivity to framycetin or to any excipient. **Warnings & Precautions** : Prolonged local use leads to skin sensitisation and possible cross sensitivity to other aminoglycosides. Hypersensitivity reactions may occur during local treatment. Topical use in perforated tympanic membranes may result in deafness. Aminoglycoside antibiotics may cause irreversible, partial or total deafness when given systemically or when applied topically to open wounds or damaged skin. This effect is dose related and is enhanced by renal or hepatic impairment. Although this effect has not been reported following topical treatment the possibility should be considered when high dose topical treatment is given to small children or infants. **Adverse Effects** : Local allergic reactions, hypersensitivity type rarely reported. **Use in Pregnancy** : Aminoglycosides cross the placenta. Because of their chemical similarity, all aminoglycosides must be considered potentially nephrotoxic and ototoxic to the foetus. It should also be noted that therapeutic blood levels in the mother do not equate with safety for the foetus.

**For further information, please write to** Sanofi House, CT Survey No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Andheri – 400 072

**Date of Text Approval : June 2005**

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