

Abridged Prescribing Information Nystaform HC Cream

See Nystaform HC Cream Summary of Product Characteristics (SmPC) prior to prescribing.

Presentation: Cream containing nystatin (100,000 I.U./g), chlorhexidine hydrochloride (1.0% w/w) and hydrocortisone (0.5% w/w) for topical administration.

Indications: Treatment of infected dermatoses where fungal (particularly monilial) and/or bacterial infections are present.

Posology and Method of Administration: Adults and children: For topical application only. Apply to the infected area 2-3 times daily. Treatment should be for a maximum of 7 days. If the condition does not improve within seven days, return to doctor.

Contraindications: Known sensitivity to the active substances, especially those with a history of chlorhexidine-related allergic reactions. Tuberculous lesions of the skin.

Special Warnings and Precautions for Use: For external use only. Avoid contact with the eyes. If sensitivity occurs or if new infection appears, discontinue use and institute alternative therapy. Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis). Chlorhexidine is known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock. Should not be administered to anyone with a potential history of an allergic reaction to a chlorhexidine-containing compound.

In infants, long-term continuous topical steroid therapy should be avoided. Adrenal suppression can occur when extensive areas are treated, particularly under occlusion. Long term continuous or inappropriate use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advice is recommended in these cases or other treatment options should be considered.

Pregnancy and Lactation: Nystatin and corticosteroids should be administered with caution during the early months of pregnancy and its use requires that the anticipated benefits outweigh the possible risks.

Undesirable Effects: *Skin disorders:* Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation and blisters.

Immune disorders: Hypersensitivity including anaphylactic shock.

Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules.

Precautions for Storage: Store below 25°C.

Pack Size and Price: 30 g aluminium tubes with screw caps, £9.66

Legal Category: POM

Marketing Authorisation Number: PL 00551/0019

Marketing Authorisation Holder: Typharm Limited, Unit 1, 39 Mahoney Green,
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

Adverse events should also be reported to Typharm Limited on 02037 694160.