

Policy for the Prescribing of Antifungals for the Treatment of Oropharyngeal Candidiasis in Neonates and Babies in General Practice.

(Sept. 2013)

Introduction

This policy has been developed to improve access to health care by enabling non-medical (independent and non-independent) prescribers to prescribe miconazole and nystatin, as stated in this policy, for neonates and babies. **NB Miconazole oral gel is not licensed for use in infants under four months old or in those whose swallowing reflex is not yet sufficiently developed due to the (small) risk of choking but is the preferred 1st line agent.** Miconazole can be prescribed 'off-label' by independent prescribers but should not be used if the child is taking other drugs extensively metabolised by the liver (please see BNFC for further guidance on interactions).

Throughout this policy the term 'non-independent prescriber' refers to those who are able to prescribe from a limited formulary and as such are not allowed to prescribe 'off-label'. However, the 'off-label' use of nystatin has been endorsed by the Nurse Prescribers' Advisory Group, Department of Health based on the poor systemic absorption of nystatin from the gastro-intestinal tract and when the prescriber is satisfied that the diagnosis is that of thrush.

This policy replaces the previous policy, "Policy for the Prescribing of Drugs used in the Treatment of Oropharyngeal Candidiasis in Neonates".

Scope

This policy applies to all NHS Rotherham CCG non-medical (independent and non-independent) prescribers who prescribe for children.

Policy Objectives

- To improve patients access to health care.
- To enable medication to be prescribed by a qualified non-medical prescriber without the need for referral to a medical practitioner.

Implementation

The NHS Rotherham CCG Medicine's Management team guidelines have been produced and approved by the NHS Rotherham CCG Medicine's Management Committee. These will be made available to all prescribers via the CCG intra- and internet.

The guidelines will be reviewed on a regular basis in light of new evidence, which may become available. The prescriber must accept professional, clinical and legal responsibility for this prescribing. The prescriber should explain the situation to the person with parental responsibility where possible but where it is not, the prescriber should act in accordance with best practice in the given situation and within the policy of the employing organisation. This should be recorded in the patient's record. Written information should be offered whenever possible.

Dissemination:

General Practitioners
Practice Nurses

Miconazole use for Oropharyngeal Candidiasis in Neonates.

Children's BNF 2013-2014

Following a review of the safety data by the MHRA, the lower age limit for miconazole oral gel has been revised to 4 months due to the risk of choking.

To prevent re-infection it is important to ensure the mother's breast nipple and the teats of feeding bottles are cleaned adequately. If candidal infection fails to respond after 1 to 2 weeks of treatment with miconazole the child should be sent for investigation to eliminate the possibility of underlying disease. Persistent infection may also be caused by re-infection from the genitourinary or gastro-intestinal tract.

Use of miconazole for oropharyngeal candidiasis in neonates and babies.

Apply to all areas of mouth, cheeks, gums, roof of mouth and the tongue with clean fingertip. Caution is required to ensure that the gel does not obstruct the throat. The gel should not be applied to the back of the throat and the full dose may need to be divided into smaller portions. The dose should be measured by oral syringe or 2.5ml medicine spoon and then administered by a fingertip.

Drug	Treatment licence	Children's BNF	
Miconazole oral Gel	Not licensed less than 4 months old or during the first 5-6 months of life in a pre-term infant.	Treatment: neonate 1ml 2-4 times daily 1 month-2 years 2.5ml twice daily	Use after food; retain near lesions Treatment should continue for 48 hours after lesions have disappeared

In neonates nystatin oral suspension is not licensed, but is used, for the treatment of oropharyngeal candidiasis. To prevent re-infection it is important to ensure the mother's breast nipple and the teats of feeding bottles are cleaned adequately. If candidal infection fails to respond after 1 to 2 weeks of treatment with nystatin the child should be sent for investigation to eliminate the possibility of underlying disease. Persistent infection may also be caused by re-infection from the genito-urinary or gastro-intestinal tract.

Use of nystatin for oropharyngeal candidiasis in neonates and babies

Drug	Treatment licence	Children's BNF	Comments
Nystatin Suspension	Not licensed less than 1 month	Treatment : Neonate 100,000 u (1ml) four times a day after feeds 1mth -18yrs 100,000 u (1ml) four times a day after meals.	Not absorbed from GI tract. Treatment usually given for 7 days and should continue for 48 hours after lesions have disappeared.

To prevent re-infection, both mother and infant need to be treated simultaneously, even if only one shows symptoms of thrush.

Signs and symptoms in the mother.

Surface Thrush:

- Sudden onset of pain in both nipples after some days or weeks of pain-free breastfeeding. Nipples may be so painful the mother starts to dread feed times.
- The pain is not relieved by improved attachment.
- Cracked nipples, which do not heal.
- Nipples may be very sensitive to any touch and may be itchy.
- Loss of colour to the nipples or areola.
- Mothers may have had a bout of vaginal thrush or taken a recent course of antibiotics.

Independent Prescribers-Miconazole 2% Cream x 45g for the Mother

Apply a small amount to nipples *after every feed*. Gently wipe off any cream, which can be seen before next feed (do this gently to avoid further nipple damage; there is no need to wash cream off).

Non-independent Prescribers- Miconazole 2% Cream x 45g for the Mother

Apply a small quantity to the nipples *twice a day* for 10 days after the lesions have disappeared to prevent relapse. **Note:** This is the licensed dosage frequency-non-independent prescribers are not authorised to prescribe off-label.

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Improving Patients Access to Medicine DOH 2006

SHA Non medical Prescribing Leads guidance DOH 2007

The NHS Rotherham CCG Medicines Management Committee endorsed the prescribing of miconazole and nystatin to neonates and babies in accordance with the information in the Children's BNF 2013-2014 and the DH Non-Medical Prescribing recommendation December 2008, at the meeting on 18th September 2013.