Dosing of Nystatin Suspension

**Issues**

- The recent copies of the BNF have changed the previous advice on the dosing of nystatin suspension from 1mL four times a day to 4-6mL four times a day.
- Latest BNF statement
  - adult and child over 2 years, 400 000–600 000 units 4 times daily (half dose in each side of the mouth);
  - infant and child 1 month–2 years, 200 000 units 4 times daily (half dose in each side of the mouth);
- There are two licensed products on the market with differing dosing:
  - **Nystan - E. R. Squibb & Sons Limited**
    - Neonates – birth to 1 month – 1mL QDS
    - Infants – 1 month to 2 years – 2mL QDS
    - Children (>2years) and adults – 4-6ml QDS
  - **Nystatin Oral Suspension – Sandoz**
    - Infants – 1 month to 2 years – 1mL QDS
    - Children (>2years) and adults – 1mL QDS for denture sores and oral infections
- No mention of immunocompromised etc in the SPCs for the above
- Change to the new regime would increase usage within the Trust
- The data supporting the change is scant and doesn’t appear to being followed in other local Trusts.

**Supporting Data**

- Dose in the BNF remained at 1mL qds in edition 71 – the change to 4-6mL occurred from edition 72
- BMS were questioned on the fact that their dosage schedule has changed to 4-6mL QDS – their rationale is based on an EPAR and 3 supplied papers.
  - The recommendations for dosing in adults and children within the SmPC are specifically referenced to the following publications (which are enclosed for your reference):

These references were published from 1995 to 1997 and are the only publications referenced to the adult and children dosing recommendation within the SmPC.

- All three BMS papers are around 10 years old, and refer to complex immunocompromised patient groups – who may require higher doses.
- Discussion with Sandoz suggests that they are not planning to change the dose recommendations away from 1mL QDS
- The BNF have not claimed any solid rationale for changing the dosage regime.
- Other local Trusts are maintaining the treatment dose for non-immunologically compromised patients as being 1mL QDS. Mid Yorks have moved over to the use of oral fluconazole.

**Recommendation**
- Maintain dosing at 1mL qds for denture sores and oral infections in non-immunocompromised patients
- Dosing in immunocompromised, palliative and GI candidiasis could use the higher dose regime, as is current practice.
- That this recommendation is accepted until further evidence comes to light.

**Other potential options**
- Miconazole oral gel - issues with interaction with warfarin
- Fluconazole

Yours sincerely

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