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Miconazole Oral gel to treat oral thrush in babies

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BfN information on thrush and breastfeeding was withdrawn from sale in 2008 and re-launched in 2009. The reason for the changes was that Janssen-Cilag, the manufacturers of Daktarin Oral gel, altered the licensed application with respect to the age from which it is recommended. They now suggest that this product is **unsuitable for use in babies under 4 months** and only with care between 4 and 6 months ⁽¹⁾.

Despite extensive consultations with the manufacturer and breastfeeding experts in the US, Canada and Australia, it has proved difficult to discover the reason behind the change. It appears to originate from concerns regarding the administration of the gel and the risk of an infant choking due to the viscosity of the gel, rather than the medication itself ⁽²⁾.

The alternative licensed anti fungal agents available to treat oral candida in an infant below 4 months are nystatin suspension and oral fluconazole suspension for the baby. The current research evidence for nystatin suspension is poor according to Hoppe ⁽³⁾.

If practitioners choose to continue to use miconazole oral gel they should ensure that the mother/carer is aware that the gel should be applied **gently**; in **small amounts at a time** until all the mucosal surfaces are coated. It is important that the **spoon is not used** to administer the gel and that the back of the throat is not touched either by the adult's finger or by the gel ⁽⁴⁾.

Health care providers must ensure, when recommending this product, that the client understands how to apply the product safely i.e. **Using a clean finger, apply small amounts of gel at a time to the inside cheeks and over the tongue, four times a day after feeds.**

Practitioners who recommend miconazole the oral gel should note that responsibility for use of the oral gel in a baby under 4 months of age remains with the person who prescribes or recommends its use.

The license application does not necessarily imply a risk, but should be considered professionally on an individual basis.

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The Breastfeeding Network is a Registered Scottish Charity No SC027007

References

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