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**Press Release: 8th July 2008.**

**The Breastfeeding Network *Thrush and Breastfeeding Leaflet* Update on the use of miconazole oral gel.**

The Breastfeeding Network information on thrush and breastfeeding was withdrawn from sale in June 2008. The BfN can take no responsibility for any leaflets photocopied or distributed subsequent to our press release of the 9<sup>th</sup> June 2008. BfN always strives to provide the most up-to-date and research based information. New fact sheets and information on the website [[www.breastfeedingnetwork.org.uk](http://www.breastfeedingnetwork.org.uk)] will be updated and a new Thrush and Breastfeeding leaflet will be developed.

The reason for the withdrawal of the BfN leaflet was that Janssen-Cilag, the manufacturers of Daktarin Oral gel<sup>®</sup>, have altered the licensed application with respect to the age from which it is recommended<sup>i</sup>. They now suggest that this product is **unsuitable for use in babies under 4 months** and only with care between 4 and 6 months<sup>ii</sup>.

Despite extensive consultations with the manufacturer and breastfeeding experts in the UK, USA, Canada and Australia, it has proved difficult to discover the reason behind the change at this time.

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<sup>iii</sup>. There is one published report<sup>iv</sup> of a 17 day old baby (born at 36 weeks) in Holland who choked on gel applied to the mother's nipple. The baby recovered without further problems and needed no medical intervention. The paper mentions 9 other babies (aged between two and twenty weeks) all of who suffered some form of difficulty in breathing temporarily but with no long term ill effects. Only one of the ten babies was admitted to hospital. The authors of the paper suggest that it is important to consider the potential for airway obstruction and resultant asphyxiation in young babies with impaired swallowing. Instructions should therefore be provided regarding the correct application of the gel.

The alternative licensed anti fungal agents available to treat oral candida in an infant below 4 months are nystatin suspension<sup>v</sup> and oral fluconazole suspension.

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 a **spoon is not used**

To find your nearest Breastfeeding Supporter call the **Supporterline 0844 412 4664**

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to administer the gel and that the **back of the throat is not touched** either by the adult's finger or by the gel.

Practitioners who recommend miconazole 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.

A temporary version of the leaflet "Thrush and Breastfeeding" has been uploaded onto the website with information to miconazole gel being removed at this time [[www.breastfeedingnetwork.org.uk/thrush-and-breastfeeding.html](http://www.breastfeedingnetwork.org.uk/thrush-and-breastfeeding.html)]. We are constantly reviewing the information available as new research is conducted. Therefore, from time-to-time the information on this website may be updated - please be sure to check you have the latest available details

## References

<sup>i</sup> <http://emc.medicines.org.uk/emc/assets/c/html/displayDocPrinterFriendly.asp?documentid=7301>

<sup>ii</sup> <http://www.pharmj.com/editorial/20080531/products/p650products.html>

<sup>iii</sup> <http://www.thewomens.org.au/ThrushinLactation>

<sup>iv</sup> De Vries TW, Wewerinke ME, de Langen JJ. [Near asphyxiation of a neonate due to miconazole oral gel]. Ned Tijdschr Geneesk 2006;148:1598–600.

<sup>v</sup> Hoppe JE, et al. 1997, Treatment of oropharyngeal candidiasis in immunocompetent infants: a randomised multicentre study of miconazole gel vs nystatin suspension, Paed Infect Dis 16:288-93.