

Miconazole Gel and the Breastfed baby with oral Thrush (Candida)

This factsheet is intended to provide access to relevant evidence-based information. The national guidelines, research, data, pharmacokinetic properties and links shared are taken from various reference sources, they were checked at the time of publication for appropriateness and were in date. These are provided where we believe the information may be useful but we do not take any responsibility for their content. This factsheet is provided to empower users to make an informed decision about their treatment; but it does not constitute medical advice and cannot replace medical assessment, diagnosis, treatment or follow up from appropriately trained healthcare professionals with relevant competence.

The Breastfeeding Network factsheets will be reviewed on an ongoing basis, usually within three years or sooner where major clinical updates or evidence are published. No responsibility can be taken by the Breastfeeding Network or contributing authors for the way in which the information is used.

If you have any questions about this information, you can contact the Drugs in Breastmilk team through their [Facebook page](#) or on druginformation@breastfeedingnetwork.org.uk.

***Note: as of June 2024 there are shortages of miconazole oral gel in the UK, and you may not be able to obtain it. Please speak to your pharmacist about other treatment options.**

Miconazole oral gel (Daktarin oral gel®) is used to treat fungal and associated bacterial infections in the mouth and throat, such as thrush. If your baby is diagnosed with thrush in their mouth or throat, miconazole oral gel may be prescribed or recommended. This gel is no longer licenced for use in babies under 4 months old. However, it can be prescribed or recommended "off-licence". This factsheet explains why the gel is not licenced for use in babies under 4 months old, and how to use it safely, particularly in younger babies.

Why was the licence changed to over 4 months?

In 2008 Janssen-Cilag, the manufacturers of miconazole oral gel (Daktarin oral gel®), altered the licensed application of the product with respect to the age from which it is recommended. They recommend that it is not licenced for use in babies under 4 months of age and only with care between 4 and 6 months (EMC).

Despite conversations with the manufacturers and breastfeeding experts in USA, Canada and Australia it proved difficult to discover the reason for the change. It appears to originate from the concerns regarding the administration of the gel and the infant choking on the viscosity of the gel, rather than the medication itself (The Royal Women's Hospital, Australia).

This change appears to originate from a published report (De Vries, 1996) documenting a 17 day old baby (born at 36 weeks gestation) who choked when exposed to miconazole oral gel applied to her mother's nipples before and after feeds on the advice of a pharmacist. The baby suddenly stopped feeding and breathing, became cyanotic and lost consciousness. The mother scooped out the visible miconazole gel and the baby recovered within a few moments. The doctor who was called could find no abnormalities and the baby recovered without further problem. The report mentions nine other

To talk to a mum who knows about breastfeeding call the National Breastfeeding Helpline 0300 100 0212

Calls to 0300 numbers cost no more than calls to UK numbers starting 01 and 02 and will be part of any inclusive minutes that apply to your provider and call package.

cases of babies who suffered some form of difficulty with breathing, one of who was admitted to hospital, but all recovered spontaneously.

The alternative licensed anti-fungal agents available to treat oral candida (thrush) in an infant below 4 months of age are nystatin oral suspension and oral fluconazole suspension for the baby. The current research evidence for nystatin is poor according to Hoppe (1996, 1997).

How to use Miconazole oral gel safely in babies

If practitioners choose to continue to recommend 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 surfaces of the mouth are covered. It is important that a 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 (Ainsworth 2009).

Healthcare providers must ensure that when recommending this product that the parent/carer is aware of how to apply the gel safely i.e. using a clean finger, apply small amounts of gel at a time, four times a day after feeds.

The responsibility for the use of miconazole oral gel in a baby under 4 months lies with the practitioner who prescribes or recommends its use.

The licensed application does not necessarily imply a risk if used appropriately but each prescription should be considered on an individual basis. Under no circumstances should miconazole oral gel be applied to the mother's nipples as a means of treating the baby or the mother due to the risk of choking.

References

- Ainsworth, S., & Jones, W. (2009). It sticks in our throats too. *BMJ (Clinical research ed.)*, 338, a3178. <https://doi.org/10.1136/bmj.a3178>
- de Vries, T. W., Wewerinke, M. E., & de Langen, J. J. (2004). Bijna-verstikking van een zuigeling door miconazol orale gel [Near asphyxiation of a neonate due to miconazole oral gel]. *Nederlands tijdschrift voor geneeskunde*, 148(32), 1598–1600.
- Electronic Medicines Compendium (EMC) – miconazole oral gel SPC. <https://www.medicines.org.uk/emc/product/14746/smpc>
- Hoppe, J. E., & Hahn, H. (1996). Randomized comparison of two nystatin oral gels with miconazole oral gel for treatment of oral thrush in infants. Antimycotics Study Group. *Infection*, 24(2), 136–139. <https://doi.org/10.1007/BF01713319>
- Hoppe J. E. (1997). Treatment of oropharyngeal candidiasis in immunocompetent infants: a randomized multicenter study of miconazole gel vs. nystatin suspension. The Antifungals Study Group. *The Pediatric infectious disease journal*, 16(3), 288–293. <https://doi.org/10.1097/00006454-199703000-00007>
- The Royal Women's Hospital, Victoria, Australia: <https://www.thewomens.org.au/health-information/fact-sheets#breast-and-nipple-thrush>