Miconazole/Miconazole-hydrocortisone topical cream Newborn use only

2020

Alert	Daktarin cream contains sodium benzoate - Avoid exposure of >99mg/kg/day of sodium benzoate in neonates.
Indication	Topical antifungal treatment
Action	First-generation imidazole group of azole antifungal agent. It binds to the fungal cytochromes P450 and interfere with ergosterol synthesis in the cell membrane.
Drug type	Antifungal agent.
Trade name	Miconazole 2% cream - Daktarin, Resolve Miconazole 2%/hydrocortisone 0.5% cream – Resolve plus 0.5% Miconazole 2%/hydrocortisone 1.0% cream – Resolve plus 1.0%
Presentation	Cream
Dose	Apply cream topically 3 times a day
Dose adjustment	Therapeutic hypothermia – Not applicable. ECMO – Not applicable. Renal impairment – Not applicable. Hepatic impairment – Not applicable.
Maximum dose	Not applicable
Total cumulative dose	Not applicable
Route	Topical
Preparation	Not applicable
Administration	A thin layer should be applied to the skin
Monitoring	Not applicable
Contraindications	Hypersensitivity to miconazole, other similar antifungals (e.g. ketoconazole) or excipients.
Precautions	Prolonged use may result in overgrowth of non-susceptible microorganisms
Drug interactions	
Adverse reactions	Very rare: anaphylactic reaction, hypersensitivity, angioneurotic oedema, urticaria, dermatitis.
Compatibility	Not applicable
Incompatibility	Not applicable
Stability	Not applicable
Storage	Store below 25°C
Excipients	Daktarin: Butylated hydroxyanisole, liquid paraffin, ethylene glycol, apricot kernel oil PEG-6 esters, tefose 63 and purified water with benzoic acid as a preservative. Resolve: Phenethyl alcohol; protective silicone cream base. Resolve plus: Phenethyl alcohol, 1,3-butylene glycol, cetostearyl alcohol, citric acid, dimeticone 350, disodium edetate, self-emulsifying glyceryl monostearate, light liquid paraffin, PEG-40 stearate, povidone, dibasic sodium phosphate and xanthan gum.
Special comments	The azole group of antifungals are synthetic compounds that have azole rings. Ketoconazole, clotrimazole, and miconazole are imidazoles; fluconazole and itraconazole are triazoles.(1)
Evidence	**Efficacy** **<u>Miconazole topical therapy for candidal diaper dermatitis (CDD):</u>** A double-blind, randomised study evaluated the efficacy and safety of 0.25% miconazole in a zinc oxide/petrolatum vehicle. The overall rate of cure (clinical cure plus microbiologic cure) was 23% for the miconazole group and 10% for the vehicle control group (P=.005); the rate of clinical cure (complete rash clearance at day 14) was 38% for the miconazole group and 11% for the vehicle control group(<0.001); and the rate of microbiologic cure was 50% for the miconazole group and 23% for the vehicle control group.(2) Blanco et al, in their prospective, multicenter, open-label study investigated the potential resistance of Candida spp. to repeated topical use of a 7-day course of 0.25% miconazole ointment in infants age 15 months and younger with moderate to severe CDD. There was no evidence of resistance to miconazole in Candida spp. after single or repeated treatment courses. For the initial episode of CDD, 49.4% achieved a clinical cure, 45.8% achieved a mycologic cure, and 29.2% achieved an overall cure (clinical and mycologic).(3) Twelve of 14 premature infants with CDD were cured by topical administration of miconazole for 7 to 14 days.(4) While concomitant oral antifungal therapy is recommended for clearance of the intestinal fungal reservoir,(5) studies are lacking to recommend or refute this practice.

	Miconazole/steroid combination as topical therapy: In a double-blind randomised trial, infants with moderate to severe napkin dermatitis were assessed using either topical miconazole/hydrocortisone preparation or nystatin/benzalkonium chloride/dimethicone/hydrocortisone preparation. Creams were applied to the affected area 3-times daily for 7 days. Both treatments produced a high and similar overall cure rate (80% and 84%, respectively). Staining of napkins was less frequent in miconazole/hydrocortisone cream.(6) **Safety** No clinically significant adverse effects have been noted in trials evaluating topical application.(2, 3, 7) **Pharmacokinetics** An uncontrolled, open-label, non-crossover, clinical pharmacology trial in infants with DD tested multiple daily applications of 0.25% miconazole ointment or 2% miconazole cream. Plasma concentrations of miconazole were not detectable in majority of infants in ointment group. In 4 of the 5 infants in cream group, plasma concentrations of 5.2 to 7.4 ng/mL were detected. No adverse events were reported for any of the infants.(7)
Practice points	
References	1. Kicklighter SD. Antifungal agents and fungal prophylaxis in the neonate. NeoReviews. 2002;3(12):e249-e55. 2. Spraker MK, Gisoldi EM, Siegfried EC, Fling JA, De Espinosa ZD, Quiring JN, et al. Topical miconazole nitrate ointment in the treatment of diaper dermatitis complicated by candidiasis. CUTIS-NEW YORK-. 2006;77(2):113. 3. Blanco D, van Rossem K. A prospective two-year assessment of miconazole resistance in Candida spp. with repeated treatment with 0.25% miconazole nitrate ointment in neonates and infants with moderate to severe diaper dermatitis complicated by cutaneous candidiasis. Pediatric Dermatology. 2013;30(6):717-24. 4. Vanheule R, Adriaensen K, De Hauwere R, Van Cutsem J, De Cree J. Prevalence and treatment with miconazole of fungal skin infections in children and premature infants. Castellania. 1974;2:91-2. 5. HOPPE JE. Treatment of oropharyngeal candidiasis and candidal diaper dermatitis in neonates and infants: review and reappraisal. The Pediatric infectious disease journal. 1997;16(9):885-94. 6. Bowring A, Mackay D, Taylor F. The treatment of napkin dermatitis: a double-blind comparison of two steroid-antibiotic combinations. Pharmatherapeutica. 1984;3(9):613-7. 7. Eichenfield L. Comparative absorption of 0.25% and 2% miconazole nitrate preparations in infants with diaper dermatitis: P820. Journal of the American Academy of Dermatology. 2007;56(2).

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Authors Contribution

Original author/s	Srinivas Bolisetty
Evidence Review	Tim Schindler
Expert review	Orli Wargon
Nursing Review	Kirsty Minter, Eszter Jozsa, Samantha Hassall
Pharmacy Review	Michelle Jenkins, Thao Tran
ANMF Group contributors	Nilkant Phad, Bhavesh Mehta, John Sinn, Carmen Burman, Jessica Mehegan, Helen Huynh, Cindy Chen
Final editing and review of the original	Srinivas Bolisetty, Thao Tran
Electronic version	Cindy Chen, Ian Callander
Facilitator	Srinivas Bolisetty