Topics: Evening primrose oil (EPO, Gamma-linolenic acid (GLA) Omega-6 fatty acids, skin, topical treatment, diaper rash.

Objective: To determine if topically applied Efamol® EPO is safe and can protect from nappy rash as well as a standard baby skin protection cream (Penaten Baby Wundschutzcreme, Johnson & Johnson – the leading brand of baby wound care cream in Germany and one of the leading brands in other European countries.

Background: Nappy Rash, also called diaper rash, diaper dermatitis or irritant contact diaper dermatitis is a rash that affects the skin under or around a baby's nappy (diaper). It causes discomfort to the infant, anxiety to the caregivers and contributes to the load on the health care system. It is caused by a combination of factors beginning with prolonged exposure to moisture, urine and faeces. Treatment includes topical ointments and creams with zinc oxide, petroleum, cod liver oil, dimethicone, linolin or corticosteroids. Since infants have a larger surface area to volume ratio and have a higher precutaneous absorption than children and adults it is important to limit their exposure to toxic substances. Therefore, a skin care product such as EPO that is free of perfumes, colorants, preservatives and potential allergenic additives would be beneficial.

Method: This open, randomized, controlled, parallel trial included 66 healthy males and females aged between 2 weeks and 6 months and wearing nappies on a regular basis. None had skin diseases, nappy rash in the past 4 weeks prior to the trial or nappy rash symptoms (irritated skin) at the time of trial entry. On Day 0, guardians were provided with either Efamol® EPO or Penaten to use as a substitute for their regular nappy rash cream. An application instruction leaflet and demonstration, and application diary was provided. The guardians were asked to complete a questionnaire on their current treatment regime and to describe past nappy irritations. They were instructed during the treatment phase to pay specific attention to reactions of their infant to the test product, report any incompatibilities directly to the study director and consult their paediatrician in case of nappy rash. In the application diary, guardians were asked to rate the symptoms of *dryness* and *rash* on a 4-point scale (+++ = very strong, ++ = strong, + = slight, 0 = none) and *redness* on a 3-point scale (++ = very red, + = red, 0 = normal). On Day 28 and 58 they were asked to fill out a questionnaire on their experience with the test product with specific attention to the occurrence of nappy rash symptoms (*Redness, Rash* and *Dryness)*.

Clinical Assessments

1. Subjective Evaluation (Questionnaire)
2. Frequency/Intensity of Nappy Rash Symptoms.
3. Time of Occurrence of Nappy Rash

Findings:

1. Subjective Evaluation (Questionnaire)

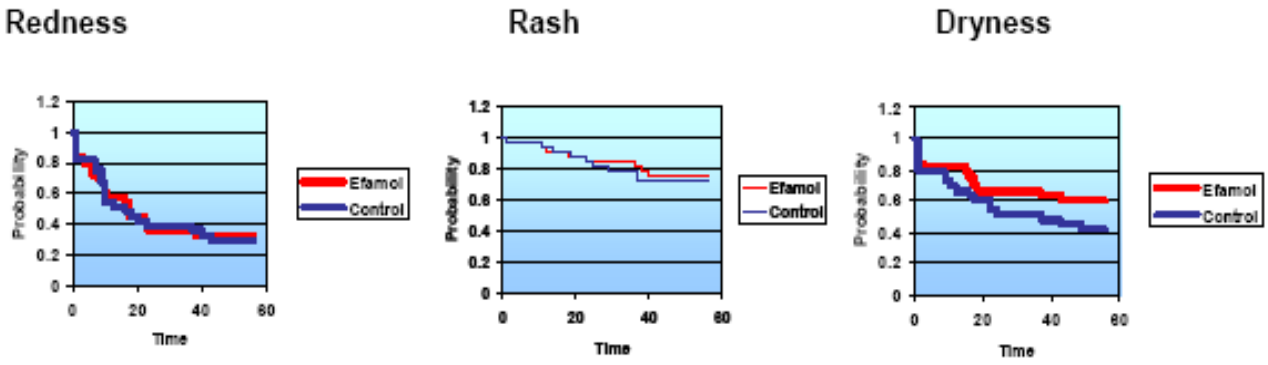
There were no differences in nappy rash symptoms (frequency, intensity or time of occurrence) between the two groups of infants at the start of the study. During the treatment phase, nappy rash symptoms and symptom severity decreased in both groups. The guardians rated both products very favourably for protective effectiveness and overall satisfaction and most preferred the test product over the products they had used previously. Efamol® EPO was rated slightly better than the control for spreadability, pleasant skin sensation and overall infant well-being.

2. Frequency/Intensity of Nappy Rash Symptoms.

Both products were equally effective to reduce the frequency and severity of skin *redness, rash* and *dryness.*

3. Time of Occurrence of Nappy Rash

There was an equally gradual decline in the symptoms of *redness, rash,* d*ryness* in both groups with no significant difference between the two treatments by the end of 8 weeks. The following graphs show the decline in redness, rash and dryness over time.



Conclusion: Efamol® EPO provides protection from nappy rash (symptoms) as effectively as a leading brand of baby skin care cream and was rated as equally favourable by infant's caregivers.

Relevance to Efamol® EPO

Reference:

Muggli R. Natural management of napkin rash. Eur J Pediat Dermatol 2009;19:43-6.

PRESS RELEASE

Topical Efamol® Evening Primrose Oil prevents nappy rash[1].

A new study completed in Bonn, Germany has confirmed for the first time that Efamol Evening Primrose Oil (EPO) works as well as a leading baby skin care cream to prevent nappy rash in infants. Nappy rash is the most common dermatologic disorder of infancy and is characterized by acute inflammation of the skin in the napkin area that lasts for several days. It is caused by a combination of factors beginning with prolonged exposure to moisture, urine and faeces that eventually leads to break down of the skin surface. It causes discomfort to the infant, anxiety to the caregivers and contributes significantly to the financial load on the health care system. The Avon Longitudinal Study of Pregnancy and Childhood (ALSPAC) found that 25% of all infants in the UK were affected by nappy rash during the first four weeks of life.

This randomised, open, controlled clinical study compared the safety and effectiveness of topically applied Efamol® EPO to protect from skin reddening and other symptoms of nappy rash compared to a leading baby skin protection cream called Penaten® Baby Wundschutzcreme by Johnson & Johnson. The trial included 66 babies between 2 weeks and 6 months of age that were clinically healthy and wearing nappies on a regular basis. Guardians of the babies were instructed to apply either Efamol® EPO or Penaten as a substitute for their regular nappy rash cream. In addition, they were asked to complete a questionnaire on their current treatment regime of their infant, to describe past problems with irritations in the nappy area and to monitor and record symptoms of redness, rash and dryness for an eight week period.

During the treatment phase, both products were equally effective to reduce the frequency and severity of skin *redness, rash* and *dryness.* In addition, there was an equally gradual decline in the symptoms of *redness, rash* and *dryness* in both groups with no significant difference between the two treatments by the end of eight weeks. The guardians rated both products very favourably for protective effectiveness and overall satisfaction and most preferred either Efamol® EPO or Penaten over the product they had previously been using. Efamol® EPO was rated slightly better than the control product for spreadability, pleasant skin sensation and overall well-being of the infant.

Standard treatments for nappy rash include topical ointments and creams with zinc oxide, petroleum, cod liver oil, dimethicone, linolin or corticosteroids. Since infants have a larger surface area to volume ratio and have a higher rate of absorption through the skin than children and adults it is important to limit their exposure to toxic substance. Therefore, a skin care product such as EPO that is free of perfumes, colorants, preservatives and potential allergenic additives would be beneficial. This study is the first to show that Efamol® EPO can prevent nappy rash and confirms it is a safe natural means of preventing an irritating problem for both mother and baby.

References:

1. Muggli R. Natural management of napkin rash. Eur J Pediat Dermatol 2009;19:43-6
2. Philipp R, Hughes R, Golding J, The ALSPAC survey Team. Getting to the bottom of nappy rash. British Journal of General Practice. 1997;47:493-497.