

# Dianatal® Obstetric Gel

## Scientific Expert Report

Basel / Marburg / Zürich  
September 2008

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## 1. Product and quality

### Dianatal® Obstetric Gel

Sterile single-use syringes containing 11ml obstetric gel:

- 2 syringes Dianatal® stage I: white plunger
- 1 syringe Dianatal® stage II: blue plunger
- 2 Dianatal® Obstetric Gel applicators

Special properties:

Dianatal® stage I: highly bioadhesive: white plunger

Dianatal® stage II: moderately bioadhesive: blue plunger

Dianatal® obstetric gel is sterile and packaged in sterile single-use syringes. It is non-allergenic, bioadhesive, electroconductive, isotonic, slightly acidic, latex-free, free of preservatives, and kind on mucous membranes and on the eyes.

Dianatal® obstetric gel does not contain any pharmaceutically active ingredients.

Dianatal® obstetric gel is an odourless, almost colourless gel, packed in sterile single-use packaging by autoclave. The gel is highly viscous, isotonic, with a slightly acidic pH of 5.5 – 6.5 and electrical conductivity of 5.0 – 9.0 mS . cm<sup>-1</sup>.

Dianatal® Obstetric Gel is a sterile inert birth gel with no pharmacological effects. Dianatal® was developed for the use during vaginal birth in humans, in order to ease the birth for mother and child by introducing a mucoadhesive film onto the birth canal. Dianatal® is provided in two pharmaceutical forms: Dianatal® Stage I (applied during dilation stage) and Dianatal® Stage II (applied during expulsion stage). Both are sterile local mucous membrane moist gels containing the ingredients propylene glycol, Natrosol 250M, Carbopol 974P NF, sodium chloride and sodium hydroxide. Dianatal® Obstetric Gel has a purely physical activity and has no pharmacological activity. The ingredients propylene glycol, Natrosol 250M and Carbopol 974P NF are judged to contribute to the clinical effect of reducing friction and enhancing gliding of the newborn.

The ingredients propylene glycol, Natrosol 250M and Carbopol 974P NF are regarded as contributing to the clinical effect, and the excipients are purified water used as solvent and sodium chloride and sodium hydroxide used for buffering and as pH adjuster. The gel is sterile packed in disposable plastic syringes (11 ml). The vaginal applicators are of medical PVC, sterile, separately packed. Dianatal® Obstetric Gel is sterile, latex free, electric conductive and free of conservatives.

European Medical Device Classification:

Dianatal® Obstetric Gel is classified as a medical device of the class IIa as it is inert and has no pharmacological activity.

## 2. Scientific evaluation

### I: Evaluation of biocompatibility

Dianatal® Obstetric Gel was examined in accordance with international and FDA guidelines in regards to its biocompatibility (Toxikon Europe, Interleuvenlaan 3/3, B-3001 Leuven, Belgium). The following investigations were performed:

- Agar diffusion test
- Buehler Sensitization Test
- Embryotoxicity Test
- Human Blood Haemolysis Test
- Intracutaneous injection test
- Oral irritation test
- Primary ocular irritation test
- Primary skin irritation test
- Primary Vaginal Exposure Test
- Rabbit Pyrogen Test
- Systemic Injection Test

In accordance with these investigations, no indication of a damaging effect on humans exists. The product and its application are harmless from a biocompatibility point of view.

## 2. Biomechanical scientific evaluation

Annual Conference of the Swiss Society of Gynecology and Obstetrics, Interlaken, June 2008  
Scientific presentation, Prof. Dr. Robert Riener, ETH Zurich and University of Zurich

Quantification of friction reduction by obstetric gels during delivery

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Dianatal Stage 1 and Stage II were investigated in a mammal model under mechanical conditions comparable to human childbirth with respect to pressure, speed and contact surface. The investigations were performed by a special motorized measurement device developed for this study using porcine vaginal tissue. In a first test session, the movement speed of the skin relative to the birth canal was modified in order to investigate dynamic friction. In a second test session,



the dwell time (i.e. resting time before movement initiation) was modified in order to study static friction forces.

At higher movement speeds (50 cm/h, 100 cm/h), Dianatal Stage I and Stage II significantly reduced the dynamic friction force by 30% - 40% in comparison to distilled water as a reference. At the lowest movement speed (10 cm/h), Dianatal Stage I significantly reduced the dynamic friction force whereas Dianatal Stage II did reduce dynamic friction but not significantly. After different dwell times, the static friction forces during the trials were generally lower by the application of Dianatal Obstetric Gel compared to water as a control.

The results of the performed biomechanical investigation show that different Gel formulations do show differences in friction force reduction. The biomechanical results support the beneficial effects of obstetric gels during human childbirth which has already been shown in clinical trials.

### 3. Clinical scientific evaluation

Dianatal® Obstetric Gel can be used in following indications:

A: Preventative use: application during labor stage one and labor stage 2 (starting at the onset of regular contractions) in primiparous and multiparous women with vaginal delivery intend

B: Therapeutic use: application in case of:

- indication for obstructed or delayed delivery
- labor arrest
- preterm delivery
- facilitation of vaginal operative procedures
- facilitation of manual placenta delivery
- indication for labor facilitation in case of history with cesarean section, state after obstructed labor, big baby

Dianatal® Obstetric Gel has been clinically investigated according to the two usage forms. Following are the Results of the performed clinical investigations.

A: Clinical investigation in regards to the preventative use of Dianatal

Results published:

- Obstetric gel shortens second stage of labor and prevents perineal trauma in nulliparous women: a randomized controlled trial on labor facilitation. Schaub AF, Litschgi M, Hoesli I, Holzgreve W, Bleul U, Geissbuhler V. J Perinat Med 2008; 36 (2): 129-135.
- The use of an obstetric gel reduces labor duration. Geissbühler V., Hösli I., Litschgi M., Drewe J., Holzgreve W., Schaub AF. Abstract. Annual Conference of the Swiss Society of Gynecology and Obstetrics, Interlaken, June 2008

In two ObGyn Departments (Women Hospitals Frauenfeld and Schaffhausen, Switzerland) 251 primiparous women have been recruited to conduct a randomized controlled prospective trial. The investigated intervention was the application of a specially designed obstetric gel in the first and second stage of labor (1S, 2 S).

181 landbirths did meet the inclusion criterias and have been analysed. For further analysis the primiparous women with spontaneous delivery in occipito-anterior position without a Kristeller maneuver (SDK) have been further analyzed and have been divided into subgroups dependent on the use of epidural (EDA) and amniotomy (AMN).

#### Results:

In the 74 SDK +/- AMN and +/- EDA labor Stage 2 (2 s) duration was significant reduced by 26 min ( $p < 0.025$ ). In SDK without AMN and +/- EDA ( $n = 53$ ) labor stage 2 was significant reduced by 33 min ( $p < 0.035$ ). In SDK without EDA and +/- AMN ( $n = 47$ ) labor stage I was significant reduced by 65 min ( $p < 0.049$ ). In SDK without EDA and without AMN ( $n = 31$ ) total labor duration was significant reduced by 106 min ( $p < 0.015$ ). In SDK without PDA and +/- AMN ( $n = 47$ ) total labor duration was significant reduced by 86 min ( $p < 0.014$ ). In SDK without EDA and without AMN ( $n = 31$ ) labor Stage I was reduced by 82 min bordering significance ( $p < 0.056$ ). In SDK without EDA and +/- AMN ( $n = 47$ ) labor stage 2 was reduced by 21 min but not significant ( $p < 0.086$ ).

It further has been shown the in women with spontaneous delivery in occipito-anterior position with or without a Kristeller manoeuvre perineal lacerations have been significantly reduced (twofold risk reduction,  $n = 95$ ,  $p < 0.024$ ).

Consolidated results of the complete multicenter Study (Frauenfeld, Schaffhausen, Basel): Presented at the Annual Conference of the German Society of Gynecology and Obstetrics: September 2008, Hamburg:

In three ObGyn Departments (Women Hospitals Frauenfeld and Schaffhausen, Basel, Switzerland) 347 primiparous women have been recruited to conduct a randomized controlled prospective trial. The investigated intervention was the application of a specially designed obstetric gel in the first and second stage of labor (1S, 2 S).

267 landbirths did meet the inclusion criterias and have been analysed. For further analysis the primiparous women with spontaneous delivery in occipito-anterior position without a Kristeller maneuver (SDK) have been further analyzed and have been divided into subgroups dependent on the use of epidural (EDA) and amniotomy (AMN).

In the 106 SDK +/- AMN and +/- EDA labor Stage 2 (2 s) duration was significant reduced by the intervention by 21 min ( $p < 0.0016$ ), labor Stag1 1 was reduced by 23 minutes but not significantly. The rate of intact perineum was increased from 27 to 39 percent, but not significant.

#### Conclusion:

The preventative use of Dianatal® Obstetric Gel during labor Stage I and Stage 2 significantly reduces labor duration by 30 % in spontaneous vaginal deliveries (Stage I and Stage 2). Furthermore the use of Dianatal® Obstetric Gel during labor Stage I and Stage 2 significantly reduces perineal lacerations (twofold risk reduction) and protects the perineum. The reduction of the first stage of labor and the total labor duration in women not using EDA supports the hypothesis that friction forces are also relevant during labor stage 1 and can be effectively reduced



by the use of Dianatal® Obstetric Gel. Side effects for mother or newborn have not been noticed, vaginal operative procedures have not been negatively influenced but facilitated.

B: Clinical investigation in regards to the therapeutic use of Dianatal

At the Department of Obstetrics, University Women Hospital Marburg, Germany, 36 primiparous women presenting with obstructed labor have been investigated in regards to the effect of the therapeutic use of Dianatal® Obstetric Gel. Following endpoints have been investigated: Acceptance, labor facilitation effect, reduction of perineal lacerations.

Results:

Acceptance, tolerability was 100 %. The labor facilitation effect was 50 %, perineal lacerations have been reduced from 30 % to 6 %.

Conclusion:

The therapeutic use of Dianatal® Obstetric Gel in case of obstructed labor shows to have a positive impact on supporting/facilitating vaginal delivery. The therapeutic use of Dianatal® Obstetric Gel broadens the obstetric intervention spectra of vaginal operative procedures or cesarean section and offers a new therapeutic option in case of obstructed labor. Side effects for mother or newborn have not been noticed, vaginal operative procedures have not been negatively influenced but facilitated.

### 3. Summary and conclusion

Dianatal® Obstetric Gel is a sterile inert birth gel with no pharmacological effects. Dianatal® guarantees the special properties needed for safe human child birth facilitation such as sterility, mucoadhesivity, latex freeness, conservative and preservative freeness, non allergenic potential and electric conductivity. Dianatal® Obstetric Gel is further isotonic, slightly acidic and kind on mucous membranes and on the eyes.

It can be stated from pharmacopea references, the results of toxicology studies and of clinical trials, that Natrosol 250M, Carbopol 974P NF and propylene glycol in Dianatal® Obstetric Gel prove to be safe for mother and child.

It further can be stated from a clinical standpoint that Dianatal® Obstetric Gel has been shown to be effective and safe for the intended use to "ease childbirth and to protect the perineum" in humans. Furthermore Dianatal® Obstetric Gel seems to be favorable for vaginal operative procedures.



**DIANATAL**  
obstetric gel



**Genehmigung**  
Richtlinie 93/42/EWG Anhang V, Artikel 3  
Qualitätsmanagementsystem Produktion

Registrier Nr.: DD 60019731 0001

Bericht Nr.: 21129808 003

**Hersteller:** MPC INTERNATIONAL S. A.  
26 Boulevard Royal  
L-2449 Luxemburg  
Luxemburg

**Geltungsbereich:** Produktion von sterilen Gleitgelen  
Produkte: siehe Anlage

**Gültig bis:** 16.10.2012

Hiermit genehmigt die "Benannte Stelle" das vom Hersteller eingeführte und angewandte Qualitätsmanagementsystem. Die Anforderungen des Anhangs V, Artikel 3 der EG-Richtlinie werden erfüllt. Der Hersteller unterliegt der EG-Überwachung nach Anhang V, Artikel 4 der Richtlinie. Der Inhaber ist berechtigt, diese Bescheinigung im Rahmen seiner Herstellerkonformitätserklärung zu verwenden.

Köln, den 12.11.2007



**TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln**  
Akkreditiert von der Zentralstelle der Länder für Sicherheitstechnik (ZLS) und der  
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notifiziert unter der Nr. **0197** bei der Kommission der Europäischen Gemeinschaft.

Ⓒ Die CE-Kennzeichnung darf bei Einhaltung aller zutreffenden EG-Richtlinien angebracht werden. Ⓒ



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obstetric gel



**TÜV Rheinland**  
**Product Safety GmbH**  
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Anlage zu  
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Geltungsbereich: Produkte:  
- Dianatal

Köln, 12.11.2007

