



## Saving time and energy

### Dianatal: The new option

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# Child Birth can be a fantastic experience !

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But it holds risks for mothers and newborns -

Vaginal birth has inherent risks

- For the mother (incontinence, birthcanal injuries, sexual dysfunction, etc.)
- For the child (birth trauma [broken clavícula etc.], hypoxic lesions, infections)

and needs medical interventions more often than expected:

Outcomes in primiparous with intention of vaginal delivery 2006 (CH):

- ~ 25 % vaginal operative procedures
- ~ 20 % 2°c- sections

# Child Birth is labor !



Work to overcome friction

That is why multiparous women deliver faster, with less pain and with much lower complications than primiparous

# The HCB PAOS 2004



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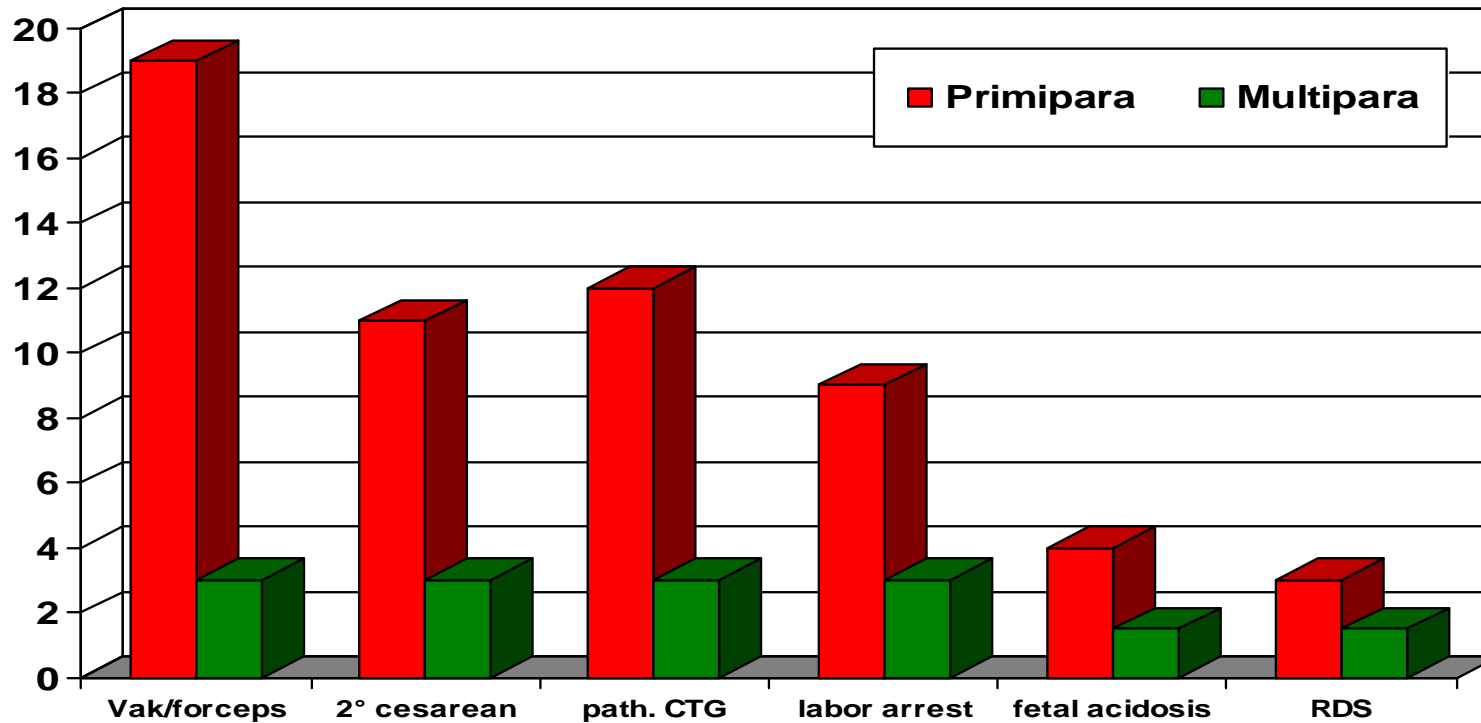
## The HCB Parity Adjusted Outcome Study 2004

- period: 1993 until 2003
- Switzerland
- Source: 352'215 deliveries, ASF nationwide statistics
- Discriminating factor: friction [parity & birth weight (4000 g)]
- Included very low risk deliveries: 188'339
  - Primipara: 82'003
  - Multipara: 103'106 (2 to 4)
  - Grandpara: 3230 (> 4)

# Labor outcomes depend on friction



all = P < 0.001



**labor outcomes are significantly dependent on friction**

# Every women's dream

**DIANATAL**<sup>®</sup>  
obstetric gel



- a quick and easy delivery
- with maximum security for herself and the child
- an experience one can not describe

# A step towards the dream

**DIANATAL®**  
obstetric gel

## Dianatal® Obstetric Gel

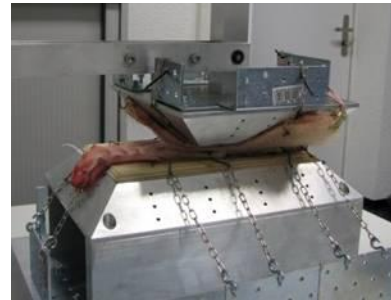
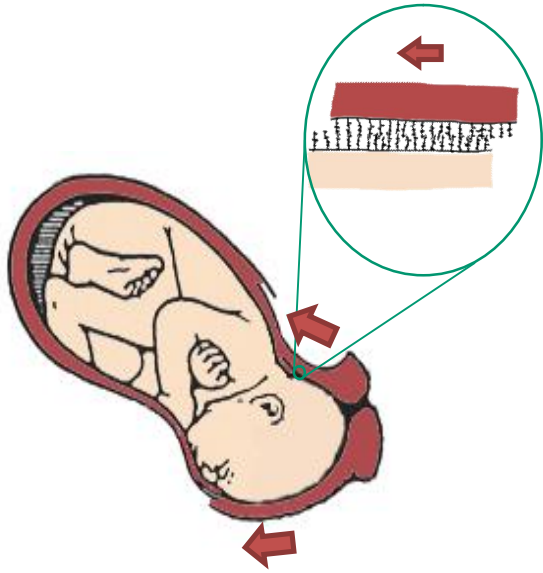


New in Human Obstetrics –

Although a Gold Standard in Vetmed

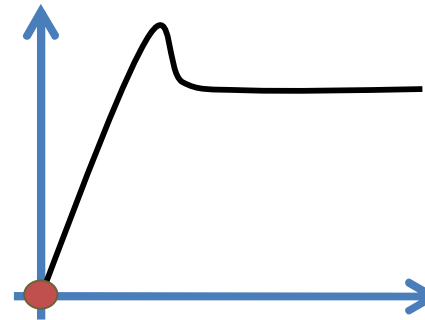
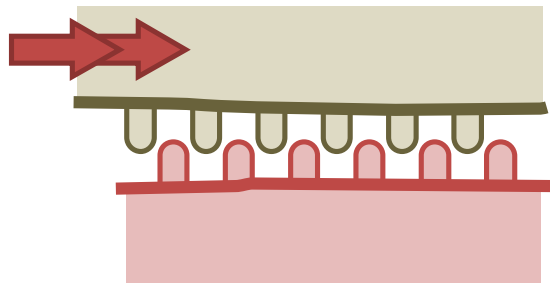
Significantly reduces the opposing friction force and facilitates vaginal childbirth saving time and energy.

# ETH Zürich: Birth model

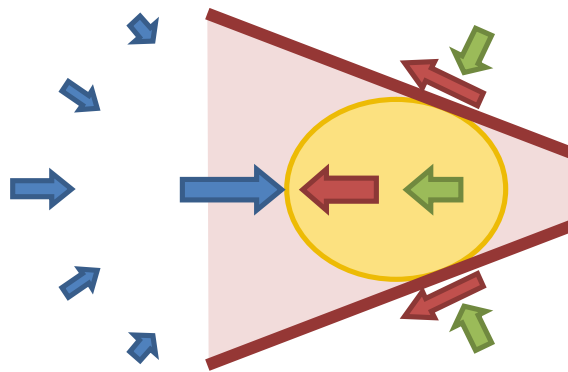


*ETH Zürich: Birth model*

adhesion friction / gliding friction



# ETHZ: Friction is no fiction



Newborn expulsion

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= uterine contractions

*minus* elastic forces

*minus* friction force

(friction coefficient/newborn mass)

Dianatal<sup>®</sup> Obstetric Gel

# ETHZ: birth model results



1. Dianatal reduces adhesive friction significantly by 50 %
2. Dianatal reduces gliding friction significantly by 50 %
3. **Not every Gel is a Birth Gel:**  
Dianatal Stage 1 and Stage 2 show different effects: Dianatal Stage 1 influences adhesive friction more effectively

Control: water

# Randomized trial results



## HCB Swiss Study 2005 to 2007:

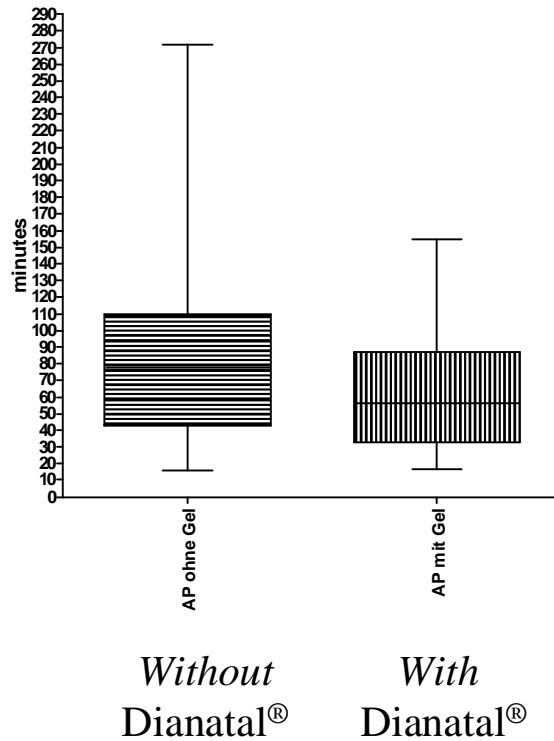
- randomized prospective trial with active control at three Swiss Obstetrics Dept.
- active control, blinding not possible, placebo not possible

347 primiparous women randomized into

- Group A: standard of care without Dianatal Obstetric Gel
  - Group B: standard of care with Dianatal Obstetric Gel
- Intervention: Dianatal application onto the birth canal starting at early labor stage 1 (before 4 cm dilatation) End points: Labor duration, perineal outcomes, intervention rates
- Study report/surveillance: Prof. Dr. J. Drewe, Dept. for Clinical Pharmacology, University Hospital Basel:
- Centers:           Cantonal Hospital Frauenfeld, Cantonal Hospital Schaffhausen,  
                          University Hospital Basel

# Results of Frauenfeld und Schaffhausen:

Published: J. Perinat. Med. 36 (2008) 129-135



Dianatal<sup>®</sup>:  
Reduces labor stage 2 significant  
by 26 min

N = 74, delta 26 min,  $p < 0.05$  ( $p = 0.026$ )

Stage 2 without Dianatal: 88 min  
Stage 2 with Dianatal: 62 min

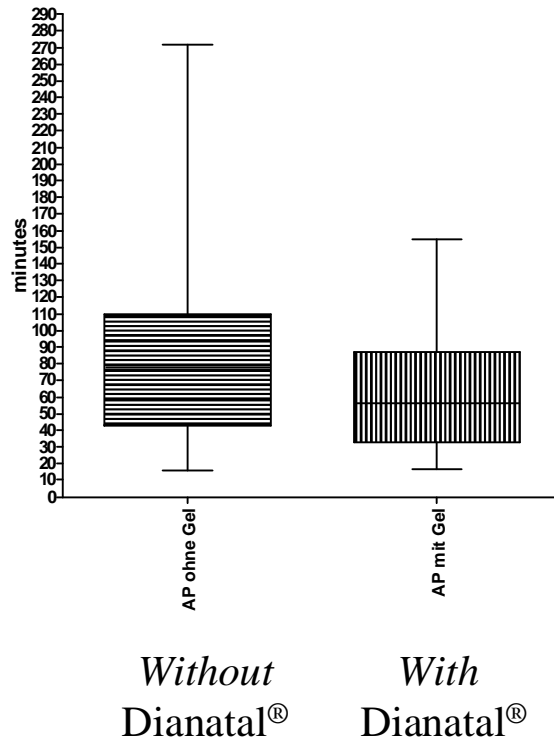
Delta: 29 %

group +/- EDA +/- AMN

## Results of the three study centers:

Presentation PD Dr. I. Hösli, Hamburg 2008

**DIANATAL®**  
obstetric gel



Dianatal®:  
Reduces labor stage 2 significant  
by 22 min

N = 106, delta 22 min,  $p < 0.05$  ( $p = 0.016$ )

Stage 2 without Dianatal: 81 min  
Stage 2 with Dianatal: 59 min

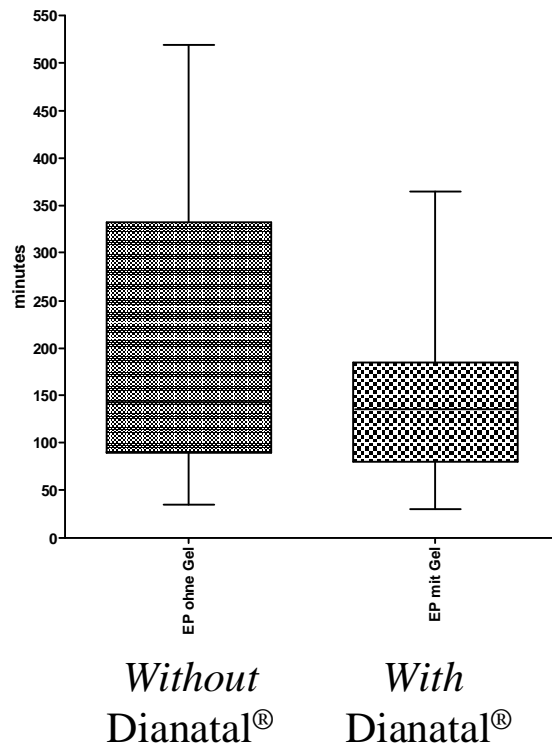
Delta: 27 %

group +/- EDA +/- AMN

No center effect, but application quality matters: Dianatal effect was highest in FF (FF > SH > BS)

# Results of Frauenfeld und Schaffhausen:

Published: Human Study Report, Januar 2007, Prof. J. Drewe



Dianatal®:  
Reduces labor stage 1 significant  
by 65 min

N = 47, delta 65 min, p < 0.05 (p= 0.049)

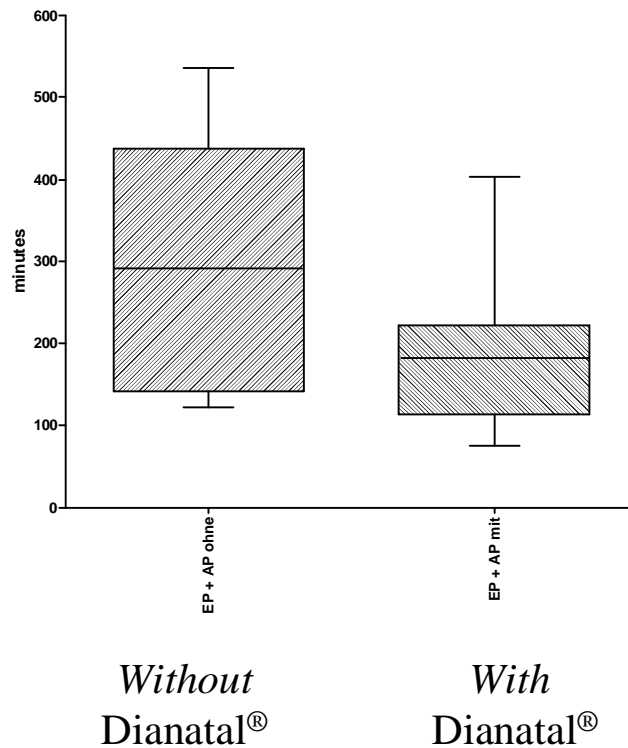
Stage 1 without Dianatal: 203 min  
Stage 1 with Dianatal: 138 min

Delta: 32 %

Group without EDA +/- AMN

# Results of Frauenfeld und Schaffhausen:

Published: Human Study Report, Januar 2007, Prof. J. Drewe



Dianatal®:  
Reduces Stage 1&2 significant  
by 106 minutes

N = 31, delta 106 min, p < 0.05 (p = 0.015)

Stage1&2 without Dianatal: 294 min  
Stage1&2 with Dianatal: 188 min

Delta: 36.15 %

group without EDA without AMN

## Results of Frauenfeld und Schaffhausen:

Published: J. Perinat. Med. 36 (2008) 129-135



Significant reduction of perineal tears: risk twofold reduced.

N = 95, odds ratio 2.7, p < 0.05

	N	Intact perineum diff.	Odds Ratio	p value
Spontaneous	74	14%	2.2	0.072
Kristeller	21	22%	8	0.068
<b>Spontaneous and Kristeller</b>	<b>95</b>	<b>15%</b>	<b>2.7</b>	<b>0.024</b>

# Dianatal® Obstetric Gel



- 
- Reduces labor duration significant by 30 % in primiparous women
    - Stage 1: up to 65 min, Stage 2: up to 33 min
  - Protects pelvic floor and perineum (twofold risk reduction for laceration)
  - Is safe and shows no side effects, facilitates vaginal operative procedures

# Dianatal® obstetric gel kit

**DIANATAL®**  
obstetric gel



- **3 sterile single-use 11ml syringes**
  - **2 Stage 1**  
highly bioadhesive
  - **1 Stage 2 (blue piston)**  
moderately bioadhesive
- **2 sterile single-use Dianatal applicators**
- **instructions for use**

- 
- **CE marked: Medical Device Class II a: CE 0197**
  - **Patent-protected: EP 1467707**
  - **Swiss invention: Dr. A.F. Schaub**
  - **Manufactured in Germany**

# Not every Gel is a Birth Gel

**DIANATAL®**  
obstetric gel



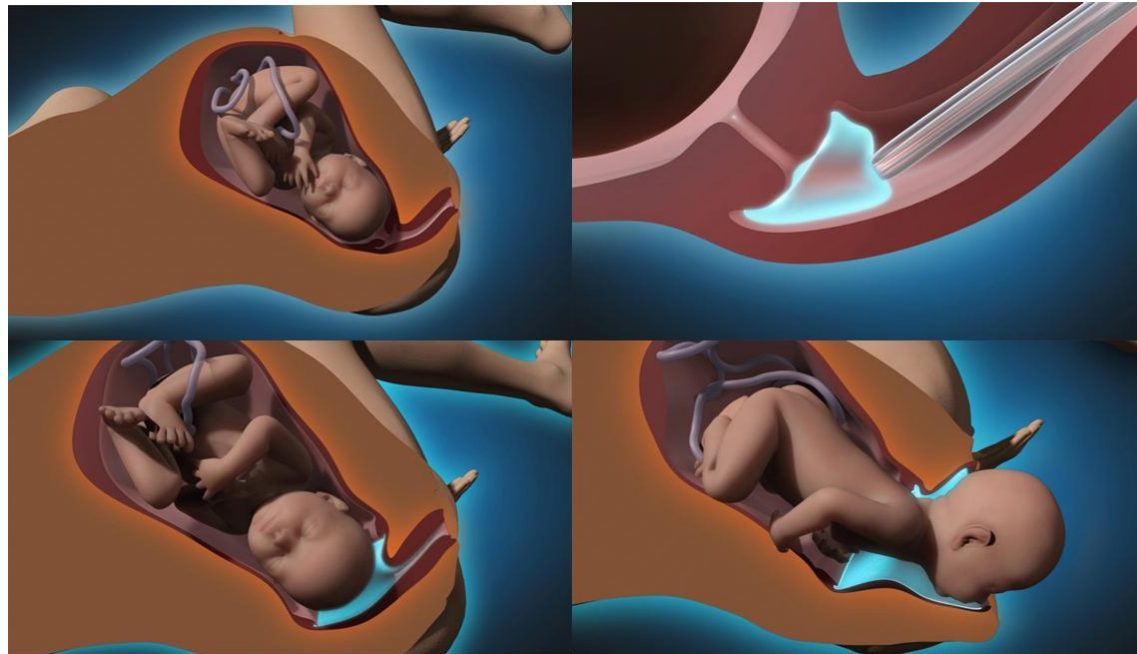
- **Dianatal® birth gel is**

- **Sterile**
- **Non-allergenic**
- **Bioadhesive**
- **Electroconductive**
- **Isotonic**
- **Latex-free**
- **Free of preservatives**
- **Kind on mucous tissue and eyes**

- **And fully biocompatible**

Agar diffusion test, Buehler sensitization test, Embryotoxicity test, Human blood hemolysis 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

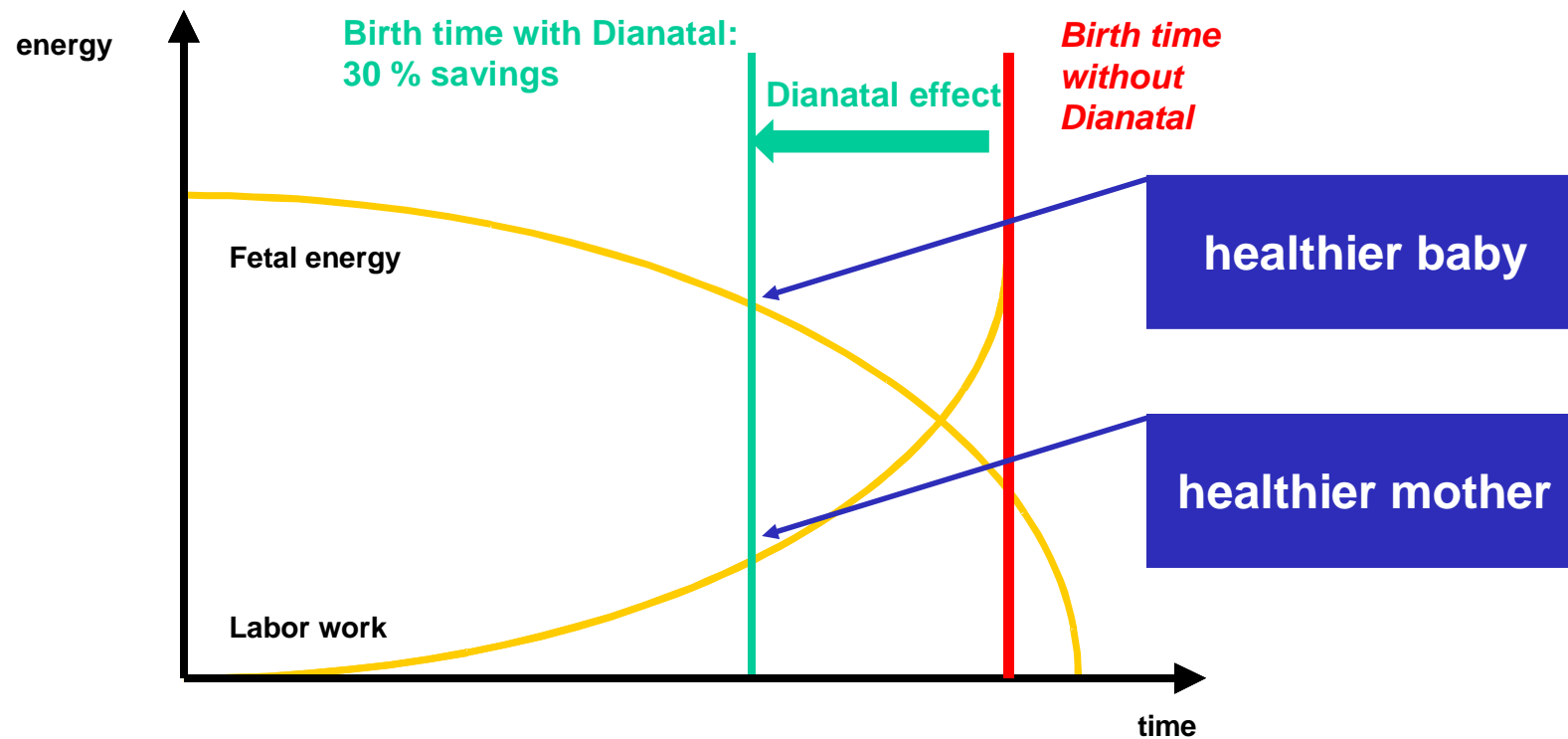
# Gel Birth: instructions for use



- 3 to 5 ml Dianatal® is administered in a two hours interval to the presenting part after vaginal examinations
- Dianatal® Stage 1 is preferably used during the Stage 1
- Dianatal® Stage 2 is preferably used during the Stage 2
- Do use 20 to 30 ml of Dianatal® obstetric gel in total to ensure optimal child birth facilitation. Ad fluid in dry vaginal conditions
- Do use a dry towel during delivery to prevent slipping

# Delivery time shift - a **big** difference

Shift towards left means **time and energy savings**



26 / 106 minutes  
a real difference

**DIANATAL**<sup>®</sup>  
obstetric gel



Thank you