

# DESMOPRESSIN

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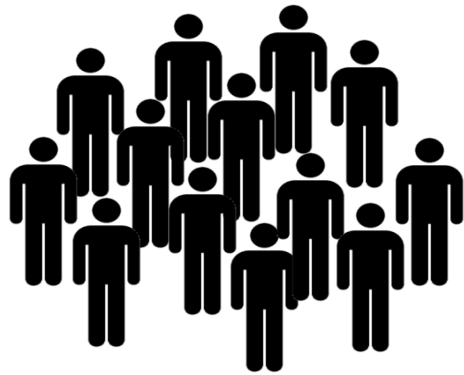
# WHAT IS NEW?

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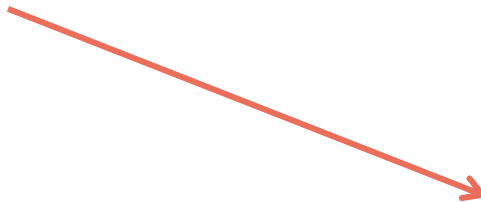
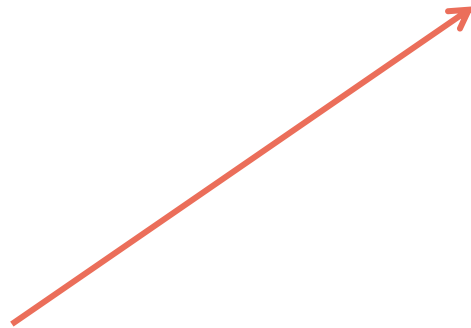
## Paediatric drug development: towards maturity



# DESMOPRESSIN: INTRO



MNE



**Complete response ( $\frac{1}{3}$ )**



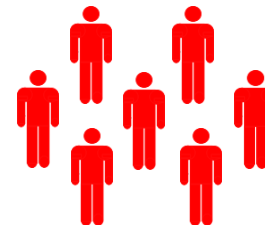
100% reduction

**Partial response ( $\frac{1}{3}$ )**



50 to 99% reduction

**No-response ( $\frac{1}{3}$ )**



<50% reduction

# DESMOPRESSIN: INTRO

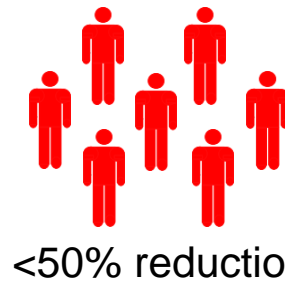
Complete response ( $\frac{1}{3}$ )



Why do we observe no or partial anti-enuretic effect?

MNE

No-response ( $\frac{1}{3}$ )



# DESMOPRESSIN: INTRO

Timing of administration?

Formulation?

Age-dependency?



Dose?

Fluid intake?

Food interaction?

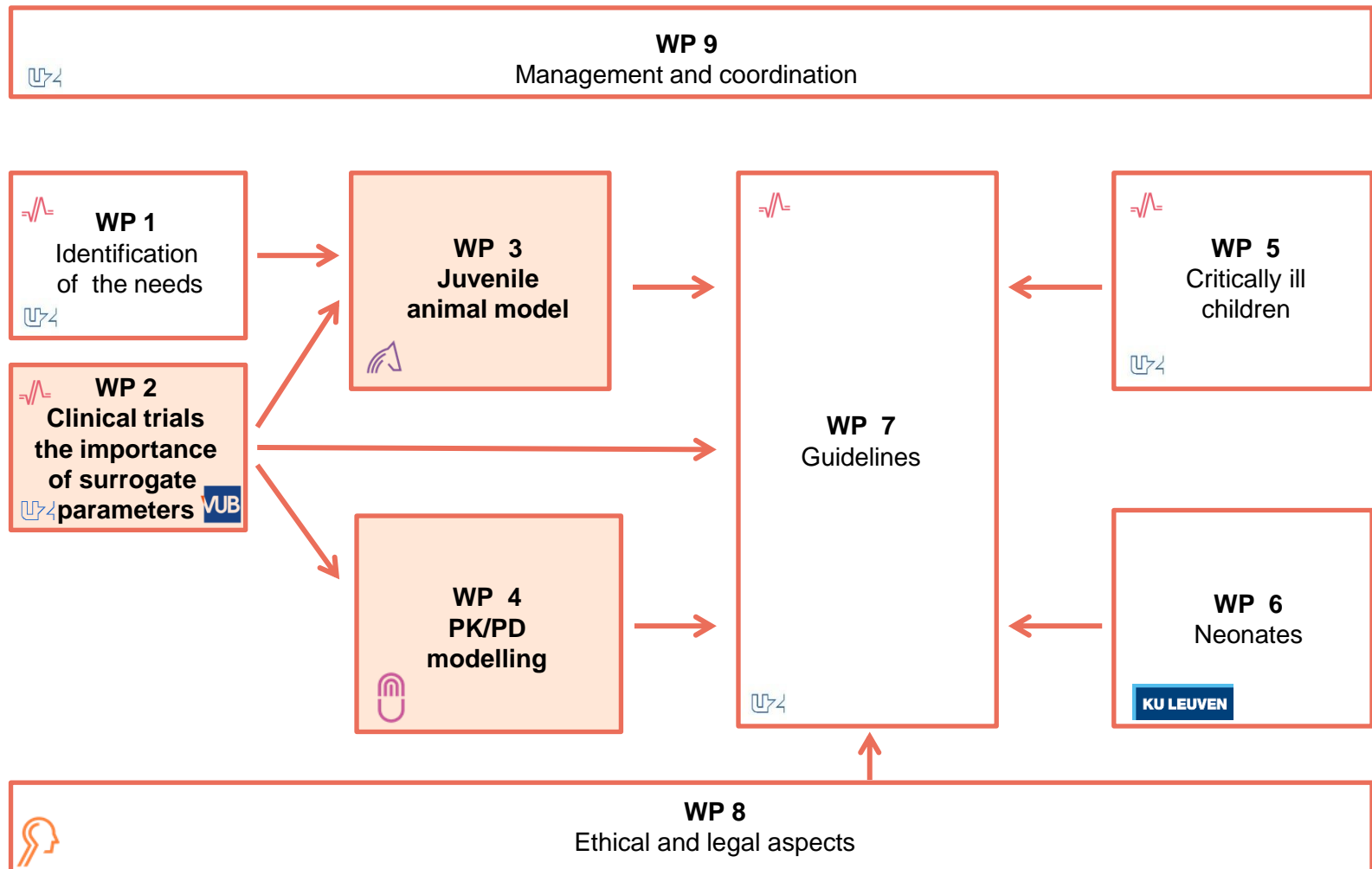
# DESMOPRESSIN: INTRO

Timing of administration?

**Need for PK/PD  
characteristics of  
desmopressin**

ncy?

Food interaction?



# DESMOPRESSIN: PROBLEM SETTING

## **Children grow and mature**

⇒ Size/age dependency of PK?

## **Food effect was shown on the PK in adults (Rittig et al., 1998)**

⇒ Children are often not fasted 1h before bedtime  
(recommended dosing time)!

## **Bioequivalence of two formulations (melt and tablet) in adults (120µg/200µg)**

⇒ Is this true in the paediatric population?

## **Difficult to perform full PK studies**

⇒ Can the piglet be a suitable animal model?



# DESMOPRESSIN: AGE-DEPENDENCY

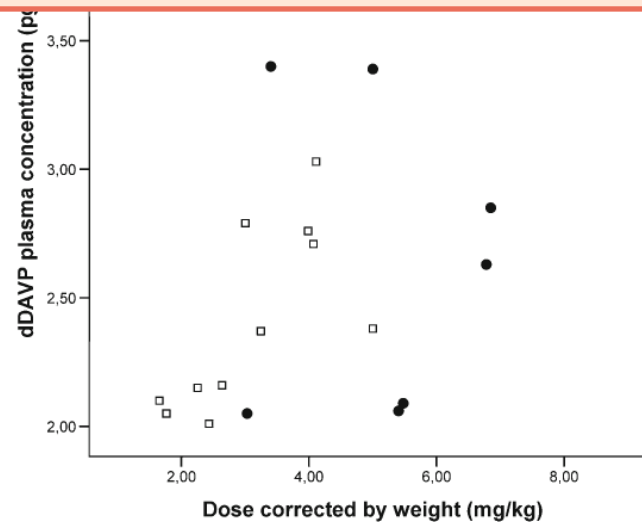
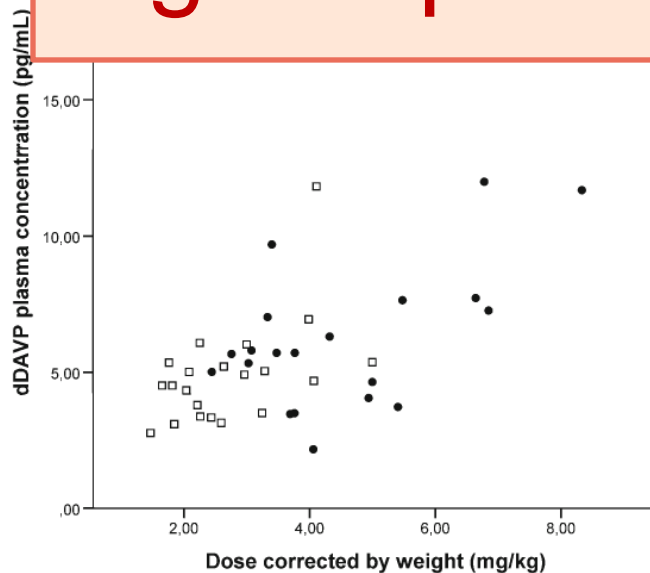
Eur J Pediatr (2014) 173:223–228  
DOI 10.1007/s00431-013-2108-2

ORIGINAL ARTICLE

## Pharmacokinetics of desmopressin administered as tablet and oral lyophilisate formulation in children with monosymptomatic nocturnal enuresis

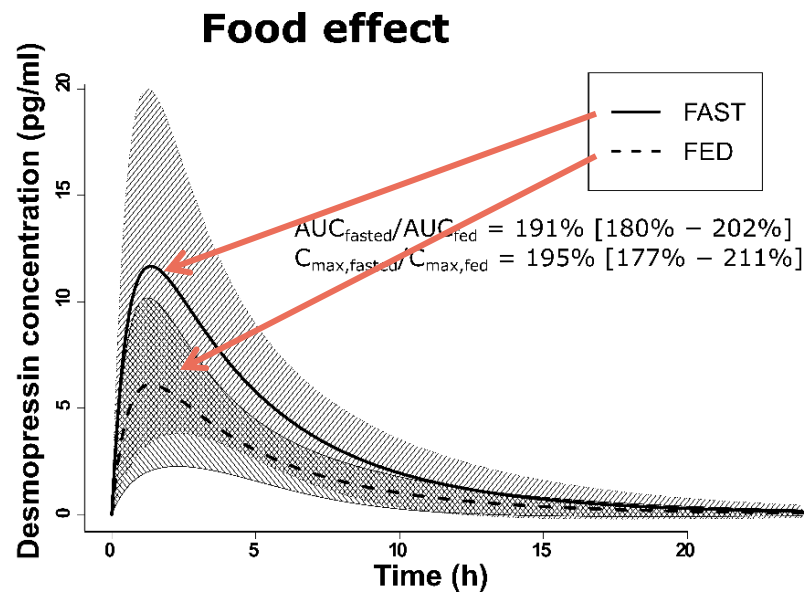
Pauline De Bruyne · Ann De Guchtenaere ·  
Charlotte Van Herzele · Ann Raes · Jo Dehoorne ·  
Piet Hoebeke · Erik Van Laecke · Johan Vande Walle

Age-dependency only for the melt



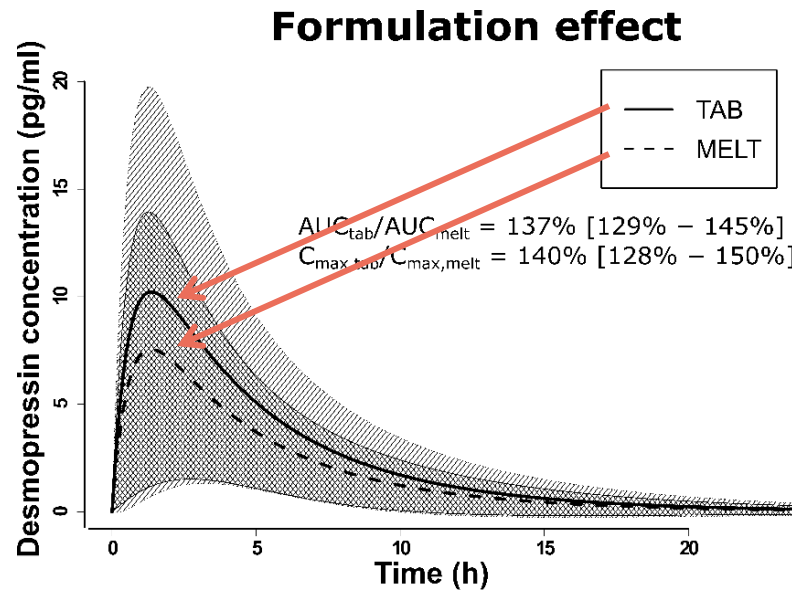


# DESMOPRESSIN: FOOD INTERACTION



*Michelet et al. (2016)*

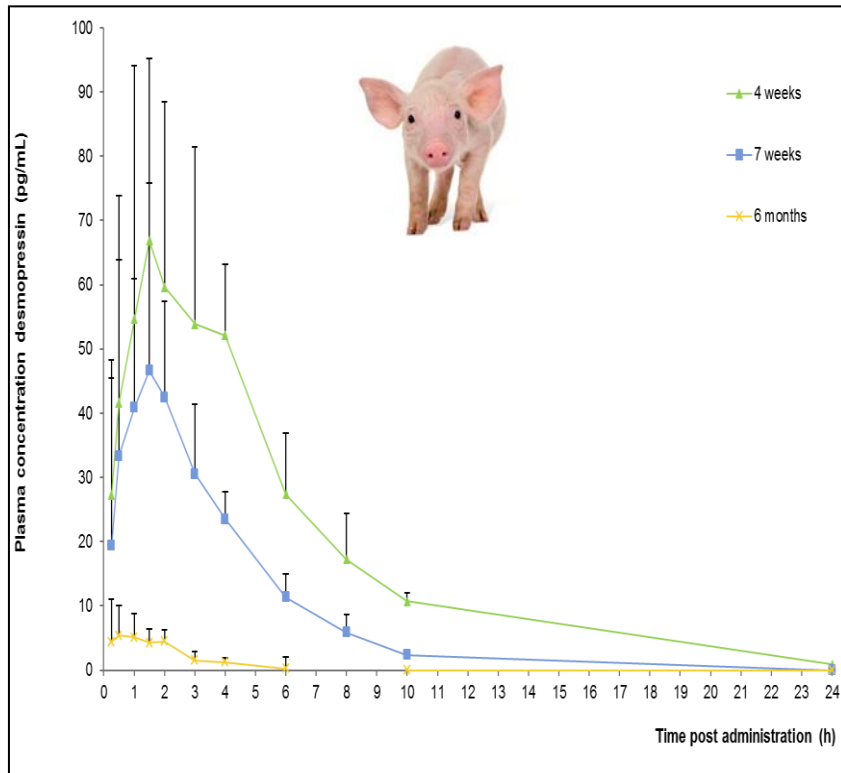
# DESMOPRESSIN: BIOEQUIVALENCE



*Michelet et al. (2016)*

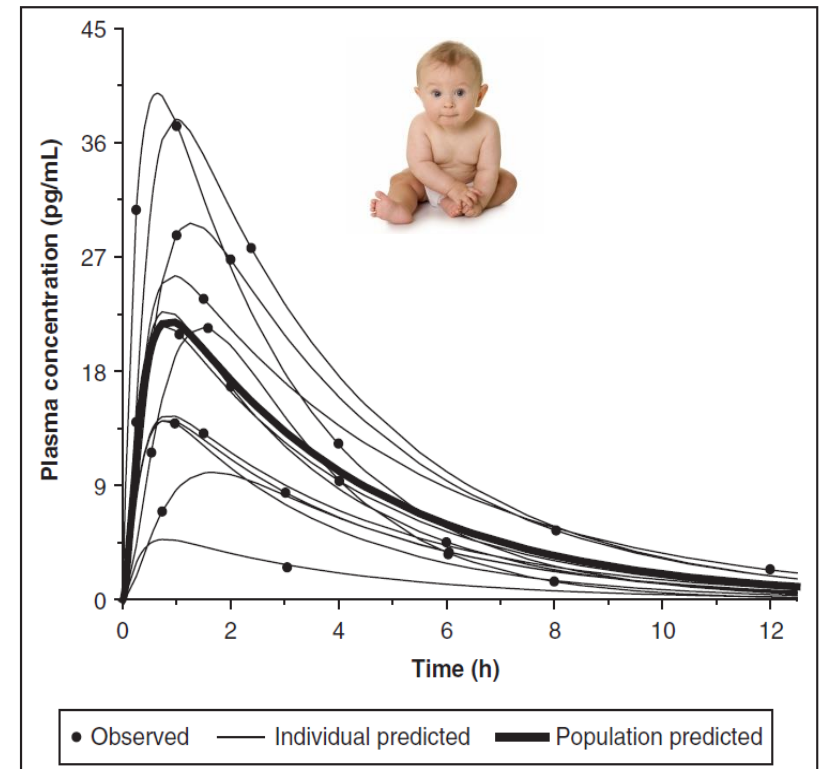
# DESMOPRESSIN: COMPARISON CHILDREN-PIGLETS

*Gasthuys et al. (2018)*



Two absorption peaks

*Osterberg et al. (2006)*



Two absorption peaks

# DESMOPRESSIN: CONCLUSIONS

## **Children grow and mature**

⇒ Size/age dependency of PK? **YES (melt)**

## **Food effect was shown on the PK in adults (Rittig et al., 1998)**

⇒ Children are often not fasted 1h before bedtime  
(recommended dosing time)! **YES (melt superior to tablet)**

## **Bioequivalence of two formulations (melt and tablet) in adults (120µg/200µg)**

⇒ Is this true in the paediatric population? **NO (150 µg/200µg)**

## **Difficult to perform full PK/PD studies**

⇒ Can the piglet be a suitable animal model? **YES (PK)**