

## Abstract

### SAFETY AND CONTRACEPTIVE STUDIES OF UNIPRON

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**Introduction:** Two of the major challenges in reproductive health are the failure to reduce family size and acquisition of Sexually Transmitted Infections (STIs) including Human Immunodeficiency Virus (HIV). Limited availability of woman-initiated non-hormonal contraceptive programmes is a hindrance to successful contraceptive programmes in resource-constrained countries. In this study we assessed the safety of UniPron as a vaginal product and its effectiveness as a contraceptive in female olive baboons (*Papio anubis*).

#### **Objectives:**

- (i) To evaluate the effect of UniPron on baboon vaginal pH and vaginal flora
- (ii) To evaluate the effect of UniPron on blood chemistry profile of baboons
- (iii) To evaluate the effect of UniPron on baboon vaginal and cervical epithelia
- (iv) To determine the effectiveness of UniPron as contraceptive in a baboon

Outcome measures: Changes in baboon vaginal pH, vaginal flora, clinical chemistry profile and conception

**Results:** Baseline vaginal pH was  $5.8 \pm 0.8$ . There was no significant difference in the vaginal pH of Smugel treated animals compared to baseline ( $p > 0.05$ ). Similarly, analysis of blood chemistry parameters revealed no significant differences. The most frequently isolated microorganisms both at baseline and during treatment included *Corynebacterium glucuronolyticum*, *C. renale* group, *Lactococcus raffinolactis*, *Leuconostoc lactis*, *Lactobacillus acidophilus*, *L. fermentum*, *L. salivarius*, *Staphylococcus aureus*, *S. xyloxyus*, *S. hyicus*, *Aerococcus viridians*, *Escherichia coli* and *Candida albicans*.

No detectable histological changes were observed in the vaginal or cervical sections examined. During treatment intravaginally with UniPron no conception occurred in the Uni Pron treated animals, except when the treatment was stopped.

**Conclusions and Recommendations:** Unipron is safe as a vaginal product in baboons and is effective as a reversible contraceptive. Further studies should be conducted to assess the safety of UniPron as a vaginal product in women.

**Keywords:** UniPron, Safety, Contraceptive, *Papio anubis*