

# Off-Label and Unlicensed Prescribing in Paediatric Outpatients with Nephrotic Syndrome: an Indonesian Context

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## Introduction

**Off label** : use of a drug that is not included in the product labeling for that drug



### Unlicensed :

- ✓ the use of unregistered drugs or non pharmacological substance
- ✓ modification/reformulation of a licensed drug

- On-label drugs support the rational use of medicine.
- Off-label studies in a range of pediatric settings → high-rate of off-label use.
- Nephrotic syndrome → a major chronic disease in children → long-term use of medicines.

## Objectives

To estimate the prevalence of off-label and unlicensed prescribing in paediatric outpatients with nephrotic syndrome in a major teaching hospital in Indonesia

## Methods

• Medical record of outpatients with nephrotic syndrome admitted in 2015

• Data collection of patient characteristics and patient details  
• Indonesian National Drug Informatorium (IONI) as the reference

• On/off-label drug categorisation using a hierarchical system of age, indication, route of administration and dosage.

## Results

Table 1. Patients' Characteristics (n=89)

Characteristics	Value
Age group (%)	
• Child (2- 11 yr)	53 (59.6)
• Adolescent (12-18 yr)	36 (40.4)
Gender (%)	
• Male	54 (60.7)
• Female	35 (39.3)
Median number of visit to nephrology clinic (range)	5 (4-12)
Number of complications (%)	
• None	46 (51.7)
• 1 complication	43 (48.3)

Table 2. Frequency of On-Label, Off-Label and Unlicensed Drugs

Drug Class (n=1864)	On-Label (n=474, 25.4%)	Off-Label (n=1350, 72.4%)	Unlicensed (n=40, 2.1%)
Cardiovascular system	36 (4.6%)	738 (94%)	11 (1.4%)
Immuno-modulating agents	9 (1.9%)	455 (97.6%)	2 (0.4%)
Anti-infectives	13 (25%)	32 (61.5%)	7 (13.5%)
Vitamin, mineral, electrolyte	198 (91.7%)	13 (2.8%)	5 (2.3%)
Others	218 (63.2%)	112 (32.5%)	15 (4.3%)

Table 3. The Top Five of Off-Label and Unlicensed Drugs

Off-Label	Unlicensed
Prednisone	Prednisone
Losartan	Captopril
Lisinopril	Lisinopril
Methyl prednisolone	Losartan
Captopril	Furosemide

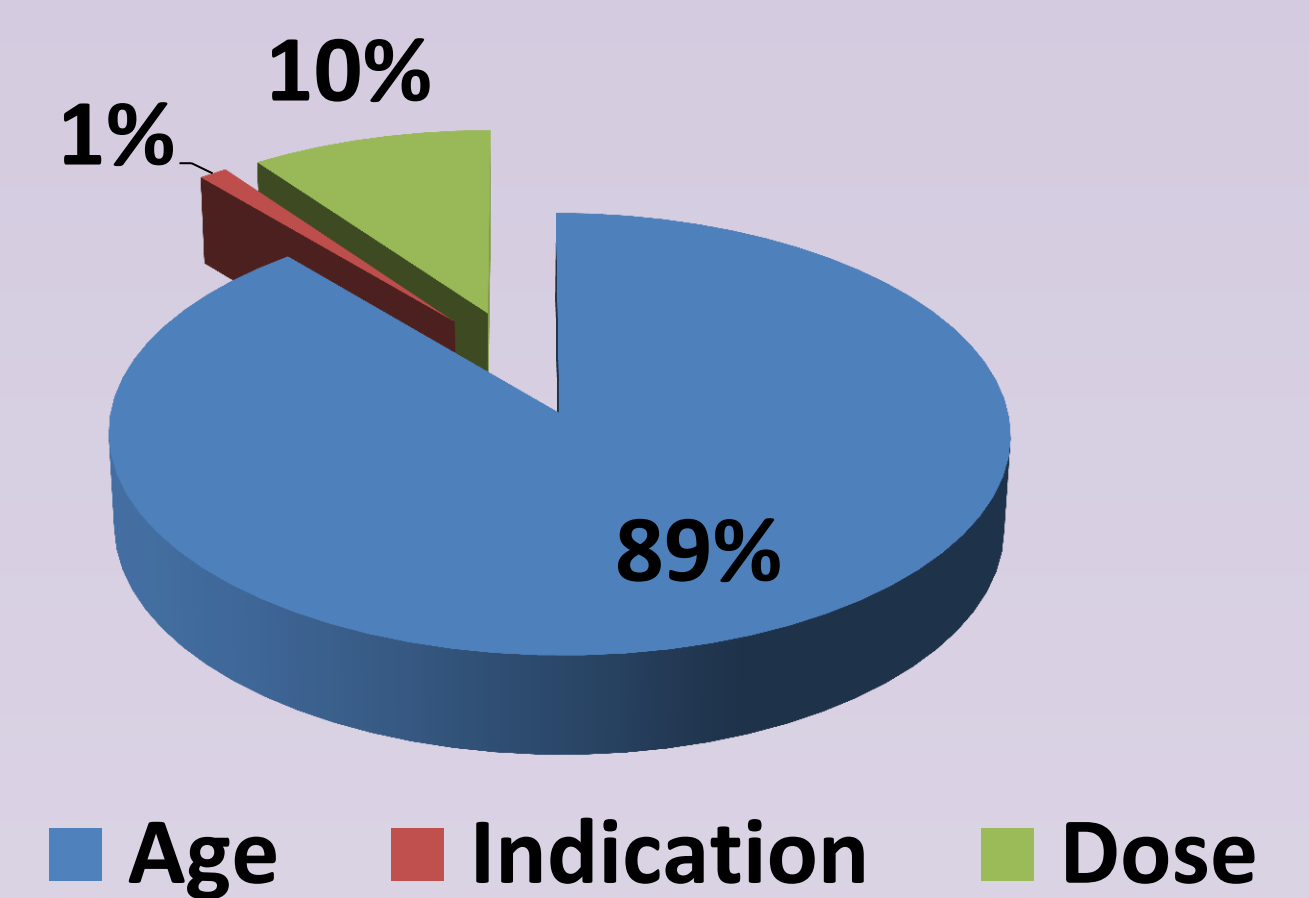


Figure 1. Reasons of Off-Label Use

## Discussion

- The proportion of off-label drugs in this study was considerably higher (72.4%) compared to other paediatric nephrology and non-nephrology studies which reported 19.7-39%.<sup>1-4</sup>
- Conversely, the prevalence of unlicensed prescribing in the present study (2.1%) was much lower than other pediatric studies (8-16%).<sup>5-8</sup>
- It is not surprising that, immunosuppressants and anti-hypertensive agents being responsible for the most frequent off-label and unlicensed drugs

## Conclusion

- Despite the high prevalence of off-label prescribing in paediatric with nephrotic syndrome the use conforms to evidence-based prescribing.
- Measures should be conducted to support clinical trials in paediatrics and revise IONI as the reference drug information.

## References

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