

# OVERVIEW OF PAEDIATRIC ORAL DOSAGE FORMS IN THE REPUBLIC OF MACEDONIA

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## Introduction

The paediatric drug development is associated with numerous challenges. As a result, only a fraction of all medicines are licensed for use in children globally.

Traditional oral solid medicines are frequently used in children, mostly due to their stability, dose uniformity and costs.

On the other hand, novel oral dosage forms offer dose flexibility and individualized therapy on the basis of paediatric age groups and inter-individual variations. Such novel oral formulations include mini-tablets, chewable and orodispersible tablets, and dosage forms dispersible into liquids or mixed with food. The inadequate marketing of paediatric medicines is of concern especially in countries with limited healthcare budgets, impeding patient access to innovative products with tangible therapeutic benefits.

## Study aim

Our aim was to study paediatric oral dosage forms marketed in the Republic of Macedonia, and determine classes of medicines without paediatric friendly formulations.

## Study methods

Our information resource included the National Register Medicinal Products, published by the Macedonian Drug Agency in 2012. We studied oral paediatric medicines formulated as traditional and novel dosage forms, and illustrated the therapeutic areas with no paediatric medicines available.

## Results

Paracetamol, metoclopramide, morphine sulfate are formulated as paediatric oral solutions (Table 1); salbutamol and loratadine as oral syrups; (Table 2) and various antibiotics as powders and granules for oral suspensions. Most medicines are marketed as tablets and capsules for older children, while only analgesics and multivitamin supplements as flexible solid dosage forms.

Table 1: Examples of Paediatric Oral Solutions

Generic name (concentration)	Therapeutic group
Paracetamol (30mg/ml)	non-opioid analgesic
Pholcodine (5mg/5ml)	cough suppressant
Butamirate (4mg/5ml)	cough suppressant
Metoclopramide (5mg/5ml)	antiemetic
Ferrous (II) succinate (800mg/15ml)	antianemic
Morphine sulfate (10mg, 30mg, 100mg/5ml)	opioid analgesic
Salbutamol (2mg/5ml)	bronchospasmodic

Table 2: Examples of Paediatric Syrups

Generic name (concentration)	Therapeutic group
Etosuximide 250mg/ml)	antiepileptic
Feniramin mlaleate(15mg/5ml)	antihistaminic
Loratadine (5mg/5ml)	antihistaminic
Ibuprofen (100mg/5ml)	NSAID
Paracetamol (120mg/5ml)	analgoantipiretic
Trimethoprim/\nsulfamethoxazole (200mg+40mgmg/5ml)	sulfonamide
Salbutamol 2mg/5ml)	bronchospasmodic

## Results (continued)

Our study illustrated several therapeutic areas with limited availability of paediatric medicines in Table 3 (antiarrhythmics, antihypertensives, proton pump inhibitors, H2-receptor antagonists, antiasthmatics, antidepressants, etc).

Table 3: Examples of medicines not available in suitable dosage form for infants and younger children

Generic name	Therapeutic group
Amiodarone, Propafenone	antiarrhythmic agent
Amitriptyline, Sertraline	antidepressant
Irbesartan, Enalapril, Captopril, Minoxidil	antihypertensive
Lansoprazole	proton pump inhibitor
Methotrexate	cytotoxic agent
Procarbazine	antineoplastic agent
Olanzapine	antipsychotic agent
Saquinavir	antiviral agent
Spirolactone	diuretic
Tiagabine	antiepileptic agent

## Discussion

Paediatric medicines are available in different varieties on the Macedonian market, predominantly as tablets, capsules, syrups and powders and granules for suspensions.

The insufficient availability of child friendly formulations in certain therapeutic areas reflects the difficulties in developing such formulations and penetrating the markets with limited national budgets.