Dispersible Tablets: A Novel Dosage Form for Children

This issue was produced through a special collaboration with the University of Nairobi, School of Pharmacy, Kenya.
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Note to our readers

The goal of Practical Pharmacy is to provide accessible, objective and accurate information on medicines issues for front-line health workers who may not have any pharmaceutical training.

In this issue we focus on Dispersible Tablets: A Novel Dosage Form for Children.

Many medicines are only available in adult strength. As an unsafe alternative to paediatric formulations, healthcare workers and parents often use fractions of adult dosage forms, or prepare makeshift prescriptions of medicines by crushing tablets or dissolving portions of capsules in water. Consequently, children are often given dosage forms that have not been developed for them, and that may not be safe for this reason.

We invite you to read more about Dispersible Tablets: A Novel Dosage Form for Children and learn how to administer them.

We welcome your feedback to know if we have been successful in achieving our goal with this issue.

Contact us at: practicalpharmacy@gmail.com

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Dispersible Tablets; what are they?

Since 2006, a lot of work has gone into identifying essential medicines for children and optimal paediatric dosage forms in general. The first WHO Model List of Essential Medicines for children was published in 2007, and the second in March 2009. The first Model Formulary for Children has been available since June 2010.

Now is an opportune time to focus on the optimal way to deliver these medicines to children in need. One such way is the use of flexible solid oral dosage forms of medicines that can be made into liquid at the time of use only.

Dispersible tablets can be dispersed in liquid before administration. The tablets may be uncoated or film-coated and usually disperse within three minutes when put in water or a small amount of breast milk. The use of ‘dispersible tablets’ is similar to ‘powder for oral suspension’ or ‘granules for oral suspension.’

Recently, the World Health Organization (WHO) and UNICEF have begun to promote the development of paediatric dosage forms for children of various ages, including dispersible tablets which disperse in water or a small amount of breast milk.

Classes of paediatric patients

A child is not a small adult. Therefore, medicines to be used in the paediatric population must allow accurate administration of the dose to children of varying ages and weights. The formulation must taste acceptable to the child and be easy for the care-giver to administer. Children of different ages require different dosage forms.

Caution: A child is not a small adult. Therefore, medicines for children must allow accurate administration of the dose to children of varying ages and weights.
Dispersible tablets are considered the most ideal since they are manufactured in a solid state and only a single dose is turned into liquid at the point of administration, while the rest remains in solid state until needed.

### Oral Dosage Forms

The oral route of medicine administration is commonly used for paediatric patients. Oral formulations are either solid or liquid. Some of the solid forms include: tablets (fast dissolving tablets, dispersible tablets, chewable, immediate release and delayed release), capsules, chewable gums, powders for oral suspension and granules for oral suspension. Liquid formulations include: solutions, suspensions, syrups and emulsions.

Difficulty in swallowing may be overcome by developing dispersible tablets which are dissolved, dispersed or mixed with food, milk or water prior to administration. These tablets are a convenient dosage form for infants, toddlers and children. It is difficult to give unpleasant tasting medicines to children.

### Some examples of dispersible tablets available for common childhood diseases

Acute respiratory infections (pneumonia and tuberculosis), diarrhoea, neonatal severe infections, malaria and HIV cause more than half of childhood deaths every year. These diseases would be easier to treat if medicines in appropriate formulations were more available. Dispersible tablets are usually packed in aluminum/polyvinyl chloride blisters or aluminum strips to ensure stability.

### Table 1: Classification of paediatric sub-group by age and weight

<table>
<thead>
<tr>
<th>Pediatric sub-group</th>
<th>Age</th>
<th>Weight (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preterm newborn infants (‘premature’)</td>
<td>&lt;37 weeks gestation</td>
<td>&lt;3.4</td>
</tr>
<tr>
<td>Full-term newborn infants (‘neonates’)</td>
<td>0 to 27 days</td>
<td>3.4</td>
</tr>
<tr>
<td>Infants and toddlers</td>
<td>28 days to 23 months</td>
<td>3.4 to 12.4</td>
</tr>
<tr>
<td>Children</td>
<td>2 to 11 years</td>
<td>12.4 to 39.0</td>
</tr>
<tr>
<td>Adolescents</td>
<td>12 to 16 / 18 years*</td>
<td>39.0 to 72.1 (male)/60.3 (female)</td>
</tr>
</tbody>
</table>

*Dependent on region as the legal age of consent varies from region to region e.g. in the USA it is 17 years and in the UK and Kenya it is 18 years.
Table 2: Some dispersible tablets available for common childhood diseases

<table>
<thead>
<tr>
<th>Disease</th>
<th>Some dispersible tablets available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuberculosis</td>
<td>Rifampicin/Isoniazid</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>Zinc sulfate</td>
</tr>
<tr>
<td>Malaria</td>
<td>Artemether/Lumefantrine (AL), Artesunate+Amodiaquine</td>
</tr>
<tr>
<td>HIV</td>
<td>Lamivudine/Stavudine</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>Amoxicillin, Amoxicillin/Clavulanate, Sulphamethoxazole/Trimethoprim</td>
</tr>
<tr>
<td></td>
<td>(Co-trimoxazole 120mg)</td>
</tr>
<tr>
<td>Pain and Fever</td>
<td>Paracetamol</td>
</tr>
</tbody>
</table>

Figure 1: Step-by-step instructions on how to prepare a dispersible tablet for easy administration to children. The tablet disperses in a small amount of water

Tablets that are too big for a child to swallow

Recommendations for use of dispersible tablets

► to be dispersed in a small amount (5 to 10mL) of liquid (clean water or milk)
► use of a clean and appropriate container is recommended to disperse the tablets
► the liquid can be gently stirred to aid dispersion before swallowing
► a proportion of the medicine may remain in the container after swallowing, it is advisable to rinse with a small amount of water or milk and swallow again
► careful handling of these tablets is necessary as they are much more fragile than the regular tablets (more friable, less resistant to rubbing)
► once removed from the blister packaging, they should be used immediately as their stability outside the blister cannot be guaranteed
## Comparison between dispersible tablets and crushed adult tablets

<table>
<thead>
<tr>
<th>Dispersible Tablets</th>
<th>Crushed adult tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>► more convenient for medicines unstable in water</td>
<td>► as they are not child-specific, their use compromises treatment efficacy and safety in children</td>
</tr>
<tr>
<td>► have less weight and volume hence easily transportable</td>
<td>► if coated to protect the stomach from the effect of that drug (enteric coated), crushing them may increase the chance of stomach ulcers</td>
</tr>
<tr>
<td>► can be used in very young children (0-6 months)</td>
<td>► if formulated to release the medicine slowly over time (modified or extended release), crushing them increases chances of side effects</td>
</tr>
<tr>
<td>► require a small amount of water for administration</td>
<td>► if sugar or film-coated, crushing unmasks the unpleasant or bitter taste</td>
</tr>
<tr>
<td>► can be dispersed in breast milk</td>
<td>► not convenient for medicines unstable in water</td>
</tr>
<tr>
<td>► may degrade at higher humidity conditions and thus need protection from moisture</td>
<td></td>
</tr>
</tbody>
</table>

## Conclusion

Dispersible tablets have significant advantages over both solid and liquid dosage forms. They remain solid during storage, which aids in stability and transform into liquid within few minutes after dispersion. Dispersible tablets will hopefully be developed for most of the available medicines in the near future to improve on the efficacy, safety and compliance of treatments in children.

**Note:** Once dispersible tablets are removed from the blister packaging, they should be used immediately as their stability outside the blister cannot be guaranteed.


