Journal of Developing Drugs
ISSN: 2329-6631

Villegas, J Develop Drugs 2013, 2:3
DOI: 10.4172/2329-6631.1000e129

Editorial Open Access

Prescribing Oral Liquid Formulations for Pediatric Patients

Susan C Villegas*

Department of Pharmacy Practice, Long Island University, USA

Prescribing oral medications for a pediatric patient involves more thought process than prescribing oral medications for an adult patient. Many factors must be considered including pharmacokinetic and pharmacodynamic parameters, but the basic thought process will involve how to deliver the appropriate dose to the patient. For an adult patient, the prescriber will evaluate the appropriate dose in relationship to the available capsule or tablet strength. Unfortunately, many children are unable or unwilling to swallow tablets or capsules and prescribing an oral liquid formulation becomes more complicated. Not all medications are commercially available in oral liquid dosage formulations. If an appropriate oral formulation is not available, the prescriber must then utilize other resources to research if an oral liquid dosage formulation can be compounded. The process can become very complicated and can lead to a variety of medication errors. More pediatric friendly formulations are needed and recent federal acts are assisting with this need.

If medications are available commercially in oral liquid dosage formulation, the preservatives and excipients must also be evaluated. Oral dosage formulations containing the ingredient sorbital can have lethal reactions for patient with fructose intolerance [1]. Preservatives like propylene glycol and benzyl alcohol can be of concern in specific populations or age groups. Benzyl alcohol, for example, has been associated with negative outcomes in the neonatal population including death [2]. Other excipients of concern include alcohol, sweeteners, flavorings, and dyes which can precipitate an allergic reaction in some patients. Alcohol and sucrose can also lead to gastrointestinal adverse effects. Ideally oral liquid dosage formulations should be alcohol free and dye free.

If a commercially available oral liquid dosage formulation is not available for a specific medication, a suspension or solution could be extemporaneously prepared. Before the medication can be compounded into an oral liquid formulation, a recipe must be identified and must include appropriate stability information and available ingredients. A few books have been published to assist in such tasks including "*Pediatric Drug Formulations*" currently in its sixth edition written by MC Nahata and "*Extemporaneous Formulations*" currently in its second edition written by R Jew, W Soo-hoo, and S. Erush. Some medications have recipes and stability information for a variety of concentrations leading to a possibility of medication errors. Pharmacies and hospitals compounding different concentrations may lend itself to a lack of standardized concentrations. If only one concentration is available of a high-risk medication like digoxin, medication errors are less likely to occur.

The most recent oral liquid formulation to receive FDA approval is enalapril maleate marketed under the brand name Epaned™ from Silvergate Pharmaceuticals Inc. [3]. The new formulation is a powder for oral solution containing 150 milligrams (mg) in a 150 milliliter (mL) bottle. The powder is intended to be reconstituted with 150 mL of Ora-Sweet™ SF for a final concentration of 1 mg/mL. Enalapril is an angiotensin-converting enzyme inhibitor and indicated for adults and children older than one month of age. Enalapril was initially approved in the United States in 1984 for the treatment of hypertension. The Centers for Disease Control and Prevention state that congenital heart defects occur in nearly 1% of births per year and are the most common type of birth defect in the United States [4]. The International Pediatric Hypertension Association states that 5 of each 100 children and adolescents may have high blood pressure [5]. Enalapril is a commonly prescribed medication and the newest formulation will provide a great benefit to the pediatric population especially infants with congenital heart defects.

The past 15 years has introduced medications with more pediatric indications and more pediatric friendly formulations as a result to new federal laws and regulations. The Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act continue to encourage further advances in pediatrics including a total of 436 studies completed from September 27, 2007 to April 5, 2013 [6]. In 2009, the National Institutes of Health and the Food and Drug Administration (FDA) introduced an initiative for developing pediatric formulations [7]. As progress continues, further pediatric friendly formulations will continue to be commercially available and will improved medication safety for pediatric patients.

References

1. Walson PD, Getschman S, Koren G (1993) Principles of drug prescribing in infants and children. A practical guide. Drugs 46: 281-288.
2. Sagraves R (1995) Pediatric dosing information for health care providers. J Pediatr Health Care 9: 272-277.
3. (2013) FDA approves Epaned, a liquid form of enalapril for children and adults. Silvergate Pharmaceuticals Inc., USA.
4. (2013) Congenital heart defects. Centers for Disease Control and Prevention, USA.
5. http://www.pediatrichypertension.org/faq.asp
6. (2013) Breakdown of FDAAA completed pediatric studies. U.S. Food and Drug Administration, USA.
7. (2012) Best Pharmaceuticals for Children Act. National Institute of Heath, USA.

***Corresponding author:** Susan C Villegas, Assistant Professor, Department of Pharmacy Practice, Long Island University, USA, Tel: 718-920-5350; E-mail: Susan.Villegas@liu.edu

Received August 29, 2013; **Accepted** August 29, 2013; **Published** September 04, 2013

Citation: Villegas SC (2013) Prescribing Oral Liquid Formulations for Pediatric Patients. J Develop Drugs 2: e129. doi:10.4172/2329-6631.1000e129