

AccuDial spins children's liquid medication dosing into the 21st Century

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AccuDial's inner and outer labels provide parents and caregivers information to precisely dose their child based on weight, not age.

"The revolution in over-the-counter dosing." That's how Palm Beach Gardens, FL-based AccuDial Pharmaceutical, Inc. describes its Children's AccuDial line of liquid OTC (over-the-counter) medications. The "revolution" is the product's two-part label that allows consumers to administer a precise dose—in milliliters—of a liquid medication based on his or her child's weight. That differs from many children's medications that are dosed by age or age groups.

The precise dosing is made possible due to a patented two-part label that utilizes an outer label that "spins." Primary information (Drug Facts) is displayed on the top label, which also features several windows or clear panels. The inner label is printed with weight in 2-lb increments and the correct dose in milliliters. The consumer turns the label until its window shows the specific weight of the consumer's child. Below the specific weight is the precise dose amount. The consumer, using an oral syringe that is supplied with every product, draws the precise amount of medication into the oral dosing syringe, which is calibrated to match every weight/dose on the label. The oral syringe comes wrapped in clear plastic film within an outer paperboard carton. (Watch a video about Children's AccuDial

www accuratedose.com/us_english/product_demo.html)

AccuDial can print 39 different weights with correct dose in milligrams per kilograms. A milligram per kilograms is the dosing method preferred by healthcare professionals, says AccuDial, including pediatricians, nurses, and pharmacists. Because all the weight and dosing information is located on the inner label and the outer (rotating label) contains all the Drug Fact information up to 75% more information to be printed on a 4-oz medication bottle, notes the company.

AccuDial's Web site notes, "According to the American Medical Association, 72 percent of children are dosed inaccurately with OTC medications." Both overdosing and

underdosing can pose health problems.

'Spin' label evolution

Robert Terwilliger, AccuDial's chairman of the board and chief executive officer, credits Brian Kaplan, MD, for creating the dosing system. Kaplan is the company's chief medical advisor and director. "In 2000, Doctor Kaplan, a board-certified emergency room physician, had practiced in the ER for nearly 15 years. Over that period of time he treated about 15,000 children who were admitted into the ER for dosing problems. He sought a better way of dosing and eventually developed the idea of the two-part labels." Terwilliger recalls, "Kaplan met Stephen Key of [Spin Labels](#), who had patented the technology for the outer rotating label. Spin Labels' ability to provide more label space for printed content on a container provided the answer to Kaplan's problem."

The inner and outer polypropylene labels, from different suppliers, are printed by [ROI Technologies](#) on a servo-driven 41-inch [Bielloni](#) eight-color Central Impression flexo press. The top label is 2.5-mils thick while the base label is 3.8 mils. The gearless press provides registration accuracy, quick changeover, and high-speed production.

"Kaplan held patents on the inner label where we display the child's weight and correct dose," says Terwilliger. "We do the calculation and then have the medication information printed onto both labels. We are the only over-the-counter company that is 100-percent consistent in dosing in milliliters and we provide a calibrated oral syringe for consumers so they can properly administer every dose to the child."

Terwilliger and Kaplan formed AccuDial Pharmaceutical in 2007 and began moving forward with readying the product for commercialization. AccuDial has 17 medications approved by Health Canada sold in Canada for dosing analgesic, allergy, cough and cold medications by weight instead of age.

Aligning packaging sources

AccuDial worked on packaging material selection with [Venue Marketing](#), a graphics design and ad firm that designed the labels and the packaging's colorful artwork.

[Ultra Tech Printing](#), an integrated firm with in-house graphics, platemaking, printing, and finishing operations, printed the cartons.

Consulting group [Empire Emco](#) worked with AccuDial on development, design, advanced engineering, and manufacturing services. Empire Emco manages the blow molds used to make the bottles, the child-proof dosing caps, and the oral syringes.

Says Terwilliger, “We currently own one 14-cavity blow mold for our PET bottles. We are having injection/blow molds made for high-density polyethylene bottles, in 4-, 8-, and 16-ounce sizes. The 8 and 16-ounce sizes will be used for nutritional supplement liquids.”

AccuDial custom-designed the 4-oz bottles that include a “Custom Label Well” where both labels are applied. Bottles are manufactured by [Berry Plastics](#). In addition to the 14-cavity blow mold for the 4-oz PET bottle, AccuDial also owns HDPE injection/blow-molds for 8- and 16-oz bottles. AccuDial is also developing an injection mold for new polypropylene child-proof closures, which will be sourcing through different suppliers.

Spin Labels’ Key explains that the outer label has 13 U.S. patents, along with several foreign patents. “I’m a designer by profession, and I took a concept that I designed in the toy industry to help create more real estate on the container label. It’s been used in different applications, but the AccuDial application represents the perfect marriage of great information at the right time using that technology. With the help of George Michaels at [Accraply](#), we have been able to push the technology forward to where we can make a spin label using high-speed roll-fed labeling equipment.”

Michaels, Accraply’s regional sales executive, explains, “The labeler uses roll-fed technology, with a linerless label. The equipment places the label on the container and uses electronic web tracking technology that’s used for web handling applications in the printing industry to properly maintain the position of the label during application to the bottle, which is molded with a recessed area that helps guide label placement.”

Contract packaging process

AccuDial relies on [Bio-Pharm, Inc.](#) for its contract manufacturing and packaging services. At its 40,000 sq-ft facility in Levittown, PA, Bio-Pharm fills bottles on a eight-head piston filler from [Filamatic](#), a National Instrument Co. National Instrument Co. also supplies the capper used to apply child-resistant closures on the filled bottles. Closures are supplied by different vendors.

From here, the capped bottles go through a wall into a separate room at Bio-Pharm for induction sealing on a machine from [Enercon Industries](#). Bottles then index through a feedscrew into the infeed starwheel of a pressure-sensitive labeler from [Herma](#). The machine spins the label onto the bottle. Hot melt adhesive is pattern-applied to the leading and the trailing edges of the label to hold the inner label in place.

Bottles are subsequently conveyed into the Accraply Trine roll-fed labeler for application of the outer label. “The unique thing about the Trine is that the adhesive is not on the label when the label is manufactured, but instead the adhesive is placed on the label when it is being applied to the bottle,” says Terwilliger.

Bio-Pharm packs bottles and the pouched dosing syringes into a carton on a cartoner from [Cam Pak Inc.](#). Cartons are packed into cases and closed automatically on a taper from [3M](#). Pallet loads are then shipped to AccuDose for distribution.

Global distribution plans

Children’s AccuDial now includes a family of 17 analgesic, allergy, and cough and cold pediatric medications available in more than 4,300 pharmacies and stores throughout Canada. These 4-oz varieties sell for \$6.99 Canadian (U.S.\$7.26).

For the U.S., Terwilliger says the FDA has focused on acetaminophen, and for good reason. “Acetaminophen must be dosed within a narrow range because it dissolves in the liver. There are hundreds of cases every year where children and adults die from liver failure from inaccurate doses,” he notes.

Because of the FDA’s focus on approving weight-based dosing for acetaminophen, AccuDial plans to use the spin label system for introducing its own line of the product this fall in the U.S. Plans call for the initial sale through 40 Internet drug stores. By early next year, the company plans to roll out the product in as many as 60,000 retail drug stores in the U.S.

The company also has global expansion plans for its products. Terwilliger says, “We recently signed a contract with BroadMed S.A.L. in Beirut, Lebanon to distribute product in 17 countries in the Middle East and North Africa. This opens up a market that is 50 percent larger than the United States. The population of these two regions is 460 million people, with 140 million being children.”

With that global potential and the spin labels, AccuDial believes it is positioned to change the way liquid medications will be dosed. The packaging is gaining attention. For example, Children’s AccuDial was recognized as the 2011 Product of the Year Canada in consumer drug packaging, and voted “consumer’s choice” for new product innovation. Children’s AccuDial also won The Edison Award in the Consumer Packaged Goods category.