
# Improved Blister Packaging Benefits Consumers, Caregivers, and Drug Makers

**Hallie Forcinio**

**New blister packaging offers patient compliance aids, child-resistant mechanisms, and space to include brand information.**

Enhanced blister packaging that adds a paperboard or plastic component to standard formed film–lidstock blisters is familiar in hospital settings and clinical trials. Such structures, which can provide a unit dose, help ensure patient compliance, or make a package more child-resistant (CR), are used for a growing number of physician samples and animal healthcare products. Converting packaging to this format for prescription and over-the-counter (OTC) pharmaceuticals could benefit consumers, caregivers, retailers, and drug makers. In fact, mass-merchandising giant "Wal-Mart (Bentonville, AR) has expressed interest," reports Tom Grinnan, vice-president of business development at MeadWestvaco Healthcare Packaging (Mebane, NC), "in 'consumerized packaging' that is well-branded, compliance enhanced, and easily handled by pharmacists."

Depending on the design, enhanced blister packs may be described as blister cards, heat-seal cards, foldover blisters, wallet packs, blister wallets, or compliance packs. What most of the variations have in common is a paperboard or plastic component that provides space for printing brand information, patient education, and compliance aids such as days of the week or times of day. In many cases, a CR mechanism also is incorporated.

Patients who take their medicine on schedule tend to experience more positive outcomes with quicker recoveries from acute conditions, better control of chronic maladies, fewer hospitalizations, and lower healthcare costs. Study results published in various journals indicate that packaging with built-in compliance aids significantly improves patient compliance rates. This increased degree of compliance induces the prompt refill of prescriptions or restocking an OTC drug in the medicine chest, which then generates higher sales for pharmacies and drug makers. In addition, at the pharmacy level, where staffing shortages are acute, enhanced blister packaging is considered "pass-through" because it minimizes the need for pill counting and handling and reduces labor requirements. Miscounting errors also are less likely to occur because packages contain the amount required for a specific dosage regimen.

Commercial products in enhanced blister packaging include many of the packages recognized in the annual Compliance Package of the Year competition sponsored by the Healthcare Compliance Packaging Council (HCPC) (Falls Church, VA). Winner of the top award for 2002 is a physician sample pack for the anti-epileptic drug Lamictal (lamotrigine) from GlaxoSmithKline (Research Triangle Park, NC). The wallet-pack design arranges a five-week regimen in a single foldover card. Previous packaging consisted of four separate cards. GlaxoSmithKline outsources the heat-seal carding and final assembly (Caraustar Industries, Clifton Primary Contract Packaging Operations, Clifton, NJ).

Runners-up in the 2002 competition include a bifold carded blister pack for Fosamax Once Weekly (alendronate sodium) from Merck & Co. (Whitehouse Station, NJ) and a physician sample pack for Nexium (esomeprazole magnesium) from Astra Zeneca PLC (London, UK). The Fosamax package includes a patented CR zipper back for the one-dose-per-week osteoporosis drug and is contract packaged (Contract Packaging, Sharp Corp., Conshohocken, PA).

The Nexium package provides 14 days of treatment in a cold-formed foil blister pack. Unlike many enhanced blisters, which print label and compliance information on a die-cut paperboard overlay, printing is done directly on the foil (Jones Packaging, London, ON, Canada). The Nexium design also features a tamper-evident carton.

Pharmaceutical manufacturers may choose from a growing array of enhanced blister designs. One pioneering application, the winner of the HCPC 2000 Compliance Package of the Year award is designed to run on existing cartoning and heat-sealing equipment integrates a foldover blister card and CR carton (Dosepak, Mead-

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**Carton space can hold additional patient information literature such as a CD or insert.**

Westvaco Healthcare Packaging, Mebane, NC). This integrated design extends the compliance-enhancing benefits that are inherent to blister packaging and simultaneously supports CR and branding initiatives. The CR locking mechanism on the outer carton relies on cognitive ability rather than strength to open. To boost CR characteristics, a tear-resistant paperboard can be added to the carton (Endurance Paperboard, MeadWestvaco). Because card and carton remain intact from initial opening until it is discarded, full labeling information remains with the drug. For conversions from standard secondary cartons, graphics can be matched to preserve brand equity. Finally, a space created by adding a fifth and sixth panel to the carton can hold additional patient information literature such as an insert or CD. These materials can be preinserted during the conversion process, thereby eliminating that step on the filling line.

Another configuration targeted for clinical trials but with potential for broader use features a tear-resistant paperboard cover wrapped around a high-strength polypropylene frame. A proprietary locking mechanism on one side of the frame snaps closed over the cover and holds it securely in place. When the lock is disengaged and the cover is lifted, an inner blister card attached to the underside of the cover lifts with it. When the cover is closed, the blister card nests back inside the frame, leaving sufficient space for CDs, brochures, safety and compliance guidelines, and other product information. The design is particularly well-suited for fragile products because it places full CR and rigid protection on the exterior of the package, allowing peel-drop, peel-push, and other easy-open style blisters to be housed inside (Surepak, MeadWestvaco Healthcare Packaging).

Standardized tooling produces half-format trays capable of holding ≤24 tablets, capsules, or full-format trays, which can accommodate ≤60 pills. To strengthen brand identity, trays can carry a debossed logo or be produced in a particular color. To cut costs, trays can be produced in volume in advance and assembled as needed with the printed paperboard overlay.

As Merck did with its drug Fosamax, pharmaceutical manufacturers often outsource the design and production of carded blisters. One contract packager with pharmaceutical expertise offers a trifold wallet design with a variety of features, including closure tabs, pockets for patient information booklets, coupons, labels and business cards, a patient record log, and a patented tablet storage compartment for regimens that require fractional doses (Carded Blisters, Sharp Corp.,

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Conshohocken, PA). This sliding-window innovation dates back to 1996 when it was designed by personnel at Bristol-Myers Squibb for a BuSpar Starter Kit, one of the first commercial applications of the trifold carded blister concept. The antianxiety drug typically begins with half doses each morning and evening for the first week. This dosage necessitates breaking tablets in half and saving the second half for the next dosage time. Without the storage compartment, the half tablet can be easily lost or forgotten.

For maximum compliance, carded blister packs have the potential to record when a dose is removed by incorporating thin-film electronics that are based on 13.56 MHz radio frequency identification (RFID) technology and by adding patented sensors in the blister wallet structure (Medic ECM Electronic Compliance Monitor, Information Mediary Corp., Ottawa, ON, Canada). These additional features can be inserted into packaging by using existing equipment and add virtually no bulk or weight to the package. The state-of-the-art electronics also can be tailored to monitor other conditions such as temperature, vibration, humidity, radiation, light, or shock. The electronics also can be programmed to provide patients with visual or auditory reminders.

Targeted for clinical trials where knowing how compliant patients are can mean the difference between a successful market introduction and a costly failure, the card is read by a handheld scanner at refill points or follow-up visits to retrieve data on dosage times (Med-ic CertiScan Electronic Compliance Monitoring Software). This action eliminates the need for time-consuming pill counting, medication diary preparation, and manual data entry. It also simplifies the organization of data and report formatting and enables study leaders to identify noncompliant clinical-trial participants so their data do not skew results.

**By extending the forming web beyond the foil lidstock, Toren Consulting creates a foldable blister pack with a CR feature.**

The first applications for the RFID-based packs are expected to launch before the end of 2003. RFID tags used in the packaging currently are manufactured off-




**(Top) Dosepak's design integrates a folded blister card with a carton.**
**(Middle) Surepak cradles a blister pack and patient information in a polypropylene frame with a paperboard cover.**
**(Bottom) A proprietary CR device on Surepak keeps kids out and eases elderly access.**

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shore, and converting the blister wallets is outsourced to an exclusive partner (International Paper's Shorewood Packaging, Stamford, CT).

Another design results in a foldover pack that not only protects the blister lidstock but also imparts CR qualities (CR Folding Blister Pack, Toren Consulting Engineers, Sydney, Australia). The CR locking feature is created by extending the film portion of the blister beyond the foil on two opposite sides and thermoforming a press-stud mechanism along the edges so that when it is folded over, the male and female parts snap together. To unlock, a patient or caregiver pushes the tapered end of a pencil or pen into the conical shape formed at the outer corners of the pack and along a small sloped section to push the two halves apart.

Available for licensing, the design is reported to be cost-competitive with existing CR blister packs, compliant with British Standard BS 8404 for nonreclosable pharmaceutical packages, can be produced on existing blister packaging lines by adding a folding station to the cartoning machine, and adaptable to customized blister layouts. To enhance CR qualities, an opaque forming web is recommended so that the product is not readily visible through the package.

As usage of carded blister packs has increased, equipment makers have developed automated equipment to attach the paperboard overlays. One example is a machine that integrates with thermoform–fill–seal equipment or is fed by manually loaded blister hoppers. Capable of producing <80 wallets/min with as many as four blister cards each, the unit is compatible with a wide range of card sizes and dose counts as well as CR and non-CR formats (NewWallet, Dividella AG, Wareham, MA).

Enhanced blister structures typically carry a $0.10–$0.15 per piece premium. However, increasing compliance just a few percent for a $1-billion drug can have a multimillion-dollar effect on revenue. Considering the well-documented evidence that health benefits are related to improved compliance, enhanced blister structures can be a quadruple win—benefiting patient, caregiver, retailer, and manufacturer. **PT**