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(54) **CHILD-RESISTANT PACKAGING FOR PHARMACEUTICAL PRODUCTS**

Publication Classification

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(57) **ABSTRACT**

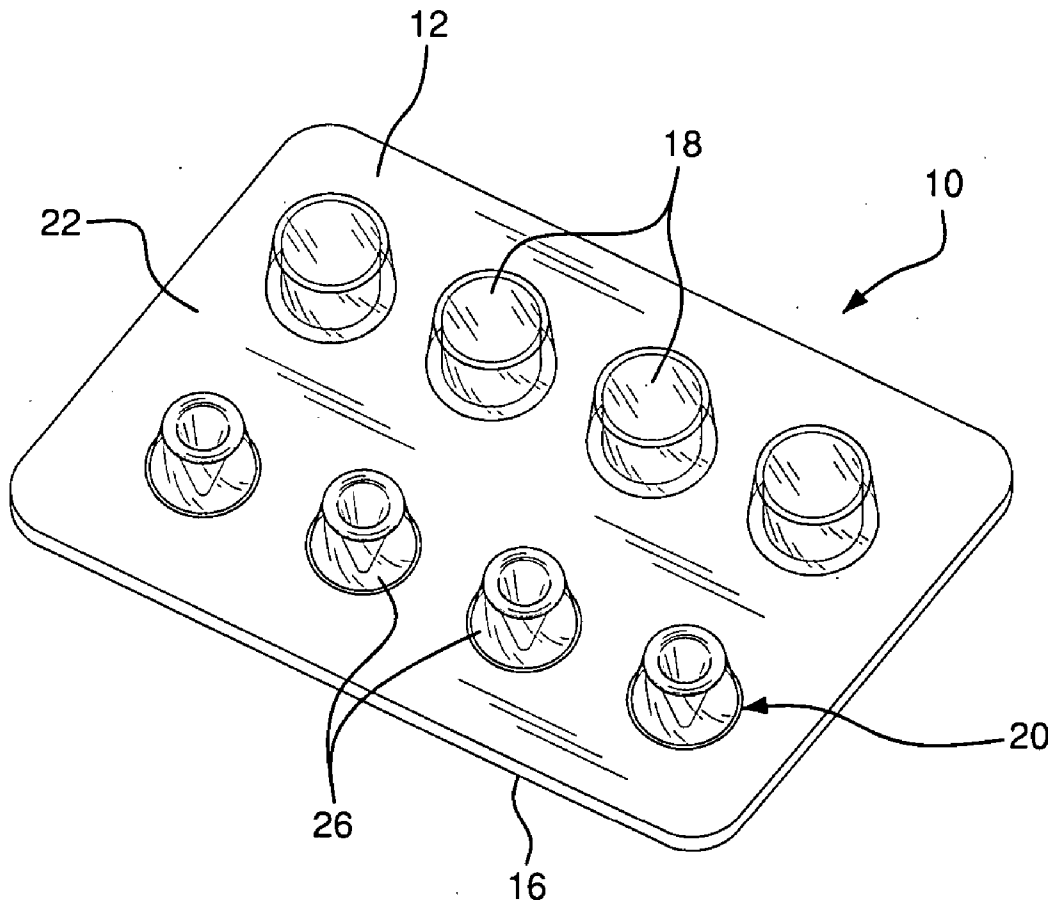
A child-resistant package for pharmaceutical articles includes a blister pack having a product casing layer defining blisters, a foil closure layer enclosing articles in the blisters and a reinforcing layer preventing dispensing of each article until an access mechanism is used. Each access mechanism includes a puncturing element of the product casing layer and a tear-away element of the reinforcing layer defined by a perforation line. The puncturing element includes a pointed portion for separating a first end of the tear-away element. Application of pulling force to the first end further separates the tear-away element to expose the foil layer adjacent the blister for dispensing the article. According to one embodiment, the package includes an outer jacket having a mounting portion receiving the blister pack and a cover movable with respect to the mounting portion between opened and closed positions.

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Related U.S. Application Data

(60) Provisional application No. 60/777,346, filed on Feb. 28, 2006.



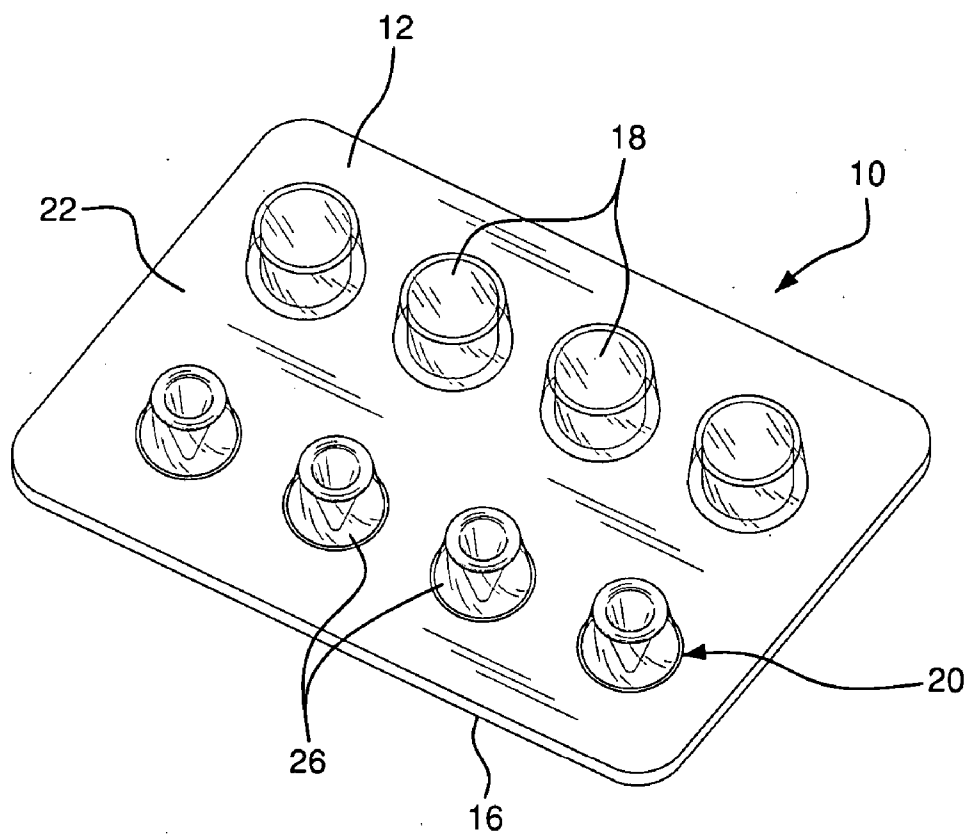


FIG. 1

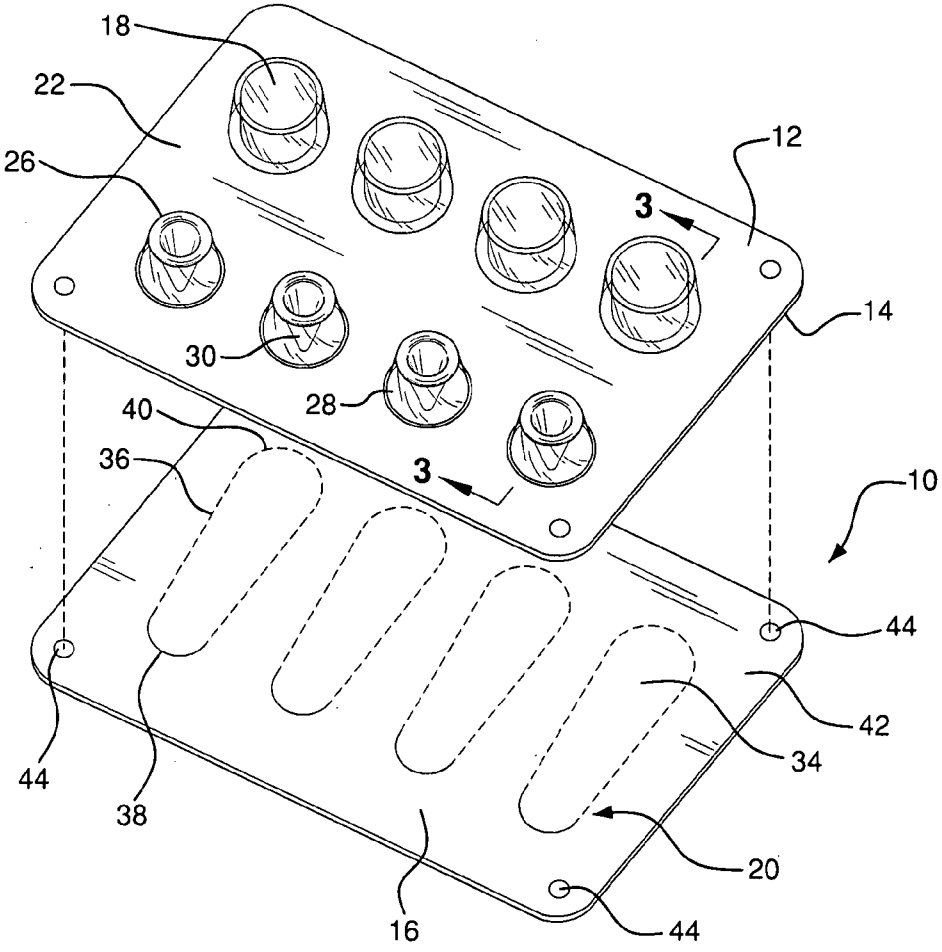


FIG. 2

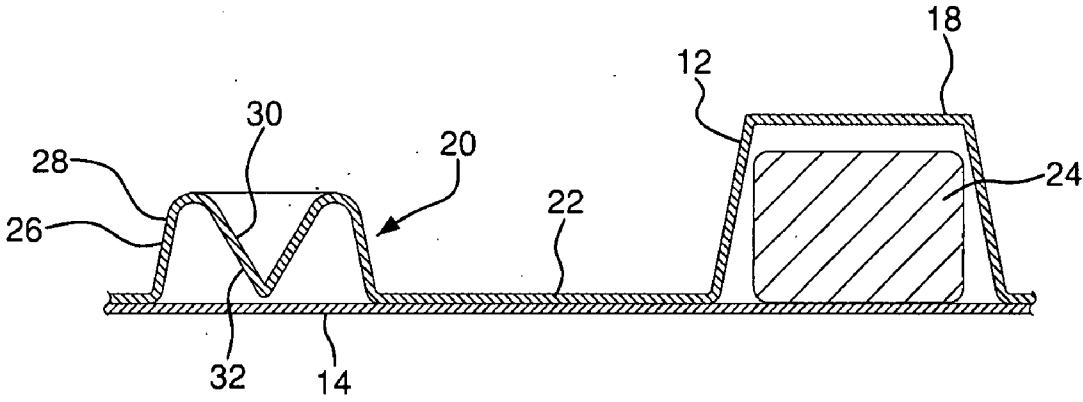


FIG. 3

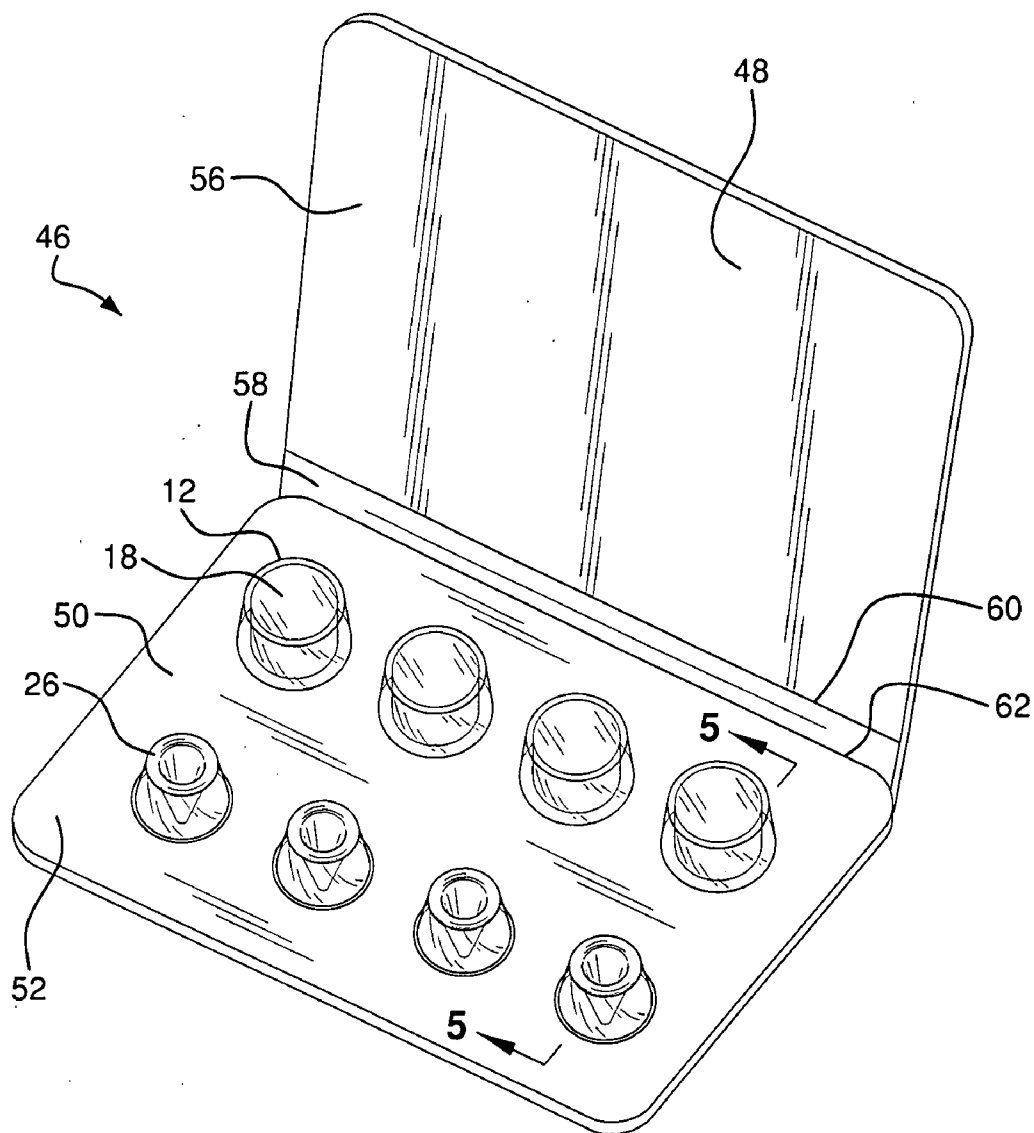


FIG. 4

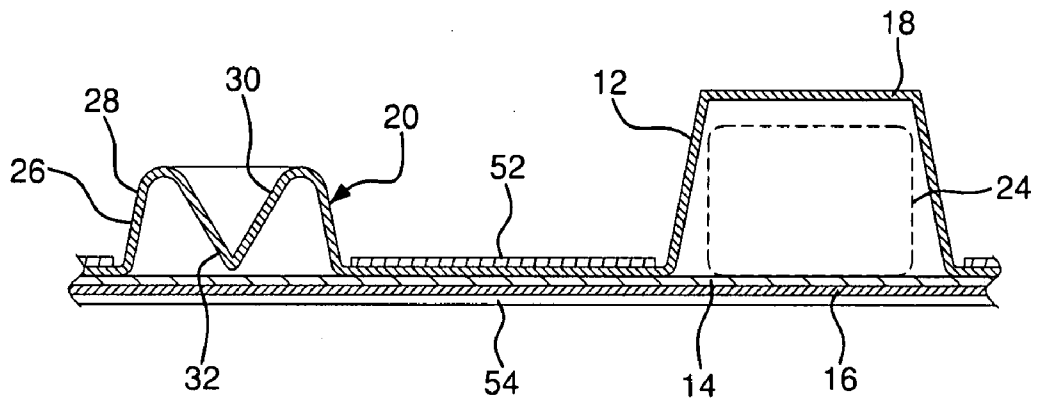


FIG. 5

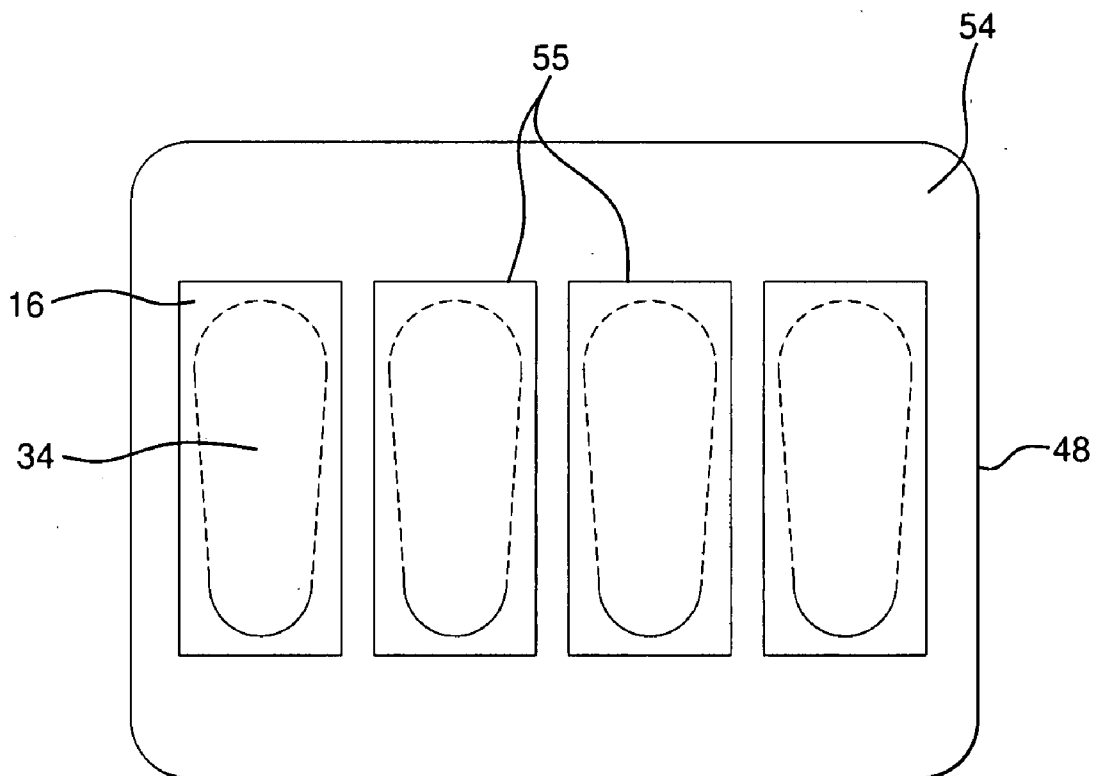


FIG. 6

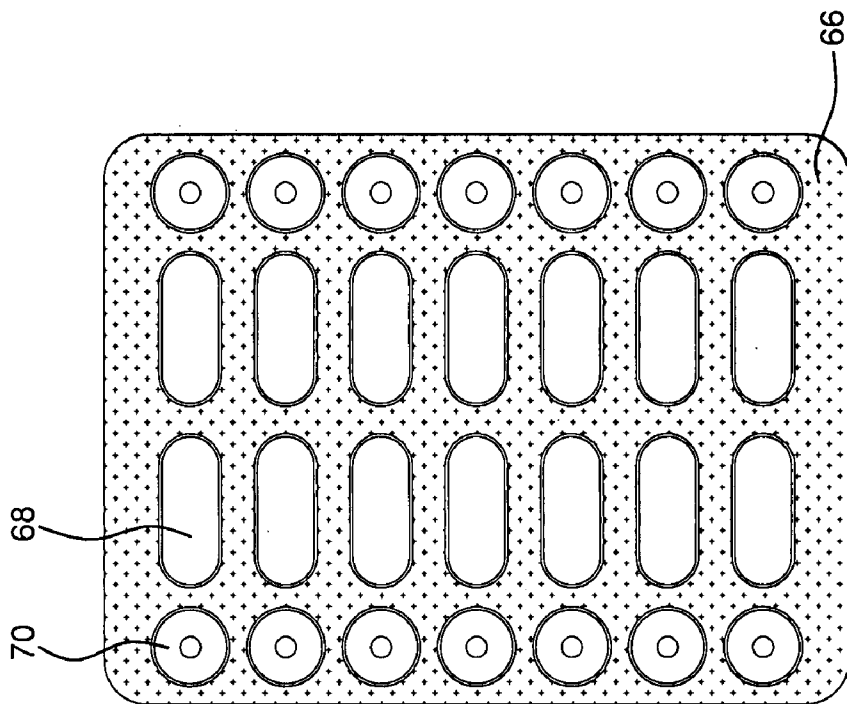


FIG. 8

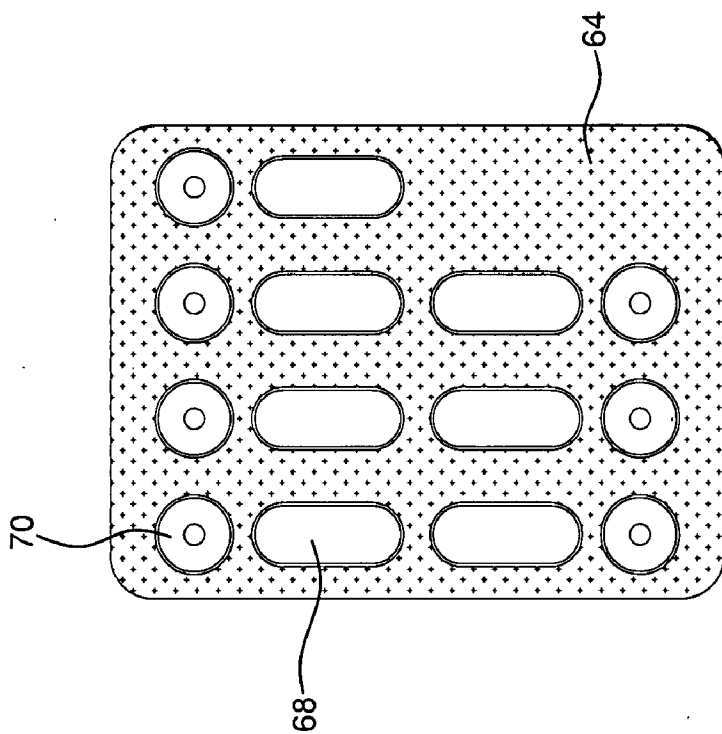


FIG. 7

CHILD-RESISTANT PACKAGING FOR PHARMACEUTICAL PRODUCTS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority of U.S. Provisional Application No. 60/777,346, filed Feb. 28, 2006.

FIELD OF THE INVENTION

[0002] The invention relates to packaging and, more particularly, to child-resistant packaging for pharmaceutical products in the form of pills, tablets or capsules.

BACKGROUND OF THE INVENTION

[0003] Blister packaging for pharmaceutical products such as pills, tablets, and capsules includes a product casing layer and a foil closure layer. The product casing layer is formed from a moldable material to define blisters each adapted to receive one of the pills, tablets, or capsules within an interior of the blister. The foil closure layer is secured to a base portion of the product casing layer surrounding the blisters (e.g., by heat-sealing) to enclose the pills, tablets, or capsules within the blisters. To dispense the pills, tablets, or capsules from the packaging, a user depresses one of the blisters such that the enclosed product is driven into compressive contact with the foil layer with sufficient force to rupture the foil layer.

[0004] Child-resistant packaging for pharmaceutical products include features requiring certain cognitive skills for gaining access to, or dispensing, the pharmaceutical product such that access to the pharmaceutical product by a young child is limited. A well known example is the twist-off cap for a pill bottle that requires application of simultaneous twisting and axial forces to remove the cap. For blister-type packages, it is known to include an outer package for containing a blister pack in which either or both the outer package and blister pack must be manipulated in a certain manner to provide for dispensing of the pharmaceutical product. For example, it is known to provide a blister pack slidably mounted in an outer package for movement of the blister pack with respect to the outer package between first and second positions. Openings in the outer package are respectively misaligned and aligned with the blisters of the blister pack in the first and second positions to disable and enable a dispensing actuation of the blisters.

[0005] Prior child-resistant packages, which desirably function to limit access to the contents by small children, also can undesirably limit access to the contents by elderly or infirm patients who, although possessing the necessary cognitive skills, lack sufficient strength or manual dexterity to manipulate the packaging in the required manner. Also, the features of prior child-resistant packaging that operate to limit access may add significant expense to the packaging, particularly packaging requiring interaction between an outer package and a blister pack housed within the outer package.

[0006] What is needed is a child-resistant package for pharmaceutical products such as pills, capsules, and tablets that functions to limit access to the package contents by a small child who may be harmed by the contents but that also provides for access to the contents of the package by an

elderly or infirm person having limited strength or dexterity. More particularly, what is needed is a blister-type packaging for pharmaceutical products in which the child-resistant features may be included in a stand-alone blister pack having a relatively uncomplicated construction for providing cost-saving efficiencies.

SUMMARY OF THE INVENTION

[0007] According to one aspect of the invention, there is provided a child-resistant packaging for pharmaceutical articles such as pills, tablets, and capsules comprising a blister pack having a product casing layer and a foil closure layer. The product casing layer includes a plurality of blisters each defining an interior for receiving one of the articles. The foil closure layer is secured to the product casing layer to enclose the articles within the blisters. The packaging also includes a reinforcing layer adapted to limit dispensing of the articles from the package until an access mechanism of the package has been actuated by a user.

[0008] The packaging includes a plurality of access mechanisms each associated with one of the blisters to provide for dispensing of the article contained within the blister following actuation of the access mechanism. Each access mechanism includes a puncturing element defined by the product casing layer and a tear-away element defined by the reinforcing layer. The puncturing element preferably includes a conical outer wall portion and an inner wall portion supported by the outer wall portion and having a pointed end portion. The tear-away element of the access mechanism is preferably defined by weakening the reinforcing layer, most preferably by a perforation line. The tear-away element includes a first end located beneath the associated puncturing element and an opposite second end located beneath the associated blister.

[0009] The inner wall portion of the puncturing element is adapted to deflect under a compressive load applied to the puncturing element. This results in application of a separating pressure to the reinforcing layer and the foil layer sufficient to separate the first end of the associated tear-away element from an adjacent base portion of the reinforcing layer. The separation of the first end facilitates grasping of the tear-away element for application of a pulling force to the tear-away element to advance an opening in the reinforcing layer towards the second end of the tear-away element. According to one embodiment, the tear-away element is reduced in width adjacent the first end to increase the separating pressure for a given applied load. The tear-away element may also be made weaker adjacent the first end, for example by increasing the percentage of perforation in a perforation line defining the tear-away element.

[0010] Prior to actuation of the access mechanism, the presence of the reinforcing layer beneath the associated blister prevents a user from dispensing the article from the blister by application of a compressive load to the blister in the conventional manner. To dispense the article, a user first applies a compressive load to the puncturing element of the access mechanism of sufficient magnitude to separate the first end of the associated tear-away element from the adjacent base portion of the reinforcing layer. Next, the user grasps the first end of the tear-away element and applies a pulling force to the tear-away element such that an access opening in the reinforcing element is advanced toward to the

second end of the tear-away element. Following sufficient advancement of the access opening toward the second end of the tear-away element, the user may then dispense the article by applying a compressive load to the blister of sufficient magnitude such that the foil closure layer is ruptured by the article.

[0011] According to one embodiment of the invention, the blister pack is mounted in an outer jacket. The jacket includes a mounting portion having front and back panels. Preferably, the front panel defines openings adapted for receipt of the blisters and puncturing elements defined by the product casing layer of the packaging. Preferably, the jacket also includes a cover panel and a relatively narrow intermediate panel located between the cover panel and the mounting portion such that the cover panel can be moved between opened and closed positions with respect to the mounting portion of the jacket.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] For the purpose of illustrating the invention, there is shown in the drawings a form that is presently preferred; it being understood, however, that this invention is not limited to the precise arrangements and instrumentalities shown.

[0013] FIG. 1 is a perspective view of a child-resistant package for pharmaceutical products according to an exemplary embodiment of the present invention.

[0014] FIG. 2 is an exploded perspective view of a child-resistant package according to an exemplary embodiment of the invention.

[0015] FIG. 3 is a sectional view of a product casing layer of the child-resistant package of FIG. 1 taken along line 3-3 in FIG. 2.

[0016] FIG. 4 is a perspective view of a child-resistant package according to a second exemplary embodiment of the invention.

[0017] FIG. 5 is a sectional view of the packaging of FIG. 4 taken along the line 5-5 of FIG. 4.

[0018] FIG. 6 is a bottom view of a mounting portion of a jacket of the packaging of FIG. 4.

[0019] FIGS. 7 and 8 are plan views of child-resistant packages for pharmaceutical products, the packages being respectively 7 and 14 count packages.

DESCRIPTION OF THE INVENTION

[0020] Referring to the drawings, there is shown in FIGS. 1 through 3 a package 10 for pharmaceutical products such as pills, tablets, capsules, and the like. The pharmaceutical products for use with the package 10 are hereinafter sometimes referred to as "pills" to facilitate description. It should be understood, however, that the invention is not so limited. Referring to FIGS. 1 and 2, the depicted package 10 includes a product casing layer 12, a foil (e.g., aluminum) closure layer 14 and a reinforcing layer 16. The product casing layer 12 includes a plurality of blisters 18 each defining an interior for receipt of a pill. The package 10 includes a plurality of access mechanisms 20 each associated with one of the blisters 18. The access mechanism 20 is adapted to create an opening in the reinforcing layer 16 to provide for dispensing

a pill from the blister 18. As described below in greater detail, the access mechanism 20 of the present invention provides a child-resistant feature because successful use of one of the access mechanisms 20 of the package 10 to dispense a pill requires a level of cognitive development beyond that of most children, thereby limiting access by children to the pills. The package 10, however, also provides a senior-friendly construction by which an elderly or infirm person having limited strength can nevertheless use the access mechanisms 20 to dispense pills from the package 10.

[0021] Referring to the sectional view of FIG. 3, the foil closure layer 14 is preferably secured to the product casing layer 12 (e.g., by heat sealing the foil closure layer 14 to a base portion 22 of the product casing layer 12). As shown in FIG. 3, the foil closure layer 14 extends across a lower surface of the product casing layer 12 such that pills 24 located within the interiors of blisters 18 are sealed within the blisters 18 by the foil closure layer 14. Preferably, the foil closure layer 14 has a thickness selected such that the foil closure layer 14, in the absence of the reinforcing layer 16, would rupture in response to a compressive load applied to a pill-containing blister 18 (i.e., by a user pressing down on the blister in a conventional manner). The presence of the reinforcing layer 16 beneath the foil closure layer 14, however, prevents a user from dispensing pills from the package 10 in the conventional manner until the user utilizes one of the access mechanisms 20 in the manner described below.

[0022] Each access mechanism 20 includes a puncturing element 26 carried by the product casing layer 12. Preferably, the product casing layer 12 is formed from a moldable plastic material (e.g., an injection molded plastic) such that the puncturing elements 26 of the access mechanisms 20 are integrally defined by the product casing layer 12. The puncturing element 26 includes a substantially conical outer wall portion 28 and an inner wall portion 30 supported by the outer wall portion 28 such that the inner wall portion 30 is located within an interior defined by the outer wall portion 28. As shown, the inner wall portion 30 preferably tapers to a substantially pointed end 32.

[0023] Preferably, the inner wall portion 30 and outer wall portion 28 are substantially equal in height, as shown, such that the substantially pointed end 32 of the inner wall portion 30 is located at approximately the same level as the base portion 22 of the product casing layer 12. Arranged in this manner, the puncturing element 26 is adapted to deflect with respect to the surrounding base portion 22 in response to a compressive load applied to the puncturing element 26 (e.g., by a user's thumb) to drive the substantially pointed end 32 of the inner wall portion 30 into contact with the foil closure layer 14 and the reinforcing layer 16 underlying the puncturing element 26. The substantially pointed end 32 provides a reduced contact area for the puncturing element 26, thereby increasing the pressure applied to the closure and reinforcing layers 14, 16 for a given load applied to the puncturing element 26.

[0024] Each access mechanism 20 also includes a tear-away element 34 formed from part of the reinforcing layer 16 by a perforation line 36. As shown, each tear-away element 34 is elongated, and has a first end 38, which is located to underlie the substantially pointed end 32 of the puncturing element 26 of the access mechanism 20, and an

opposite second end 40, which is located to underlie the blister 18 associated with the access mechanism 20. As described above, the puncturing element 26 of each access mechanism 20 is adapted to deflect under compressive load toward the base portion 22 of the product casing layer 12 such that the substantially pointed end 32 of the inner wall portion 30 is driven into contact with the underlying closure and reinforcing layers 14, 16.

[0025] Contact between the substantially pointed end 32 and the layers 14, 16 results in pressure being applied to the tear-away element 34 of the access mechanism 20 to driv- ingly separate the first end 38 of the tear-away element 34 from a surrounding portion 42 of the reinforcing layer 16 to create an access opening in the reinforcing layer 16. The separation between the first end 38 of the tear-away element 34 and the portion 42 of reinforcing layer 16 also enables a user to grasp the first end 38 and thereby apply a pulling force to the tear-away element 34. The pulling force further separates the tear-away element 34 from the base portion 42 of the reinforcing layer 16 to extend the access opening towards the blister 18 located adjacent the second end 40 of the tear-away element 34.

[0026] When the tear-away element 34 has been pulled to an extent that the access opening in the reinforcing layer 16 extends to a location underlying the associated blister 18 in the product casing layer 12, a pill contained in the blister 18 may be dispensed. The separation between the tear-away element 34 of the access mechanism 20 and the surrounding base portion 42 of the reinforcing layer 16 results in separation between the tear-away element 34 and the closure layer 14 beneath the blister 18. As such, the portion of the closure layer 14 beneath the blister 18 is no longer reinforced by the reinforcing layer 16. Application of compressive load to the blister 18 (i.e., in the conventional manner for dispensing pills from blister packages) results in contact between a pill contained in the blister 18 and the closure layer 14 and an associated pressure sufficient to rupture the foil closure layer 14 and dispense the pill.

[0027] Although it is presently preferred that pulling the tear-away element 34 separates the tear-away element from the foil closure layer 14, it is not a requirement. It is conceivable that the foil closure layer 14 could be bonded to the tear-away element 34 such that pulling the tear-away element 34 results in a tearing separation between the product casing layer 12 and a corresponding portion of the foil closure layer 14 located atop the tear-away element 34. In this manner, the access opening created in the reinforcing layer 16 by pulling the tear-away element 34 would also extend through the closure layer 14 to communicate with the interior of the associated blister 18. Such tearing of the foil closure layer 14 could also be facilitated by including a perforation line in the foil closure layer corresponding to the perforation line 36 in the reinforcing layer 16.

[0028] As shown, the width of each of the tear-away elements 34 preferably varies such that the tear-away element 34 is relatively narrow adjacent the first end 38. As a result, the amount (i.e., length) of the perforation line 36 over which an applied load is distributed (i.e., the portion of the perforation line 36 that extends around and defines the first end 38 of tear-away element 34) is reduced. In this manner, the effective separating pressure acting on the first end 38 will be increased compared to that which would be

applied were the width not narrowed at the first end 38. The tendency of the tear-away element 34 to separate at the first end 38 can also be increased by increasing the percentage of perforation (i.e., the discontinuities) in the perforation line 36 adjacent the first end 38 compared to that in other portions of the perforation line 36.

[0029] The reinforcing layer 16 may be made from poly- vinyl chloride (PVC), polyvinylidene chloride (PVDC), or a polychlorotrifluoroethylene (PCTFE) such as Aclar® by Honeywell International. PCTFE is used extensively in pharmaceutical packaging and provides excellent moisture barrier capabilities. The invention, however, is not limited to any particular material for the reinforcing layer and other materials could be used to provide moisture barrier protec- tion for the product stored within the blisters 18. The reinforcing layer 16 and product casing layer 12 are prefer- ably secured to each other (e.g., using sonic welding). The reinforcing layer 16 and product casing layer 12 may be secured together at discrete peripheral locations 44, as shown in FIG. 1. Alternatively, the reinforcing layer 16 and product casing layer 12 may be secured together along a substantially continuous weld line extending about the perimeter of the product casing layer 12. The bonding between the reinforcing layer 16 and the product casing layer 12 at peripheral locations or along a perimeter line leaves the tear-away elements 34, which are located interi- orly from the peripheral locations 44, free to separate from the product casing layer 12 when the access mechanisms 20 are actuated to dispense pills from the package 10 as described above.

[0030] To facilitate bonding between the product casing layer 12 and the reinforcing layer 16, the intermediately- located foil closure layer 14 could be discontinued at the bonding locations. This is not a requirement of the invention, however, and the bonding (e.g., sonic welding) between the product casing layer 12 and the reinforcing layer 16 could be executed without pre-existing discontinuities being provided in the intermediately located foil layer 14. It is also not a requirement of the invention that the product casing layer 12 be bonded to the reinforcing layer. For example, it is conceived that a hinged piece of PVC (or other suitable material) could include a portion forming the reinforcing layer 16. The hinged piece would preferably be folded around the product casing layer 12 and foil layer 14 and sealed about the periphery of the hinged piece such that the product casing layer 12 and foil layer 14 are captured within the hinged piece. Preferably, the hinged piece defines open- ings adapted to receive the blisters 18 and puncturing elements 26 of the product casing layer 12.

[0031] In the event that sonic welding is used to bond the product casing layer 12 and the reinforcing layer 16 at the peripheral bond locations 44 (or perimeter weld line) in the above-described manner, it is conceivable that the sonic welding apparatus could be adapted to also create the perforation lines 36 in the reinforcing layer 16 that define the tear-away elements 34. Such a feature would desirably facilitate manufacture by eliminating the need for separate apparatus to perform these functions (i.e., welding and perforating).

[0032] As described above, the reinforcing layer 16 of package 10 is depicted with perforation lines 36 defining the tear-away elements 34. It is not a requirement of the inven-

tion, however, that the tear-away elements 34 be defined by perforation lines (i.e., spaced discontinuities in the material). It is conceivable that other means, such as score lines or otherwise weakened portions of the material, could be used to define the boundaries of the tear-away elements 34 of reinforcing layer 16.

[0033] Referring to FIGS. 4 through 6, there is shown a package 46 for pharmaceutical products according to a second exemplary embodiment of the invention. The package 46 includes a product casing layer 12, foil closure layer 14 and reinforcing layer 16 similar in construction to the corresponding elements of package 10. The package 46, however, also includes a jacket 48 in which the product casing layer 12, foil closure layer 14 and reinforcing layer 16 are mounted. The jacket 48 of package 46 is preferably made from paper (e.g., cardboard) and includes a mounting portion 50 having front and back panels 52, 54 between which the layers 12, 14, 16 of package 46 are mounted. As shown, the front panel 52 of the mounting portion 50 of jacket 48 defines openings in which the blisters 18 and puncturing elements 26 of the product casing layer 12 are received.

[0034] Preferably, the back panel 54 of the mounting portion 50 defines openings 55 at locations that correspond to the locations of the perforation lines 36 in the reinforcing layer 16 of package 46. Such a construction facilitates access to the tear-away elements 34 defined by reinforcing layer 16 for grasping and pulling of the tear-away elements 34 in the manner described above for package 10. It is conceivable that, instead of defining openings at the locations of the tear-away elements 34, the back panel 54 of the mounting portion 50 of jacket 48 could define perforation lines adapted to be torn when the tear-away elements in reinforcing layer 16 are grasped and pulled.

[0035] The jacket 48 could also include a cover panel 56, as shown, and a relatively narrow intermediate panel 58 located between the cover panel 56 and the mounting portion 50 of jacket 48. The jacket 48 preferably includes fold lines 60, 62 respectively located between the cover panel 56 and the intermediate panel 58 and between the intermediate panel 58 and the mounting portion 50. Constructed in this manner, the jacket 48 is adapted to be opened and closed in book-like fashion. Each of the mounting portion 50 and cover panel 56 desirably provides surfaces for display of product indicia and product-related information.

[0036] The present invention is not limited to 4 count packages such as depicted in FIGS. 1 through 6. Referring to FIG. 7, there is shown a package 64 according to the invention having a seven count configuration. Referring to FIG. 8, there is shown a package 66 having a 14 count configuration. Each of the packages 64, 66 includes blisters 68 for enclosing a pharmaceutical product such as a pill, capsule or tablet. Each of the packages 64, 66 also includes puncturing elements 70 of access mechanisms for use in dispensing the pharmaceutical products from the packages 64, 66 in the above-described manner.

[0037] The present invention is also not limited to packaging for pharmaceutical products having any particular shape. Such variation is shown, for example, by comparing the generally elongated shape of the blisters 68 of packages 64, 66 with the generally circular shape of the blisters 18 of packages 10, 46.

[0038] The foregoing describes the invention in terms of embodiments foreseen by the inventor for which an enabling description was available, notwithstanding that insubstantial modifications of the invention, not presently foreseen, may nonetheless represent equivalents thereto.

What is claimed:

1. A package for pharmaceutical articles comprising:
 - a casing layer defining a plurality of blisters each adapted for receipt of one of a plurality of pharmaceutical articles;
 - a closure secured to the casing layer to enclose the articles within the blisters; and
 - a plurality of puncturing elements each associated with one of the blisters, the puncturing element adapted to puncture the closure in response to actuation by a user to create an access opening in the closure,
- the closure adapted to prevent a user from compressively deflecting one of the blisters to dispense one of the articles from the package until the associated puncturing element is actuated by the user to create the access opening in the closure.
2. The package according to claim 1, wherein the closure comprises a foil layer and a reinforcing layer, the foil layer located between the reinforcing layer and the casing layer.
3. The package according to claim 1, wherein the puncturing elements are defined by the casing layer.
4. The package according to claim 3, wherein each puncturing element includes an outer portion supported by the casing layer and an inner portion supported by the outer portion, the inner portion tapered to define a pointed end and adapted to deflect towards the closure in response to compression applied to the puncturing element by a user.
5. The package according to claim 4, wherein the outer portion of the puncturing element is substantially conical.
6. The package according to claim 1, wherein the casing layer comprises a moldable plastic material.
7. The package according to claim 7, wherein the puncturing elements are integrally formed with the casing layer from the moldable plastic material.
8. The package according to claim 2, wherein the reinforcing layer includes a plurality of tear-away elements each extending from a first end located adjacent one of the puncturing elements to an opposite second end located adjacent one of the blisters.
9. The package according to claim 8, wherein the tear-away elements are defined by perforation of the reinforcing layer.
10. The package according to claim 1 further comprising an outer jacket, the jacket including:
 - a mounting portion in which the casing layer, closure and puncturing elements are mounted;
 - a cover panel; and
 - an intermediate panel located between the mounting portion and the cover panel such that the cover panel is movable with respect to the mounting portion between closed and opened positions.
11. A package for pharmaceutical articles comprising:
 - a product casing layer defining a plurality of blisters each adapted for receipt of one of a plurality of pharmaceutical articles;

a closure secured to the product casing layer to enclose the articles within the blisters; and

a plurality of access mechanisms each associated with one of the blisters of the product casing layer, each access mechanism including a tear-away element defined on a portion of the closure and a puncturing element adapted to puncture the closure at the tear-away element in response to actuation by a user to facilitate grasping of the tear-away element and application of a pulling force by a user,

the closure adapted to prevent a user from compressively deflecting one of the blisters to dispense one of the articles from the package until the access opening is created in the closure by actuation of the puncturing element of the associated access mechanism.

12. The package according to claim 11, wherein each tear-away element is defined by a perforation line.

13. The package according to claim 11, wherein the product casing layer comprises a moldable plastic material and wherein the puncturing elements are integrally formed with the casing layer from the moldable plastic material.

14. A package for pharmaceutical articles comprising:

a blister pack including a product casing layer and a foil closure layer, the product casing layer defining a plurality of blisters each adapted for receipt of one of a plurality of pharmaceutical articles, the foil closure layer secured to the product casing layer to enclose the articles within the blisters;

a reinforcing layer secured to the product closure layer of the blister pack such that the foil closure layer is located

between the product closure layer and the reinforcing layer, the reinforcing layer adapted to prevent a user from dispensing an article by compressively deflecting one of the blisters and rupturing the foil layer; and

a plurality of access mechanisms each including a puncturing element and a tear-away element, the tear-away element defined on a portion of the reinforcing layer and being elongated to include a first end adjacent the puncturing element and a second end adjacent an associated one of the blisters,

the puncturing element defined by the product casing layer and including an outer wall portion and an inner wall portion supported by the outer wall portion, the inner wall portion tapered to define a substantially pointed end and deflectable with respect to the outer wall portion to puncture the reinforcing layer at the first end of the tear-away element,

the puncturing of the reinforcing layer providing for grasping of the tear-away element by a user and application of a pulling force sufficient to separate at least a portion of the tear-away element from a surrounding portion of the reinforcing layer, the separation of the at least a portion of the tear-away element enabling a user to dispense an article from the associated blister by application of a compressive force to the associated blister to rupture the foil closure layer.

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