

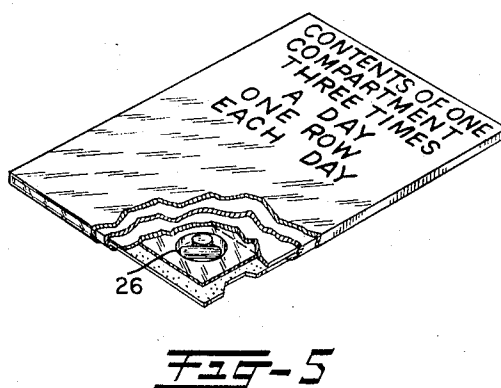
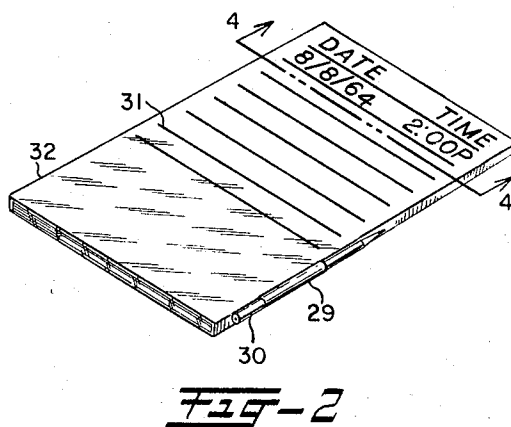
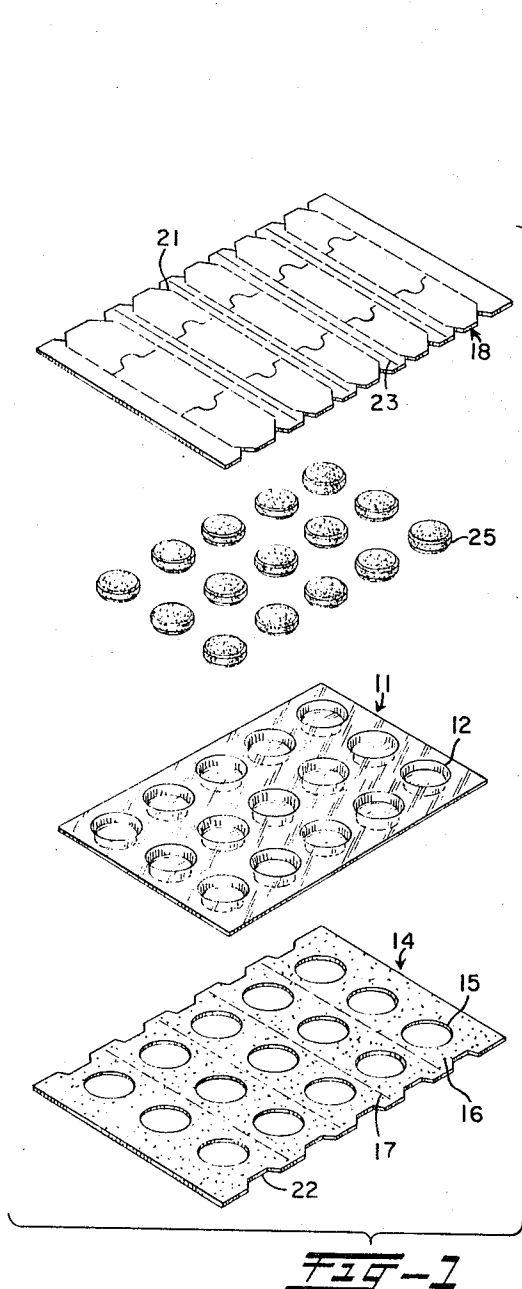
Feb. 21, 1967

M. GREIF ET AL
DIVISIBLE, MULTI-COMPARTMENT, DOSE-INDICATING,
SEPARATELY-RELEASING BLISTER PACKAGE

3,305,077

Filed Aug. 25, 1964

2 Sheets-Sheet 1



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2 Sheets-Sheet 2

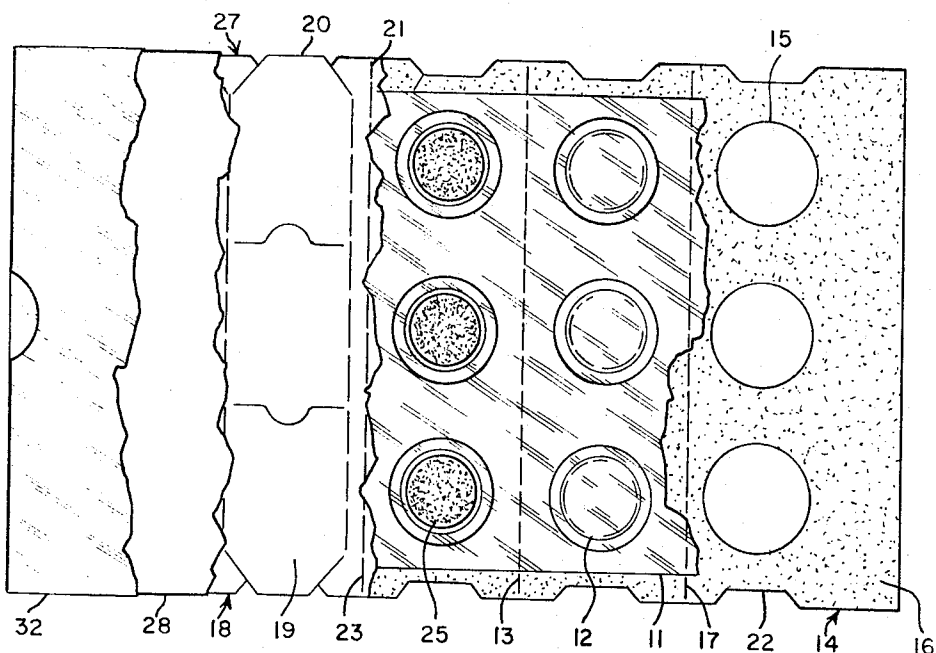


FIG-3

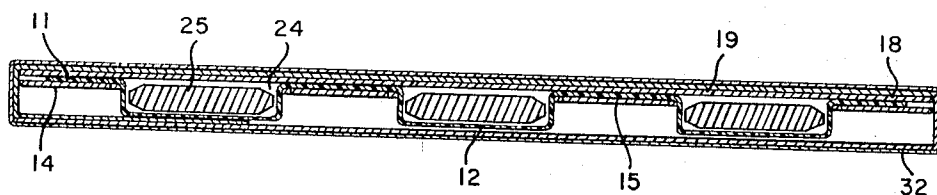


FIG-4

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3,305,077

DIVISIBLE, MULTI-COMPARTMENT, DOSE-INDICATING, SEPARATELY - RELEASING BLISTER PACKAGE

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4 Claims. (Cl. 206—42)

This invention relates to a dose-indicating package for solid medicaments in which individual doses are separately stored in separate compartments in a protected plastic blister sheet, which package is scored to permit (A) breaking into sub-division packages, and (B) separate opening of each individual compartment to release a dose of medicament, and which blisters are preferably arranged so as to be indicating and self-confirming as to doses of the medicament dispensed. Each row of the blister sheet has a number of blisters corresponding to the most probable number of daily doses and is separable; with the package containing a convenient number of rows, in a storage sheet, in a protective sleeve, preferably wrapped with a transparent sheet, such as cellophane.

In medical practice there are many times when the exact dosage prescribed is absolutely essential. For instance, with medication for a heart condition, either too little or too much can overload the heart. When a patient is on a medicament which requires long-term administration, it is very easy, particularly for the elderly and those not too well, to become confused as to whether the medicament was taken before breakfast today or yesterday, or on some other occasion.

Even for persons with normal memory it is easy to forget whether two, three or four were taken in any given day. Hence, it is highly desirable that the medicament be packed in such a fashion that the package itself, by casual inspection, gives unequivocal evidence of the proper rate of administration. Many times a patient desires to take part of a package, such as the medicament for a single day, with him and yet leave the remainder of the package elsewhere to avoid undue bulk. It is also desirable that the package be one which is capable of having two or more individual tablets, pills, capsules or other dosage forms for concurrent administration. Sometimes a single tablet would be too big. Sometimes medicaments which are to be taken together are incompatible on storage and, hence, are separately formed into dosage forms such as hard shell or soft shell capsules, tablets or pills or as solid medicament forms.

It has now been found that a blister pack can give such unequivocal evidence by forming blisters with each blister containing one or more solid dosage forms such as tablets, capsules or pills, which are to be administered at a single time; with the number of blisters in a row to correspond to the most probable number of daily doses of the medicament, and a convenient number of individual rows in a single sheet assembly for the package. The number of rows may be a weekly supply, such as seven rows; or the number of days of dosage which can be estimated to be required for any particular set of conditions; or a convenient size of package if other than one of the above two. For instance, many medicaments are prescribed three times a day with meals, which would mean three blisters in a row with from four to ten rows forming a convenient package size. These numbers, of course, are exemplary and may be varied within wide limitations depending on the actual size of the dosage form, the number of doses taken per unit of time, and a size that can be considered as convenient for a particular user.

Preferably each blister is separately sealed so that it

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may be opened at the time of use without danger of loss or contamination of medicament prior to opening at the time of administration. Preferably each row is individually detachable so that the blisters of a single row can be separated from the remainder of the package and carried in the pocket or purse of the user until time for administration.

Additionally, it is a feature of the present invention that the storage sheet assembly is conveniently packed in an outer protective sleeve. The outer sleeve containing the protected, filled blister sheet may be wrapped in cellophane or other transparent protective film, which film is ruptured at the time of use with the sheets containing individual rows of medicament being slid out of the cardboard sleeve.

The cardboard sleeve in a preferred embodiment has on one surface thereof spaces for entry by the patient of the actual time of administration with numbers coded to blister sheet numbers, if convenient, so that the user can mark down on the sleeve the actual time at which each dose was actually administered. This embodiment is particularly useful for those instances where the number of solid dosage forms to be administered per day varies or may be expected to vary depending upon the individual requirements of the user. A loop portion is formed with the sleeve and adapted to receive a pencil or other writing instrument so that the user can write down on the sleeve at the time of administration each dose and confirmed administration at pre-selected times, or as required.

The use of sleeved packages containing frangible tablets is disclosed in U.S. Patent 2,834,456, A. A. Langer, "Frangible Tablet Packaging," May 13, 1958. The use of visible blister packs without the number having any significance, and without protection, is disclosed in U.S. Patent 2,358,246, C. Nicolle, "Plastic Material Wrapper," September 12, 1944. The concept of separately detachable storage seals is disclosed in U.S. Patent 2,302,045, L. Neumann et al., "Article Holder," November 17, 1942.

The concept of having the sheet itself act as a dose indicating device to remind the user to take or confirm the administration of medicament at specified hours appears to be a novel concept, as is administration data on the sleeve, and an attached writing instrument.

Whereas it is to be understood that the materials of construction, and particularly the size and number of rows and columns is a matter of choice, one particular configuration is illustrated in the following drawings in which:

FIGURE 1 is an exploded view of the storage sheet assembly.

FIGURE 2 is an assembly view of the complete package, including writing instrument.

FIGURE 3 is a broken-away-plan view of the package showing the individual elements.

FIGURE 4 is a cross-sectional view at 4—4 of FIGURE 2.

FIGURE 5 is a pictorial view of the film-wrapped package with printed instructions and a broken-away corner to show multiple dosage forms.

The package is assembled from a plastic sheet 11 in which are formed a plurality of blisters 12. The plastic sheet is conveniently of polystyrene as polystyrene is low in cost, is easy to form, and is known to be non-toxic. The plastic sheet may be of other plastics, such as polymethyl-methacrylate or butyrates or cellulose acetate or a thermoplastic polyvinyl type or other formable, preferably transparent plastic. If medicaments are packaged the plastic sheet must be of a material proved to be non-toxic. If tablets for dyes or bleaches for laundry work or other purposes are used, any plastic may be used as toxicity is not a problem. The plastic sheet has therein a plurality of plastic sheet score lines 13.

Beneath the plastic sheet is a cardboard guard sheet 14. The guard sheet has a plurality of apertures 15 therein adapted to receive the blisters of the plastic sheet and is somewhat larger than the plastic sheet. The guard sheet may be thick enough to protect the blisters from compression, as for example where the contents of the blisters is fragile and the blister itself may be deformed under pressure. Usually, however, a thinner guard sheet is adequate and both lighter in weight and less expensive. The guard sheet has a thermoplastic coating 16, as for example a coating of polystyrene, to permit heat sealing to the plastic sheet on the side contacting the plastic sheet. The guard sheet has guard sheet score lines 17 therein.

On the other side of the plastic sheet is the cover sheet 18, the plastic sheet contacting side of which is thermoplastic coated. The cover sheet 18 has a plurality of tear-off covers 19, each of which has a fingernail liftable tab 20 and is formed from the cover sheet by the tear-off cover scores 21. Preferably the guard sheet has a plurality of notches 22 in its edge so that the fingernail liftable tab of the edge tear-off covers is over a notch and hence readily accessible. In addition to the tear-off cover scores the cover sheet has a row-breaking score 23. The individual tear-off covers 19 and the blister 12 thereunder form a single dose compartment 24 in which is placed a solid medicament 25. As shown at 25, the solid medicament is a single tablet. Other solid dosage forms, such as hard or soft gelatin capsules, pills, delayed-action tablets and the like may be stored in the compartment and, as shown in FIGURE 5, may consist of plural solid doses 26, as for example, for medical treatments requiring a tablet and capsule to be administered simultaneously or where for some reason components are not combined in a single solid dosage form. Compatibilities, manufacturing conveniences, etc. may be responsible for multiple solid form doses. Additionally, if the package is formed at the individual pharmacy level variations in dosage or selected choices of solid medicament forms for the treatment of a particular patient may be combined in the individual compartments 24.

The plastic sheet 10, the guard sheet 14, and the cover sheet 18 form the storage sheet assembly 27.

The storage sheet assembly 27 is inserted in a protective sleeve 28 of cardboard or other protective material which serves to protect the storage sheet assembly. On the side of the protective sleeve is a pencil loop 29 to contain a pencil or other marking instrument and in which is a pencil 30. On the surface of the protective sleeve 28 are a plurality of dosage data blanks 31 into which the individual user can insert the time of administration of each individual dose. About the entire assembly is a wrapper 32 of cellophane or other transparent sheet material, which may have a tear strip which serves as a transparent overwrap to permit inspection and ready visibility of the contents without chance of contamination.

Whereas the number of compartments in a single row is preferably the number corresponding to the average daily dosage of a particular medicament form, the number in a row may not exactly correspond to the daily dosage because a particular patient may have unusual requirements or the medicament may be prescribed on an "as required" basis. In such instances the dosage data blanks on the surface of the sleeve are extremely useful and serve to confirm to the patient the administration of dosages and provide a record for the attending physician to determine the actual rate of administration, which may vary from that desired or, in the case of "as required" medicaments, will show how often the patient finds medication desirable.

In the assembly of the storage sheet 27, conveniently the plastic sheet 11 is placed over the guard sheet 14 and the medicament 25 or 26 placed in each compartment. The cover sheet 18 is placed thereover. Whereas the

plastic sheet, guard sheet, and cover sheet may be initially formed with score lines 13, 17 and 23 to permit breaking off of an individual row, problems of registration are introduced and, accordingly, in a preferred assembly method the sheets are assembled without the score lines and a simultaneous multiple sealing and cutting mold is used which heats the guard sheet and cover sheet sufficiently to cause them to adhere to the plastic sheet in the general area of the break-off scores, and simultaneously cuts the breaking-off scores through all sheets at a single time so that registration is assured. The tear-off covers 19 are more readily removed if the area of heat sealing does not extend to such covers and such covers are held in place as part of the original cover sheet with the lines of weakness from scores giving a desired retention.

Obviously the size and depth of the scores is modified in accordance with conventional practice to provide a desired ease of removing the tear-off covers and breaking the storage sheet assembly into individual rows. The residual strength is such that breaking into rows and removing the tear-off covers is easily accomplished by the user but yet sufficient strength is left in the scoring that accidental release or accidental breaking on the row-breaking score lines does not occur under anticipated reasonable handling conditions.

Whereas the thermoplastic adhesives may vary over a wide range, it has been found that polystyrene sheets and polystyrene coated guard sheets and cover sheets give very good results when sealed at about 270° F. for about a 2 second weld time at 80 pounds per square inch sealing pressure. The sealing may be accomplished either by hand for use in the individual pharmacy where the dosages are adjusted to an individual patient or with more highly mechanized equipment for use by a pharmaceutical manufacturer in quantity production. Adhesive union may be accomplished using a solvent type adhesive or self-activated adhesives where an accelerator component is present in one layer and a catalyst type in the other so that on pressure activation occurs. However, such types of packaging are usually more adaptable for non-pharmaceutical usages because the solvent and activating components require additional pharmacological data to be regarded as acceptable. Heat sealed polystyrene has already been proved to be acceptable and the cost of additional verification is obviated.

Modifications in the exact size and shape of the package, including the number of rows and columns, are, of course, obvious to those skilled in the art and within the scope of the appended claims.

We claim:

1. A divisible, multi-compartment, separately-releasing, dose-indicating, dispensing blister package comprising:

- (1) a plastic sheet of generally flat configuration having formed therein a plurality of symmetrically spaced blisters, in rows and columns, each adapted to contain a single dose of at least one medicament; and adhesively united thereto,
- (2) a flat guard sheet, having apertures therein corresponding in spacing to and receiving the blisters in the plastic sheet;
- (3) a tabbed cover sheet, adhesively united to the other side of the blister sheet, having individual score lines therein surrounding the portion of the cover sheet over each blister, with a fingernail liftable tab on the portion for each blister, and with the blisters forming a plurality of compartments, said adhesively united cover sheet, guard sheet and plastic sheet having aligned score lines therein whereby that portion of the sheets containing a row of compartments may be readily broken from the remainder of the sheets containing other compartments;
- (4) a single dose of at least one medicament, comprising at least one solid dosage form, in each compartment;

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- (5) a protective sleeve over the assembly of sheets having a pencil receiving loop portion, a flat face portion of said sleeve being adapted to receive dosage data;
- (6) a pencil in said loop; and
- (7) an overwrap of transparent sheet material.
2. A divisible, multi-compartment, separately-releasing, dose-indicating, dispensing blister package comprising:
- (1) a plastic sheet of generally flat configuration having formed therein a plurality of symmetrically spaced blisters, in rows and columns, each adapted to contain a single dose of at least one medicament; and adhesively united thereto,
- (2) a flat guard sheet, having apertures therein corresponding in spacing to and receiving the blisters in the plastic sheet;
- (3) a tabbed cover sheet, adhesively united to the other side of the blister sheet, having individual score lines therein surrounding the portion of the cover sheet over each blister, with a fingernail liftable tab on the portion for each blister, and with the blisters forming a plurality of compartments, said adhesively united cover sheet, guard sheet and plastic sheet having aligned score lines therein whereby that portion of the sheets containing a row of compartments may be readily broken from the remainder of the sheets containing other compartments;
- (4) a single dose of at least one medicament, comprising at least one solid dosage form, in each compartment;
- (5) a protective sleeve over the assembly of sheets having a writing instrument receiving loop portion, a flat face portion of said sleeve being adapted to receive dosage data;
- (6) a writing instrument in said loop; and
- (7) an overwrap of transparent sheet material.
3. A divisible, multi-compartment, separately-releasing, dose-indicating, dispensing blister package comprising:
- (1) a plastic sheet of generally flat configuration having formed therein a plurality of symmetrically spaced blisters, in rows and column, each adapted to contain a single dose of at least one medicament; and adhesively united thereto,
- (2) a flat guard sheet, having apertures therein corresponding in spacing to and receiving the blisters in the plastic sheet;
- (3) a tabbed cover sheet, adhesively united to the other side of the blister sheet, having individual score lines therein surrounding the portion of the cover sheet

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- over each blister, with a fingernail liftable tab on the portion for each blister, and with the blisters forming a plurality of compartments, said adhesively united cover sheet, guard sheet and plastic sheet having aligned score lines therein whereby that portion of the sheets containing a row of compartments may be readily broken from the remainder of the sheets containing other compartments;
- (4) a single dose of at least one medicament, comprising at least one solid dosage form, in each compartment;
- (5) a protective sleeve over the assembly of sheets; and
- (6) an overwrap of transparent sheet material.
4. A divisible, multi-compartment, separately-releasing, dose-indicating, dispensing blister package comprising:
- (1) a thermoplastic sheet of generally flat configuration having formed therein a plurality of symmetrically spaced blisters, in rows and columns, each adapted to contain a single dose of at least one medicament; and adhesively united thereto,
- (2) a cardboard guard sheet, having apertures therein corresponding in spacing to and receiving the blisters in the plastic sheet, and thermoplastic coated on the thermoplastic sheet contacting side;
- (3) a cardboard tabbed cover sheet having a thermoplastic coating on the thermoplastic sheet contacting side, adhesively united to the other side of the blister sheet, having individual score lines therein surrounding the portion of the cover sheet over each blister, with a fingernail liftable tab on the portion for each blister, and with the blisters forming a plurality of compartments, said adhesively united cover sheet, guard sheet and plastic sheet having aligned score lines therein whereby that portion of the sheets containing a row of compartments may be readily broken from the remainder of the sheets containing other compartments;
- (4) a single dose of at least one medicament, comprising at least one solid dosage form, in each compartment;
- (5) a protective sleeve over the assembly of sheets; and
- (6) an overwrap of transparent sheet material.

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50 LOUIS G. MANCENE, *Primary Examiner.*