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(54) PRINTED BLISTER DEEPPFORMING FOIL

(57) The invention relates to a method for producing a pharmaceutical blister pack, preferably a pharmaceutical push-through blister pack, said pack comprising a carrier layer (1) having an upper exterior surface (5) and a lower exterior surface (7), in which carrier layer (1) a plurality of cavities (2) for receiving a pharmaceutical product (3) are formed, and a sealing layer (4), which

sealing layer (4) is bonded to the upper exterior surface (5) of the carrier layer (1) in order to seal said cavities (2), wherein the method is characterized in that it comprises at least the following steps: providing a decor layer (6) and bonding the decor layer (6) to the lower exterior surface (7) of the carrier layer (1) before the cavities (2) are formed in the carrier layer (1).

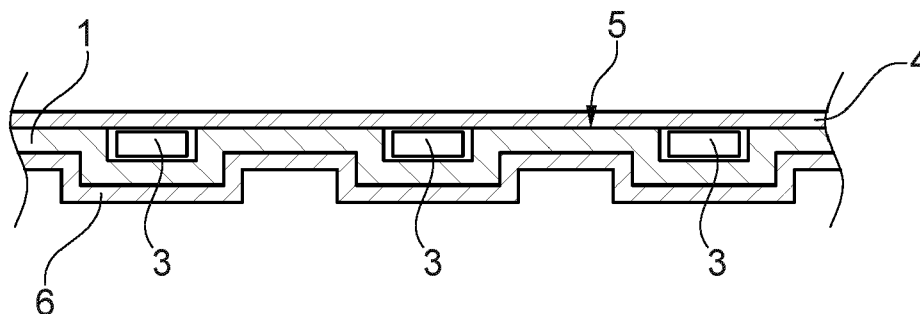


Fig. 4

Description

[0001] The present invention relates to a method for producing a pharmaceutical blister pack, preferably a pharmaceutical push-through blister pack, said pack comprising a carrier layer having an upper exterior surface and a lower exterior surface, in which carrier layer a plurality of cavities for receiving a pharmaceutical product are formed, and a sealing layer, which sealing layer is bonded to the upper exterior surface of the carrier layer in order to seal said cavities .

Prior Art

[0002] A blister pack is any of several types of pre-formed plastic packaging. The primary component of a blister pack is a cavity or pocket formed in a formable web, which web is usually made of a thermoformed plastic. The blister usually has a seal of aluminum or plastic foil. Blister packs are useful for protecting products against external factors, such as oxygen and water vapor and contamination for extended periods of time. Non-transparent blisters also protect light-sensitive products. Blister packs are usually used to package products such as medicine, foods, toys, hardware etc.

[0003] Many blister packaging machines use heat and/or pressure to form the cavity or pocket from a roll or sheet of forming foil. This is known as thermoforming or cold forming. The main advantages of (thermoformed) plastic-based blister packs are their more compact size compared to cold-formed aluminum blister packs, as well as their transparency which allows the user to see the product held in the cavities. For this reason, when it comes to pharmaceutical products, thermoformed blister packs are considered to be elderly-friendly as compared to cold-formed blister packs with regard to so-called compliance.

[0004] In medicine, patient compliance (also adherence, capacitance) describes the degree to which a patient correctly follows medical advice. Most commonly, it refers to the ability of the patient to take medications as prescribed by their physician with regards to the correct drug, dose, route, timing, and frequency. Worldwide, non-compliance is seen to be a major obstacle to the effective delivery of health care. According to the WHO, only about 50% of patients with chronic diseases living in developed countries follow treatment recommendations. Major obstacles to compliance are believed to include the complexity of modern medication regimens, the high number of different medications prescribed simultaneously, and poor health literacy.

[0005] Thus, compliance and user safety (drug safety) are particularly important issues when dealing with the packaging for pharmaceutical products (e.g. tablets or capsules). Thus, blister packs holding pharmaceutical products usually contain certain information and indications allowing the user to take his or her medicine as prescribed. Such information is usually contained in the

PIL (patient information leaflet), while some basic information is usually printed on a sealing layer of the (thermoformed) blister pack. However, by pressing out the pharmaceutical product from the blister pack, the user gradually destroys this sealing layer, thereby rendering more and more of the information printed thereon indecipherable. In addition, the information that has to be conveyed to the user must be contained on the sealing layer redundantly, i.e. multiple times, in order to avoid that this information is rendered illegible as soon as the user has pressed out the first couple of tablets from the blister pack. Thus, the individual units of printed user information contained on the sealing layer are rather small, which makes it even more difficult for users to properly read it. Also, in general the amount of information which can be printed on the sealing layer is rather small due to obvious technical reasons.

Objective of the invention

[0006] It is therefore an objective of the present invention to overcome the disadvantages described above and, in particular, to provide a blister pack for pharmaceutical products which allows for better compliance and a higher degree of safety.

[0007] Further objectives will become apparent from the description.

General discussion of the invention

[0008] One of the objectives of the present invention is achieved by a method for producing a pharmaceutical blister pack, preferably a pharmaceutical push-through blister pack, said pack comprising a carrier layer having an upper exterior surface and a lower exterior surface, in which carrier layer a plurality of cavities for receiving a pharmaceutical product are formed, and a sealing layer, which sealing layer is bonded to the upper exterior surface of the carrier layer in order to seal said cavities, wherein the method comprises at least the following steps: providing a decor layer and bonding the decor layer to the lower exterior surface of the carrier layer before the cavities are formed in the carrier layer.

[0009] In contrast to any kind of known blister packs, the blister pack obtained from the method according to the present invention makes it possible to use not only the upper exterior surface of the carrier layer to convey important information to the user (as described above), but to include such information or indications also on the lower exterior surface of the carrier layer.

[0010] Since the carrier layer - and therefore also its lower exterior surface - is deformed and becomes uneven when the cavities are (thermo)formed, printing directly on the lower exterior surface of the carrier layer is usually avoided. Such a print applied directly to the carrier layer could also lead to a risk of contamination of the pharmaceutical product which is enclosed in the cavities later on (contamination transfer could take place in the

reel of the carrier layer from the lower exterior surface of one reel layer to the upper exterior surface of the next reel layer). By employing an additional layer, i.e. the decor layer, and attaching said decor layer to the lower exterior surface of the carrier layer, it becomes possible to use (also) the lower exterior surface for displaying important information to the end user without risking contamination.

[0011] By bonding the decor layer to the lower exterior surface before the cavities have been formed, the production of the blister pack is simplified which also leads to a decrease in production costs.

[0012] Although the design of the decor layer - and with it at least some of the indications contained thereon - is altered by the subsequent forming of the cavities, this does not prevent the decor layer from being able to convey the information expressed by its design to the user. Particularly, in the case of a decor layer which is full-surface bonded to the lower exterior surface of the carrier layer, and/or in case of a decor layer which covers (substantially) the entire lower exterior surface of the carrier layer, it has been observed that the uniform and periodic distortions of the decor layer do not (substantially) impede its capability to convey the information encoded on the decor layer to the user.

[0013] Also, since the carrier layer - in contrast to the sealing layer - is not destroyed (i.e. torn) when the user presses out tablets from the blister pack, there is no need to design the decor layer in such a way that the information for the user is contained therein redundantly, i.e. multiple times. Thus, it also becomes possible to include indications, e.g. pictograms, which are sized in such a way that they cover multiple (or even a majority of the) cavities or even all cavities. This additionally increases user/drug safety and therapy compliance.

[0014] Thus, depending on the design chosen for the decor layer, it becomes possible to use (also) the lower surface of the blister pack for displaying indications, which indications are easily recognizable for the end user, and which indications are (essentially) maintained even after the user has pressed out (one, some, or even all of) the tablets contained in the cavities. The invention thus facilitates compliance and safety, especially with regard to pharmaceutical products but also foods, etc.

[0015] According to a preferred embodiment, the decor layer has a printed exterior surface which is covered, at least partially, with a print. Preferably, the decor layer has only the one printed exterior surface which is covered, at least partially, with a print, whereas an exterior surface of the decor layer opposite the printed exterior surface is not covered with a print.

[0016] Although other methods for providing the decor layer with the desired information content are conceivable (e.g. punching, embossing, etc.), printing is the preferred method. This allows for a simple and cost-efficient production method and keeps the structure of the blister pack, obtained from that method, simple. The print can be applied to the printed exterior surface in any convenient manner and using various techniques.

[0017] According to a preferred embodiment, the print comprises printed text, pictograms, and/or other printed symbols.

[0018] Whereas printed text constitutes probably the most commonly used vessel for conveying information to users, it may not always be the one suited best. In particular regarding the packaging of medications (pharmaceutical products), it has turned out that many patients appreciate a more figurative language. Many elderly patients, in particular, may experience product information, that is given on the packaging of a medication in the form of printed text, as an obstacle when trying to follow the therapy plan as close as possible. This is because this particular group of patients has problems reading small text without glasses or other visual aids. In addition, these patients usually have to deal with many different medications, each of which has to be dosed individually. Thus, printing pictograms, e.g. a heart pictogram for a medication used to treat heart conditions, on the decor layer has been found to boost compliance and drug safety, in particular with elderly patients. In addition, the use of such pictograms has been found to drastically reduce the risk of mistakes and mix-ups since the patient may easily identify the respective medication based on the pictogram. Similar effects have been observed using other simplified symbols instead of or in addition to the usual text.

[0019] According to a preferred embodiment, the print comprises signs or indications designating the kind, intended purpose, dosage, and/or other characteristics of the pharmaceutical product. It is also possible, however, that the print comprises marketing messages or marketing symbols.

[0020] The printed signs or symbols may help the patients (or users) to safely identify the kind (e.g. tablet, capsule, etc.), the purpose (e.g. treatment of heart condition, hypertension, pain treatment, etc.), the dosage (once, twice, three times a day, etc.), the time of day, or the way to take the medication (e.g. with the meal, with some water, chew or suck, etc.). In this way, compliance and drug safety may be further improved.

[0021] According to a preferred embodiment, the decor layer is bonded to the carrier layer in such a way that the printed exterior surface of the decor layer faces the carrier layer, preferably the lower exterior surface of the carrier layer.

[0022] This embodiment has multiple advantages:

[0023] Firstly, (contact) migration is prevented when the multilayer composite of carrier layer and decor layer is stored or transported on a reel, i.e. reeled up. If the decor layer would have been bonded to the carrier layer in such a way that the printed exterior surface would face away from the carrier layer, the printed exterior surface of the reeled-up multilayer composite would be in direct contact with the upper exterior surface of the carrier layer of the neighboring reel layer, which upper exterior surface later gets into direct contact with the pharmaceutical product. This would facilitate migration of migrants from the ink

onto the carrier layer (usually PVC) and later from the carrier layer to the packed pharmaceutical product. This could lead to unwanted and unaccepted contamination of the final product.

[0024] Secondly, when the printed exterior surface of the decor layer is facing the carrier layer, the print is protected from mechanical, thermal and chemical influences. This protects the print during the (thermo)forming step, i.e. during the formation of the cavities in the multilayer composite, during the sealing step, i.e. during the bonding of the sealing layer to the carrier layer holding the pharmaceutical product in its cavities, and during the intended use by the user.

[0025] Thirdly, the (optical) quality of the print is improved in this embodiment. In particular, a shiny effect can be achieved and/or improved by "sandwiching" the printed exterior surface inside the multilayer composite and there is no need for an additional layer of ink (over print varnish).

[0026] According to a preferred embodiment, a thickness of the decor layer is smaller than a thickness of the carrier layer.

[0027] This has turned out to be advantageous with regard to the (optical) quality of the decor layer, in particular of the print on the printed exterior surface, after the decor layer has been bonded to the carrier layer and the cavities have been formed. The design of the decor layer, in particular its print, appears particularly clear, even in those regions of the decor layer, where the cavities have been formed. Also, this is advantageous with regard to the haptic properties of the resulting blister pack. In addition, by bonding a (thin) additional layer, i.e. the decor layer, to the lower exterior surface of the carrier layer, permeability protection (e.g. against oxygen and water vapour) can be improved. Thus, addition functional layers, which are usually bonded to the upper exterior surface of the carrier layer in order to achieve a sufficient permeability protection, can be avoided. This further reduces production costs of the blister pack.

[0028] According to a preferred embodiment, a thickness of the carrier layer is between 50 μm and 1.000 μm , in particular between 200 μm and 300 μm , more particularly 250 μm , and/or a thickness of the decor layer is between 5 μm and 500 μm , in particular 10 μm and 70 μm , more particularly 40 μm .

[0029] This choice of thicknesses enhances the advantageous effects described above even further. Using a thickness of (around) 250 μm for the carrier layer and a thickness of (around) 40 μm for the decor layer has turned out to be particularly beneficial to the quality of the resulting blister pack. Whereas the carrier layer's thickness guarantees the desired haptic properties of the blister pack during intended use (i.e. pressing out the tablets contained in the cavities) and also a certain degree of protection against physical influences (e.g. deformation, damage), the decor layer's thickness is chosen such that the information to be conveyed to the end user can be recognized clearly over the whole ex-

tension of the decor layer.

[0030] According to a preferred embodiment, the decor layer is made of an optically transparent material.

[0031] This further increases the compliance and safety for the resulting blister pack, since it enables the user, in particular the elderly user, to actually see the pharmaceutical product contained in the cavities (at least their outlines), which facilitates the correct identification of the desired drug by the user. In addition, it enables the printed exterior surface to face the lower exterior surface of the carrier layer when bonding the decor layer to the carrier layer, which has many advantages (as described above).

[0032] In general, the carrier layer can be made of all types of deep-forming foils, including coldforming foil, or its components e.g. PVC, PVDC, PE, Aclar® (Honeywell), PA, Aluminium, PP and PET including all laminates and combinations (also extruded materials) with this materials in different thicknesses and including all possible coatings, e.g. with AL₂O₃, SiO₂, EVOH. According to a preferred embodiment, however, the carrier layer is realized as a PVC foil.

[0033] Using a carrier layer consisting of (or comprising) PVC (polyvinyl chloride) leads to reduced production costs and facilitates the formation of the cavities in the carrier layer. Additionally, using a carrier layer made of (or comprising) PVC facilitates the bonding of additional functional layers to the carrier layer, e.g. functional layers such as PVDC or Aclar® layers for improved permeability protection.

[0034] In general, the decor layer can be made of several crude oil based, cellulose based and Polyactide based films, such as: cPA, PET GAG, cPP, OPS and other materials. According to a preferred embodiment, however, the decor layer is realized as a cast PA foil.

[0035] Extensive testing has shown that such a decor layer is very well suited for being printed and subsequently bonded to another layer, i.e. the carrier layer, to form a multilayer composite, which multilayer composite later on is subjected to a cold forming or thermoforming process. This preferred embodiment thus has the advantage, that the resulting blister pack exhibits a high stability with regard to the bond between the decor layer and the carrier layer, as well as a particularly high quality of information/indications conveyed to the user by the decor layer

[0036] According to a preferred embodiment, an amount of ink transferred to the decor layer when applying the print to the printed exterior surface is a function of a cavity depth of the cavities, which cavities are to be formed in the carrier layer. Preferably, the amount of transferred ink increases with cavity depth.

[0037] By taking into consideration the depth, form or size of the cavities which are to be formed in the carrier layer, when printing on the decor layer, the quality of the print can be kept constant for various blister packs. In particular, it becomes possible that indications printed on the decor layer appear in the same quality for various

cavity forms and sizes. This allows to produce different blister packs with a uniform appearance.

[0038] According to a preferred embodiment, the decor layer is bonded to the lower exterior surface by means of lamination using an adhesive.

[0039] This embodiment provides for a particularly simple method of bonding the two layers (carrier and decor) together; surprisingly, this bonding method does not impair the (optical) quality of the final blister pack, in particular when the decor layer is bonded to the carrier layer with its printed exterior surface facing the carrier layer.

[0040] According to a preferred embodiment, the adhesive is a two-component solvent-based adhesive, preferably with isocyanate as a first component and polyol as a second component.

[0041] Such adhesives give superb bond strength and are particularly well suited for bonding a thick layer (carrier layer) and a thin layer (decor layer). In addition, whereas other adhesives are rigid and can crack during deep drawing, this adhesive is well suited for thermoforming, or deep drawing applications.

[0042] According to a preferred embodiment, a gram-mage of adhesive per square meter used in the lamination process is between 0,5 g/m² and 20 g/m², in particular between 3 g/m² and 5 g/m², more particularly between 3,5 g/m² and 4,5 g/m².

[0043] This embodiment achieves a sufficiently strong bond between the decor layer and the carrier layer, without impairing the optical quality of the decor layer on the final blister pack.

[0044] According to a preferred embodiment, after bonding the decor layer to the carrier layer, the obtained layer bonding (multilayer composite) is subjected to a curing process before further processing steps, in particular slitting steps, are performed. Preferably, a curing time of this curing process is at least 5 days. Preferably, during the curing process, the layer bonding is exposed to an ambient air temperature between 15 °C and 25 °C (at normal pressure).

[0045] This curing step further increases the quality of the final product, i.e. the blister pack obtained from the method.

[0046] It is, however, conceivable that the curing process may also be shorter than 5 days or omitted entirely.

[0047] An objective of the present invention is achieved by a method for producing a pharmaceutical blister pack, preferably a pharmaceutical push-through blister pack, said pack comprising a multi-purpose layer made of aluminum having an upper exterior surface and a lower exterior surface, in which multi-purpose layer a plurality of cavities for receiving a pharmaceutical product are formed, and a sealing layer made of aluminum, which sealing layer is bonded to the upper exterior surface of the carrier layer in order to seal said cavities, wherein a print is applied to the lower exterior surface of the multi-purpose layer before the cavities are formed in the multi-purpose layer.

[0048] This makes it possible to achieve the above-mentioned advantages with respect to compliance and safety also in cases where the blister pack may not comprise any plastic materials, i.e. in case of blister packs made only of aluminum. This is particularly advantageous with respect to recyclability of the blister pack.

Brief description of the figures

[0049] Preferred exemplary embodiments of the invention will be discussed below in greater detail. However, the following statements are intended neither to limit nor to conclusively reflect the idea of the invention.

Fig. 1 shows a first step of the production method according to the invention;

Fig. 2 shows a second step of the production method according to the invention;

Fig. 3 shows a third step of the production method according to the invention;

Fig. 4 shows a fourth step of the production method according to the invention.

Ways of carrying out the invention

[0050] The method for producing a pharmaceutical blister pack according to the present invention is illustrated in Fig. 1-4. According to the shown embodiment, the method comprises the following steps:

[0051] As shown in Fig. 1, a (sheet-like) decor layer 6 is provided, preferably (reeled-up) on a reel (not depicted). Said decor layer 6 is made of transparent material and has a printed exterior surface 8 carrying a print. The form of the print is chosen in accordance with the producer of a pharmaceutical product 3 which is to be packed in the blister pack. In particular, the print may contain or represent signs or indications designating the kind, intended purpose, dosage, and/or other characteristics of the pharmaceutical product 3, aimed at improving compliance and drug safety.

[0052] As shown in Fig. 2, in a next step of the method the decor layer 6 is bonded to a carrier layer 1, such that the printed exterior surface 8 of the decor layer 6 faces (and/or contacts) a lower exterior surface 7 of said carrier layer 1. The lower exterior surface 7 is the surface of the (sheet-like) carrier layer 1 which is opposite of an upper exterior surface 5 of the carrier layer 1. The main purpose of said upper exterior surface 5 is to facilitate the sealing (Fig. 4) of the pharmaceutical product 3 inside cavities 2 of the blister pack (which cavities have not yet been created in Fig. 2). By bonding the two layers (carrier layer 1 and decor layer 6 together), a laminated structure (or multilayer composite or layer bonding) is obtained. The carrier layer 1 may also be provided on a reel (reeled-up) and the lamination process may thus be a reel-to-reel process, such that the resulting laminated structure is also reeled-up on a reel.

[0053] As shown in Fig. 3, in a next step of the method the cavities 2 are created. To this end, the laminated structure is subjected, e.g. directly from the reel, to any kind of forming procedure, e.g. thermoforming or cold forming (or cold working). By forming the laminated structure as desired, the cavities 2 are established in the carrier layer 1. However, due to the forming procedure, not only the carrier layer 1 but, as can be seen in Fig. 3, also the decor layer 6, which is bonded to (the lower exterior surface 7 of) the carrier layer 1, is given a form resembling the form of the cavities 2. Thus, a laminated and formed structure is obtained.

[0054] As shown in Fig. 4, the next steps of the method include positioning the pharmaceutical product 3 (here: tablets) in the cavities 2 and sealing said cavities 2 by bonding a sealing layer 4 to the upper exterior surface 5 of the carrier layer 1. It should be noted that the sealing layer 4 is bonded to the upper exterior surface 5 in such a way that the sealing layer 4 is in (flat) contact with the upper exterior surface 5 in those regions of the carrier layer 1 surrounding the cavities 2. A backside of the sealing layer 4, which is typically made of aluminum foil, may also carry a print.

[0055] It is typically after this step has been performed that the obtained laminated and formed structure, which is filled with pharmaceutical product and sealed, is cut into single blisters.

[0056] As a result, a blister pack is obtained which - in contrast to known blister packs - may provide the user (patient) with user information not only by means of the printed sealing layer 4, which sealing layer 4 is gradually destroyed when the user presses out tablets from the blister pack, but also by means of the decor layer 6. Thus, information can be conveyed to the user through text and/or symbols, which have been printed onto the decor layer 6, and can be readily recognized by the user when viewing the lower exterior surface of the blister pack.

[0057] A first exemplary embodiment of the production method according to the present invention can be carried out as follows:

[0058] The materials for the decor layer (cast PA) and the carrier layer (PVC) are provided in reels. For the designs which are requested by the customer (e.g. pharmaceutical producer) to be applied to the lower exterior surface of the carrier layer, pre-press, color separation, and, for every color, printing tool production steps are performed (cylinder for rotogravure and cliché for flexo printing). One printing tool is produced for each color.

[0059] Subsequently, the reels holding the material for the decor layer are reverse printed continuously (rotary technique) from reel to reel. The printing ink used in this printing process is the VB 25 printing ink series from the company Siegwirk Druckfarben AG & Co. KGaA. The amount of ink which is transferred to the material for the decor layer depends on the characteristics of the deep-forming step to be performed later on at the blistering line.

[0060] After the printing process has been completed, i.e. after the material for the decor layer has been printed

in accordance with the customer's specifications, the material for the decor layer is laminated with the material for the carrier layer using a laminating machine. The reeled-up material for the decor layer is glued to the reeled-up material for the carrier layer by a two-component solvent-based adhesive, Liofol LA 3966-21 and LA 6074-21 in a mixing ratio of 13:1 from the company Henkel (Henkel Central Eastern Europe Gesellschaft mbH), thereby obtaining one reel of laminated structure (multilayer composite or layer bonding).

[0061] On the printed external surface of the reeled-up decor layer material, a predefined quantity of adhesive is applied (2,5 - 4,5 g/sqm dry, equivalent approx. 5 - 9 g/sqm wet). This is done continuously using an engraved cylinder that transfers adhesive to the reeled-up decor layer material. After applying the adhesive, the reeled-up decor layer material is passed through a drying tunnel where solvents are evaporated. Subsequently, the reeled-up decor layer material is fed to a calender (a series of laminating rollers, two very close rollers where one is made of rubber and the other one is made of metal, with thermal regulation and regulation of pressure). In the calender, pressure (approx. 2 - 4 bar) and temperature (approx. 50 - 90 °C) is applied to the reeled-up decor layer material and to the reeled-up carrier layer material, thereby joining them together. The resulting laminated structure is then reeled-up for further processing (laminated reel).

[0062] The laminated reel is subsequently dispersed (hanging in the air) and left for adhesive curing for a minimum of 5 days at temperature 18 - 25 °C (at normal pressure).

[0063] Thereafter, the laminated reel is slit to final dimensions, packed, and delivered to the customer to be used on dedicated packaging machines. It is the customer who, in most cases, will perform the remaining steps of forming the cavities in the multilayer composite (e.g. by thermoforming or by cold forming), by placing the respective pharmaceutical product in those cavities, and by finally sealing the cavities by bonding the sealing layer to the upper exterior surface of the carrier layer.

[0064] A second exemplary embodiment of the production method according to the present invention can be carried out as follows:

[0065] The printing material (multi-purpose layer, aluminium foil with a thickness of approx. 70 µm) is provided on reels. For the designs which are requested by the customer (e.g. pharmaceutical producer) to be applied to the lower exterior surface of the multi-purpose layer, pre-press, color separation, and, for every color, printing tool production steps are performed (cylinder for rotogravure and cliché for flexo printing). One printing tool is produced for each color.

[0066] The reels of printing materials (multi-purpose layer) are subsequently direct printed continuously (using the rotary technique) from reel to reel. In the printing process, the NC 220 - 8 printing ink series from company Siegwirk is used. Print is protected with 100%

coverage over print varnish NC 610 also from company Siegwark.

[0067] After that, the the reeled-up printed multi-purpose layer is slit on final dimensions, packed, and delivered to customer to be used on dedicated packaging machines. It is the pharmaceutical producer who, in most cases, will perform the remaining steps of forming the cavities in the multi-purpose layer (e.g. by cold forming), by placing the respective pharmaceutical product in those cavities, and by finally sealing the cavities by bonding the sealing layer to the upper exterior surface of the multi-purpose layer layer.

Claims

1. Method for producing a pharmaceutical blister pack, preferably a pharmaceutical push-through blister pack, said pack comprising

- a carrier layer (1) having an upper exterior surface (5) and a lower exterior surface (7), in which carrier layer (1) a plurality of cavities (2) for receiving a pharmaceutical product (3) are formed, and
- a sealing layer (4), which sealing layer (4) is bonded to the upper exterior surface (5) of the carrier layer (1) in order to seal said cavities (2),

wherein the method is **characterized in that** it comprises at least the following steps:

- providing a decor layer (6) and
- bonding the decor layer (6) to the lower exterior surface (7) of the carrier layer (1) before the cavities (2) are formed in the carrier layer (1).

2. Method according to claim 1, **characterized in that** the decor layer (6) has a printed exterior surface (8) which is covered, at least partially, with a print.
3. Method according to claim 2, **characterized in that** the print comprises printed text, pictograms, and/or other printed symbols.
4. Method according to claim 2 or 3, **characterized in that** the print comprises signs or indications designating the kind, intended purpose, dosage, and/or other characteristics of the pharmaceutical product (3).
5. Method according to any of the claims 2 to 4, **characterized in that** the decor layer (6) is bonded to the carrier layer (1) in such a way that the printed exterior surface (8) of the decor layer (6) faces the carrier layer (1), preferably the lower exterior surface (7) of the carrier layer (1).

6. Method according to any of the claims 1 to 5, **characterized in that** a thickness of the carrier layer (1) is between 50 μm and 1.000 μm , in particular between 200 μm and 300 μm , more particularly 250 μm , and/or a thickness of the decor layer (6) is between 5 μm and 500 μm , in particular 10 μm and 70 μm , more particularly 40 μm .

7. Method according to any of the claims 1 to 6, **characterized in that** the decor layer (6) is made of an optically transparent material.

8. Method according to any of the claims 2 to 7, **characterized in that** an amount of ink transferred to the decor layer (6) when applying the print to the printed exterior surface (8) is a function of a cavity depth (9) of the cavities (2), which cavities (2) are to be formed in the carrier layer (1).

9. Method according to any of the claims 1 to 8, **characterized in that** the decor layer (6) is bonded to the lower exterior surface (7) by means of lamination using an adhesive.

10. Method according to claim 9, **characterized in that** the adhesive is a two-component solvent-based adhesive, preferably with isocyanate as a first component and polyol as a second component.

11. Method according to claim 9 or 10, **characterized in that** a grammage of adhesive per square meter used in the lamination process is between 0,5 g/m² and 20 g/m², in particular between 3 g/m² and 5 g/m², more particularly between 3,5 g/m² and 4,5 g/m².

12. Method according to any of the claims 1 to 11, **characterized in that** after bonding the decor layer (6) to the carrier layer (1), the obtained layer bonding is subjected to a curing process before further processing steps, in particular slitting steps, are performed.

13. Method according to claim 12, **characterized in that** a curing time is at least 5 days.

14. Method according to claim 12 or 13, **characterized in that**, during the curing process, the layer bonding is exposed to an ambient air temperature between 15 °C and 25 °C.

15. Method for producing a pharmaceutical blister pack, preferably a pharmaceutical push-through blister pack, said pack comprising

- a multi-purpose layer made of aluminum having an upper exterior surface and a lower exterior surface, in which multi-purpose layer a plurality of cavities for receiving a pharmaceu-

tical product are formed, and

- a sealing layer, which sealing layer is bonded to the upper exterior surface of the carrier layer in order to seal said cavities,

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wherein the method is **characterized in that** it comprises at least the following steps:

- applying a print to the lower exterior surface of the multi-purpose layer before the cavities are formed in the multi-purpose layer.

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Amended claims in accordance with Rule 137(2) EPC.

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1. Method for producing a pharmaceutical blister pack, preferably a pharmaceutical push-through blister pack, said pack comprising

- a carrier layer (1) having an upper exterior surface (5) and a lower exterior surface (7), in which carrier layer (1) a plurality of cavities (2) for receiving a pharmaceutical product (3) are thermoformed, and
- a sealing layer (4), which sealing layer (4) is bonded to the upper exterior surface (5) of the carrier layer (1) in order to seal said cavities (2),

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wherein the method is **characterized in that** it comprises at least the following steps:

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- providing a decor layer (6) with a printed exterior surface (8) which is covered, at least partially, with a print and
- bonding the decor layer (6) to the lower exterior surface (7) of the carrier layer (1) before the cavities (2) are thermoformed in the carrier layer (1).

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2. Method according to claim 1, **characterized in that** the print comprises printed text, pictograms, and/or other printed symbols.

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3. Method according to claim 1 or 2, **characterized in that** the print comprises signs or indications designating the kind, intended purpose, dosage, and/or other characteristics of the pharmaceutical product (3).

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4. Method according to any of the claims 1 to 3, **characterized in that** the decor layer (6) is bonded to the carrier layer (1) in such a way that the printed exterior surface (8) of the decor layer (6) faces the carrier layer (1), preferably the lower exterior surface (7) of the carrier layer (1).

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5. Method according to any of the claims 1 to 4, **characterized in that** a thickness of the carrier layer

(1) is between 50 μm and 1.000 μm , in particular between 200 μm and 300 μm , more particularly 250 μm , and/or a thickness of the decor layer (6) is between 5 μm and 500 μm , in particular 10 μm and 70 μm , more particularly 40 μm .

6. Method according to any of the claims 1 to 5, **characterized in that** the decor layer (6) is made of an optically transparent material.

7. Method according to any of the claims 1 to 6, **characterized in that** an amount of ink transferred to the decor layer (6) when applying the print to the printed exterior surface (8) is a function of a cavity depth (9) of the cavities (2), which cavities (2) are to be formed in the carrier layer (1).

8. Method according to any of the claims 1 to 7, **characterized in that** the decor layer (6) is bonded to the lower exterior surface (7) by means of lamination using an adhesive.

9. Method according to claim 8, **characterized in that** the adhesive is a two-component solvent-based adhesive, preferably with isocyanate as a first component and polyol as a second component.

10. Method according to claim 8 or 9, **characterized in that** a grammage of adhesive per square meter used in the lamination process is between 0,5 g/m² and 20 g/m², in particular between 3 g/m² and 5 g/m², more particularly between 3,5 g/m² and 4,5 g/m².

11. Method according to any of the claims 1 to 10, **characterized in that** after bonding the decor layer (6) to the carrier layer (1), the obtained layer bonding is subjected to a curing process before further processing steps, in particular slitting steps, are performed.

12. Method according to claim 11, **characterized in that** a curing time is at least 5 days.

13. Method according to claim 11 or 12, **characterized in that**, during the curing process, the layer bonding is exposed to an ambient air temperature between 15 °C and 25 °C.

14. Method for producing a pharmaceutical blister pack, preferably a pharmaceutical push-through blister pack, said pack comprising

- a multi-purpose layer made of aluminum having an upper exterior surface and a lower exterior surface, in which multi-purpose layer a plurality of cavities for receiving a pharmaceutical product are formed, and
- a sealing layer, which sealing layer is bonded to

the upper exterior surface of the carrier layer in order to seal said cavities,

wherein the method is **characterized in that** it comprises at least the following steps:

- applying a print to the lower exterior surface of the multi-purpose layer before the cavities are formed in the multi-purpose layer.

1. Method for producing a pharmaceutical blister pack, preferably a pharmaceutical push-through blister pack, said pack comprising

- a carrier layer (1) having an upper exterior surface (5) and a lower exterior surface (7), in which carrier layer (1) a plurality of cavities (2) for receiving a pharmaceutical product (3) are formed, and
- a sealing layer (4), which sealing layer (4) is bonded to the upper exterior surface (5) of the carrier layer (1) in order to seal said cavities (2), wherein the method is **characterized in that** it comprises at least the following steps:

- providing a decor layer (6) with a printed exterior surface (8) which is covered, at least partially, with a print and
- bonding the decor layer (6) to the lower exterior surface (7) of the carrier layer (1) before the cavities (2) are formed in the carrier layer (1),

wherein an amount of ink transferred to the decor layer (6) when applying the print to the printed exterior surface (8) is a function of a cavity depth (9) of the cavities (2), which cavities (2) are to be formed in the carrier layer (1), wherein the amount of transferred ink increases with cavity depth.

2. Method according to claim 1, **characterized in that** the print comprises printed text, pictograms, and/or other printed symbols.

3. Method according to claim 1 or 2, **characterized in that** the print comprises signs or indications designating the kind, intended purpose, dosage, and/or other characteristics of the pharmaceutical product (3).

4. Method according to any of the claims 1 to 3, **characterized in that** the decor layer (6) is bonded to the carrier layer (1) in such a way that the printed exterior surface (8) of the decor layer (6) faces the carrier layer (1), preferably the lower exterior surface (7) of the carrier layer (1).

5. Method according to any of the claims 1 to 4, **characterized in that** a thickness of the carrier layer (1) is between 50 μm and 1.000 μm , in particular between 200 μm and 300 μm , more particularly 250 μm , and/or a thickness of the decor layer (6) is between 5 μm and 500 μm , in particular 10 μm and 70 μm , more particularly 40 μm .

6. Method according to any of the claims 1 to 5, **characterized in that** the decor layer (6) is made of an optically transparent material.

7. Method according to any of the claims 1 to 6, **characterized in that** the decor layer (6) is bonded to the lower exterior surface (7) by means of lamination using an adhesive.

8. Method according to claim 7, **characterized in that** the adhesive is a two-component solvent-based adhesive, preferably with isocyanate as a first component and polyol as a second component.

9. Method according to claim 7 or 8, **characterized in that** a grammage of adhesive per square meter used in the lamination process is between 0,5 g/m² and 20 g/m², in particular between 3 g/m² and 5 g/m², more particularly between 3,5 g/m² and 4,5 g/m².

10. Method according to any of the claims 1 to 9, **characterized in that** after bonding the decor layer (6) to the carrier layer (1), the obtained layer bonding is subjected to a curing process before further processing steps, in particular slitting steps, are performed.

11. Method according to claim 10, **characterized in that** a curing time is at least 5 days.

12. Method according to claim 10 or 11, **characterized in that**, during the curing process, the layer bonding is exposed to an ambient air temperature between 15 °C and 25 °C.

13. Method for producing a pharmaceutical blister pack, preferably a pharmaceutical push-through blister pack, said pack comprising

- a multi-purpose layer made of aluminum having an upper exterior surface and a lower exterior surface, in which multi-purpose layer a plurality of cavities for receiving a pharmaceutical product are formed, and
- a sealing layer, which sealing layer is bonded to the upper exterior surface of the carrier layer in order to seal said cavities,

wherein the method is **characterized in that** it comprises at least the following steps:

- applying a print to the lower exterior surface of the multi-purpose layer before the cavities are formed in the multi-purpose layer.

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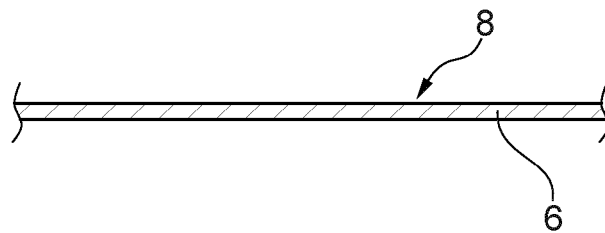


Fig. 1

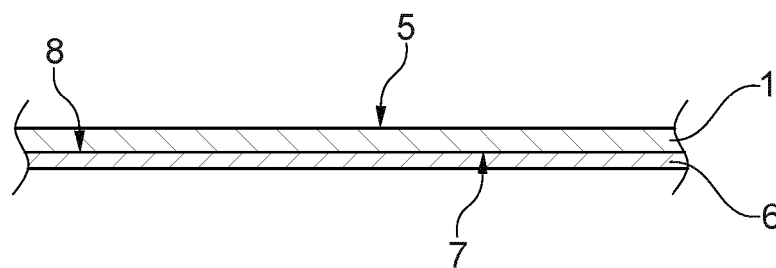


Fig. 2

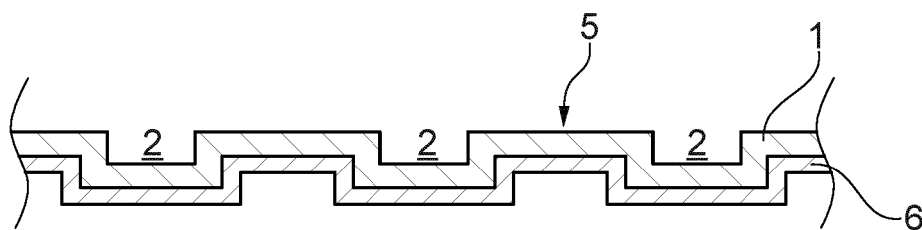


Fig. 3

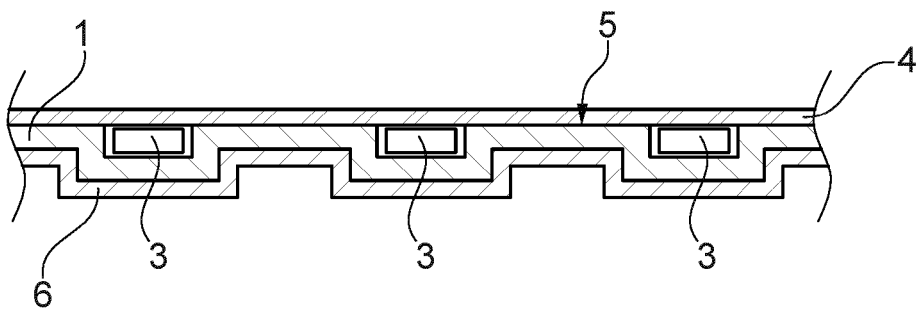


Fig. 4



EUROPEAN SEARCH REPORT

Application Number

EP 23 21 1604

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The present search report has been drawn up for all claims			
Place of search		Date of completion of the search	Examiner
The Hague		22 April 2024	Kroeders, Marleen
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document			
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