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(54) **A PHARMACEUTICAL PRODUCT COMPRISING A CONTAINER COMPRISING A PHARMACEUTICAL COMPOUND AND A LABEL HAVING LOWER MIGRATION OF LEACHABLES**

(57) It has now surprisingly found out that above-mentioned problem can be achieved by a pharmaceutical product, wherein the pharmaceutical product comprises a container comprising a pharmaceutical compound and/or a medical device suitable for receiving the pharmaceutical compound from the container, an enclosure en-

closing the container and/or the medical device, and a label comprised by the enclosure, wherein the enclosure comprises at least one wall enclosing a main cavity, wherein the main cavity is a closed cavity, wherein the cavity comprises the container and/or the medical device.

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Description

Technical Field of the Invention

[0001] The present invention is related to packaging and labelling pharmaceutical products, in particular packaging and labelling container comprising pharmaceutical compounds and/or medical devices. The present invention is further related to the use of such pharmaceutical products.

Background of the Invention

[0002] Pharmaceutical products typically consist of a pharmaceutical compound, preferably an active pharmaceutical ingredient (API), in a suitable dosage form, such as tablets, capsules, solutions, or suspensions. These products must be carefully stored and transported to maintain the integrity and efficacy of the pharmaceutical compound. To achieve this, the pharmaceutical compound is usually contained in a primary container, such as bags, vials, syringes, ampoules, blister packs, or bottles, depending on the dosage form and administration route.

[0003] The primary container serves to protect the pharmaceutical compound from environmental factors such as moisture, light, and air, which could lead to degradation of the pharmaceutical compound. In addition to the primary container, pharmaceutical products are also typically enclosed in a secondary packaging. This secondary packaging serves both a protective and regulatory function, as it provides additional layers of protection during shipping and handling, while also ensuring compliance with regulatory standards. It is usually a plastic wrapping.

[0004] In certain cases, the pharmaceutical product may also comprise a medical device that facilitates administration of the compound. For example, (prefilled) syringes, auto-injectors, or inhalers are common devices used for administering specific pharmaceutical compounds. These medical devices are often co-packaged with the pharmaceutical product or integrated into the primary container to ensure proper and efficient delivery of the pharmaceutical compound to the patient.

[0005] To provide important data about the pharmaceutical product, the primary container needs to have either a printed label attached to the primary container, or a screen directly printed onto the primary container. Sometimes the secondary packaging also comprises a label or screen with the same or additional information as the primary container. Generally, labels are an integral part of the pharmaceutical product packaging, and they must comply with regulatory requirements, providing clear and accurate information about the product. Labels may include details such as the name of the pharmaceutical compound, the dosage form, instructions for use, storage conditions, expiration date, and other essential information.

[0006] Labels comprise many different materials. Generally, a label comprises a substrate material, is printed with an ink, optionally comprises an adhesive and eventually a liner. These materials are prone for leaching chemical ingredients, such as volatiles, semi-volatiles, as well as non-volatile compounds, of various nature during the sterilization step, wherein the pharmaceutical product typically is exposed to elevated temperatures, or during shelf-life. Such leaching affects the stability and the quality of the packaged pharmaceutical compound.

[0007] As set out above, the label of a pharmaceutical product comprises important information. For example, in pharmaceutical application, different products and/or applications are color coded to reduce errors in the hospital. (cf. "Qualitätssicherung Intensiv-/Notfallmedizin: Spritzenetiketten (divi.de)").

Summary of the Invention

[0008] The need to reduce leachables and the need for intuitive, visible color-coded labels are incompatible. The colored label is therefore only provided on the secondary packaging, while on the primary container only monochrome font is provided.

[0009] As not all pharmaceutical compounds can be administered directly to a patient, the clinical staff often needs to prepare the administration by transferring the pharmaceutical compound into a medical device like a syringe or another container. As clinical staff is under time pressure a lot, not or uncolored labeled syringes/containers are posing a significant, untraceable thread for the patient.

[0010] It is therefore an object of the present invention to provide a pharmaceutical product with a higher stability during sterilization and longer lifetime during shelf-life, which does not endanger the patient.

[0011] It has now surprisingly found out that above-mentioned problem can be achieved by a pharmaceutical product, wherein the pharmaceutical product comprises

- a container comprising a pharmaceutical compound and/or a medical device suitable for receiving the pharmaceutical compound from the container,
 - an enclosure enclosing the container and/or the medical device, and
 - a label comprised by the enclosure,
- wherein the enclosure comprises at least one wall enclosing a main cavity,
- wherein the main cavity is a closed cavity,
- wherein the cavity comprises the container and/or the medical device.

[0012] It has been further surprisingly found that

above-mentioned object can be achieved by the use of a pharmaceutical product according to the present invention for sterile storing the pharmaceutical compound the use of a pharmaceutical product according to the present invention for filling the pharmaceutical compound into a medical device.

[0013] The advantage of the present invention is that the risk of degradation of the pharmaceutical compound by extractables or leachables is reduced and the danger of mislabeled transfer devices by providing the clinical staff with an additional, colored flexibly attachable label is further enhanced.

Definitions

[0014] The term '*polymer*' as used herein denotes an organic polymer, preferably a polymer selected from polyolefins, polyethylene terephthalate, polystyrene, polyvinyl chloride, or mixtures thereof, more preferably a polyolefin selected from the list consisting of polyethylene, polypropylene, or mixtures thereof.

[0015] The term '*liquid-tight*' as used herein denotes a quality of an object to function as a barrier for a liquid, preferably for a water-based liquid.

[0016] The term '*barrier layer*' as used herein denotes a material, which can slow down the process of oxygen permeation. Preferably, it comprises, more preferably consists of, a based barrier material, most preferably ethylene-vinyl alcohol (EVOH), or a metal oxide material, most preferably a silicon oxide layer or an aluminum oxide layer. Such barrier layer can require a supporting or binding layer to adhere thereto. Metal oxide-based layers can be deposited directly onto the polymer material (e.g., by chemical vapor deposition).

[0017] The term '*heat sealing*' as used herein denotes thermal welding of polymer films. In this process, at least two polymer films are heated until at least the glass transition temperature is reached and the plastics in these areas begin to become liquid or at least low viscous. By simultaneous or subsequent mechanical pressing of these areas, the polymers are mixed together at this point and, after cooling and solidification, form a fixed joint called a seam.

[0018] The term '*active pharmaceutical ingredient (API)*' as used herein denotes a substance preferably provided in a pharmaceutical product that is biologically active and responsible for producing intended therapeutic effects. APIs are the key ingredients in medications that treat, diagnose, or prevent diseases. For example, in a pain relief medication like ibuprofen, ibuprofen itself is the API, while other components in the formulation (excipients) may help with the drug's stability, absorption, or delivery. APIs can be small molecules or large molecules such as proteins or antibodies.

[0019] The term '*additive*' as used herein denotes further components, which can be present in polymer compositions to modify their physical properties. Examples of additives are antioxidant(s), stabilizer(s), such as

process stabilizers and UV stabilizers, acid scavenger(s), metal deactivators, crosslinking agents, such as free radical generating agent(s), e.g., organic peroxide(s), scorch retarder(s), crosslinking booster(s), processing aid(s), flame retardant additive(s), water tree retardant additive(s), inorganic filler(s), and voltage stabilizer(s). These groups of additives and the individual additive compounds therein are usually well known in the polymer field.

[0020] The term '*sterile*' as used denotes the status of an object having a significantly reduced number of bacteria and/or viruses on its surface to reduce the risk of an infection. In particular, the term '*sterile*' denotes an object or substance, which has a bioburden load of lower than 10^{-6} . The bioburden load can be measured i.e., according to ISO 11737-1:2018.

[0021] The term '*sterilization*' as used herein denotes a method to destroy all forms of living microorganisms from a substance. As there is always a certain probability of at least one microorganism to survive such procedure, the aim of sterilization is the reduction of initially present microorganisms or other potential pathogens. Generally, sterilization is accepted to be achieved if the bioburden load of the substance of object to be sterilized is lower than 10^{-6} . The bioburden load can be measured i.e., according to ISO 11737-1:2018. Sterilization can be achieved using several methods. In one sterilization process the object is heated up to at least 105 °C to achieve a sterile object. Thereby, the object should not be deformed by the elevated temperature. Preferably, the heating step is performed in an autoclave. In another sterilization process, the object is brought into contact with toxic gases such as a mixture of ethylene oxide and carbon dioxide. Filtration methods are also used to sterilize liquids, i.e., by using membrane filters, Seitz filters, and/or candle filters. Finally, sterilization can be achieved by indirect energy import into or onto the object, e.g., by ultrasonic waves, ultraviolet light, as well as by high energy particles (such as electrons, gamma- or X-rays).

[0022] The term '*seam*' as used herein denotes an area of at least two connected walls including at least one edge of each wall of an enclosure, preferably bag, at which the two walls are connected, i.e., by gluing or sealing, thereby forming a seam area, a seam edge, and an inner boundary of the edge.

[0023] The term '*oxygen depleted gas*' denotes a gas, which has a lower concentration of oxygen than air, preferably no or only trace amounts of oxygen. Hence, preferably, the oxygen depleted gas comprises, preferably consists of, a gas selected from nitrogen, carbon dioxide, a noble gas, or mixtures thereof. Most preferably, the oxygen depleted gas comprises, preferably consists of, nitrogen.

[0024] The term '*secondary headspace*' as used herein denote the volume between an object packaged by an enclosure and the enclosure itself. It is called secondary headspace, as the object often is a container comprising a compound, preferably a liquid compound, and another

headspace fill with gas, which is usually denoted as primary headspace. Preferably, the secondary headspace is filled with an oxygen depleted gas and/or a water depleted gas.

[0025] The term '*colored ink*' as used herein denotes an ink, which has a color different from black, preferably visually clearly distinct from black. The difference from black can be quantified using the CIELAB color space $L^*a^*b^*$, wherein L^* represents lightness (0 is black and 100 is white), a^* represents the position of the color on the green-red axis (negative values are green, positive values are red), and b^* represents the position of the color on the blue-yellow axis (negative values are blue, positive values are yellow). Black ink typically has an L^* value close to 0 and a^* and b^* values close to 0, indicating minimal color (nearly neutral in both axes). Colored inks on the other hand have non-zero a^* and/or b^* values, which indicate the presence of specific colors (red, green, blue, or yellow tones). Measurements are usually conducted using spectrometers or colorimeters.

Detailed description of the Invention

[0026] As set out above, the present invention is related to a pharmaceutical product and the use thereof, both of which will be described in the following.

Pharmaceutical product

[0027] The most general embodiment of the present invention relates to a pharmaceutical product, wherein the pharmaceutical product comprises

- a container comprising a pharmaceutical compound and/or a medical device suitable for receiving the pharmaceutical compound from the container,
- an enclosure enclosing the container and/or the medical device, and
- a label comprised by the enclosure,

wherein the enclosure comprises at least one wall enclosing a main cavity,

wherein the main cavity is a closed cavity,

wherein the cavity comprises the container and/or the medical device.

[0028] The containers comprised by the pharmaceutical product of the present invention are preferably selected from prefilled syringes, blister packs, vials, bottles, sachets, ampoules, tubes, cartridges and pens, and inhalers. Blister packs are usually used for tablets and capsules, offering individual protection. Vials are usually glass or plastic containers for injectable medications, often sealed with rubber stoppers. Bottles are usually

plastic or glass bottles for liquids, syrups, or pills. Sachets are usually single-dose packets for powders, granules, or gels. Ampoules are usually small, sealed glass containers for single-dose liquid medications. Tubes are usually used for ointments, creams, and gels. Cartridges and pens are usually used for injectables such as insulin in reusable delivery systems. Inhalers are devices for delivering respiratory medications. Preferably, the containers comprised by the pharmaceutical product of the present invention are containers suitable for comprising a liquid. Hence, preferably, the container comprised in the pharmaceutical product of the present invention is selected from the list consisting of vials, bottles, and ampoules.

[0029] The pharmaceutical compound as comprised in the container comprised in the pharmaceutical product of the present invention can be selected from a solid or a liquid compound. If the pharmaceutical compound is a solid compound, it is preferably a pulverized solid compound. Preferably, the pharmaceutical compound is present in liquid form, preferably in solution, more preferably in aqueous solution.

[0030] The pharmaceutical compound can be a compound as usually used in pharmaceutical applications, e.g. sodium chloride. However, more specifically, the pharmaceutical compound could also be an active pharmaceutical ingredient, preferably an active pharmaceutical ingredient in solution. It should be understood that in specific cases, the active pharmaceutical ingredient is sensitive to specific environmental impacts, i.e. UV or VIS radiation, oxygen, or water.

[0031] The enclosure of the pharmaceutical product of the present invention is preferably selected from the list consisting of an overwrap, a pouch, a flow-wrap, and rigid or semirigid blisters. Hence, preferably, the wall of the enclosure of the pharmaceutical product of the present invention comprises, preferably consists of, at least one polymer film, preferably a flexible, thermoformable, and/or thermoformed polymer film.

[0032] Usually, overwraps are formed by wrapping the polymer film around the product and heat sealing it at its edges. Overwraps might also be formed by more than one polymer film. A flow-wrap is similar to an overwrap but can be produced in continuous mode. Blisters are usually formed by thermoforming a plastic cavity from a thermoformable polymer film and covering the plastic cavity with a flexible polymer film.

[0033] Preferably, the at least one wall comprises, preferably consists of, at least one polymer film comprising a polymer, preferably a flexible, thermoformable, and/or thermoformed polymer film, more preferably is a flexible polymer film. More preferably, the at least one polymer film is a weldable or sealable polymer film. Additionally, preferably, the at least one polymer film is preferably a sealable polymer film. Furthermore, the polymer film is preferably a liquid-tight film.

[0034] The polymer film comprises, preferably consists of, a polymer material. The polymer material is

preferably selected from the list consisting of polyethylene, polypropylene, polyethylene terephthalate, polyamide, ethylene vinyl alcohol, or mixture thereof. More preferably the polymer material is selected from polyethylene or polypropylene. These materials have an ideal balance of material properties, processability, inertia in view of the neuraxial drug, and low price. Additionally, the polymer film can preferably comprise one or more additives. The polymer film preferably comprises at least 80 wt.-% of the polymer with respect to the total weight of the material of the container, more preferably at least 90 wt.-%, and most preferably at least 95 wt.-%.

[0035] Preferably, the polymer film has a haze value measured according to ASTM D1003, Procedure B, of less than 60%, preferably less than 30%, more preferably less than 25%, and most preferably less than 15%. This ensures that the user can see the products comprised by the enclosure.

[0036] Preferably, the polymer material of the polymer film has a glass transition temperature T_g measured according to ASTM D3418, of not more than 80 °C, preferably not more than 60 °C, more preferably not more than 40 °C, and most preferably not more than 20 °C. This ensures thermal stability in particular in view of the sterilization conditions used.

[0037] In a preferred embodiment, the polymer film comprises, preferably consists of, a multilayer polymer material. The multilayer polymer material can be prepared by coextrusion, e.g., in a blown-extrusion process, in cast-extrusion process, or in an extrusion-laminating process, optionally after deposition, preferably chemical vapor deposition, of a barrier layer onto one of the films. Hence, the polymer film of the wall of the enclosure can have an innermost layer, wherein the innermost layer denotes the layer forming at least parts, preferably all of, the inner surface of the enclosure, and the polymer film of the wall of the enclosure can have an outermost layer, wherein the outermost layer denotes the layer forming at least parts, preferably all of, the outer surface of the enclosure.

[0038] The innermost layer usually has the function of providing inertia of the polymer film of the wall of enclosure in view of packaged products, i.e. the container and the medical device. Hence, preferably, the material of the innermost layer is a material, which prevents or at least reduces migration of compounds from the multilayer polymer material into the enclosure. Furthermore, the material of the innermost layer is preferably a material which prevents or at least reduces migration of compounds from the packaged products into the multilayer polymer material of the enclosure. Particularly preferably, the material of the innermost layer is a material which prevents or at least reduces migration of the pharmaceutical compound into the multilayer polymer material of the enclosure. Hence, most preferably, the material of the innermost layer of the enclosure according to the present invention is selected from the list consisting of a polypropylene, a polyethylene, or a cyclic olefin, more pre-

ferably is a cyclic olefin.

[0039] The function of the outermost layer of the multilayer the polymer film of the wall of enclosure is to provide impact protection from the environment to protect the wall of the enclosure. Hence, preferably, the material of the outermost layer is preferably a polymer material having improved mechanical properties, such as tensile strength, impact strength, and/or toughness. Hence, preferably, the material of the outermost layer of the wall of the enclosure is a polyolefin material, most preferably is selected from a polyethylene or a polypropylene.

[0040] The multilayer polymer material of the wall of the enclosure according to the present invention preferably further comprises a barrier layer. The barrier layer preferably comprises, more preferably consists of, a material selected from ethylene vinyl alcohol (EVOH) or a metal oxide, preferably aluminum oxide or silicon oxide. It should be noted that a barrier layer made from EVOH usually does not need a support layer, as it is extruded.

[0041] The label preferably comprises, more preferably consists of, a sheet. Such a sheet can be of any shape. However, a rectangular shape is preferred. Preferred materials for the sheet can be selected from the list consisting of paper or a polymer. The polymer is preferably selected from the list consisting of polyethylene terephthalate, polyvinyl chloride, polyethylene, polypropylene, and polyamide. Usually, the sheet has a thickness in the range of from 10 to 500 μm , preferably 20 to 200 μm . It should be understood that in case the label comprises more layers, such as a liner, the thickness will be larger.

[0042] Preferably, one side of the sheet comprises information printed with an ink. The ink is typically suitable for pharmaceutical application. Inks can be selected from FDA or EMA approved inks, low migration inks, UV-curable inks, water-based inks, solvent-free inks, and generally GMP-compliant inks. The label is usually printed using methods in compliance with regulatory standards. Hence preferably the label is printed with the ink using a method selected from the list consisting of flexographic printing, heliographic printing, gravure printing, inkjet printing, thermotransfer printing, hot stamping, digital printing, screen printing, offset lithography, and laser marking.

[0043] The label preferably comprises information printed with at least one colored ink.

[0044] In a preferred embodiment of the present invention, the sheet comprises an adhesive for adhering the label to another article, preferably the container and/or the medical device. More preferably, the side of the sheet opposite to the side comprising information comprises the adhesive. The adhesive is preferably selected from the list consisting of acrylic-based adhesives, silicone-based adhesives, water-based adhesives, hot-melt adhesives, polyurethane-based adhesives, and acetate-based adhesives. More preferably, the adhesive is preferably selected from the list consisting of acrylic-based adhesives, silicone-based adhesives, polyurethane-

based adhesives, and acetate-based adhesives. Acrylic-based adhesives have the advantage of a strong bonding, a good resistance to heat and UV light, and good adherence properties to a wide range of surfaces, such as plastic, glass, metal. Silicone-based adhesives have the advantage of being flexible and resistant to high temperatures and chemicals.

[0045] Preferably, the adhesive is covered by a removable liner. The liner preferably comprises, more preferably consists of, paper, more preferably of siliconized paper. The liner has the advantage that during sterilization and/or shelf-life, i.e. in the lifespan of the product before the intended use, i.e. the application of the label to the container and/or medical device, the adhesive is protected from other surfaces adhering thereto and also from drying, if the adhesive is a solvent-based adhesive.

[0046] In a first preferred embodiment of the present invention, the label is comprised in the main cavity of the enclosure alongside the container and/or the medical device. This first preferred embodiment has the disadvantage of risk of limited visibility of the additional label, as the container and/or the medical device might cover the information printed on the label. Nevertheless, the any colored ink printed on the label should be visible. The advantage of this first preferred embodiment is that material consumption is reduced, as no additional features in the enclosure are required. Furthermore, the production process does not have to be modified, thereby not complicating the manufacturing of the pharmaceutical product. In the first preferred embodiment, the pharmaceutical product comprising container and/or medical device, and the label is preferably heat sterilized after filling and assembling. During use by the clinical staff, the label can be taken out of the enclosure and can be attached to the container and/or device before use.

[0047] In a second more preferred embodiment of the present invention, the enclosure further comprises a label cavity, wherein the label cavity is a closed cavity, and wherein the label is comprised in the label cavity. Preferably, the label cavity comprises walls, which are made from the same material as the walls of the enclosure. More preferably, the walls of the label cavity are made from a polymer film as defined for the walls of the enclosure. Even more preferably, the polymer film of the label cavity and the polymer film of the enclosure are identical. Hence, preferably, the label cavity and the enclosure are formed from the same polymer films as walls, more preferably by connecting parts of the polymer film to form the inner cavity and the label cavity, preferably by gluing or sealing the polymer films together. This second more preferred embodiment has the advantage that the separation of the label from the inner cavity significantly reduces the migration of leachables into the pharmaceutical compound. It also ensures that the information of the label can be read. Hence, the second more preferred embodiment of the invention comprises an enclosure, preferably a fully peelable enclosure, having at least two cavities, i.e. the inner cavity and the label

cavity.

[0048] In the pharmaceutical product according to the present invention, the label cavity and/or the enclosure preferably comprises an opening means. Thereby, the opening means preferably comprises, more preferably consists of, a peelable connection, more preferably a sealed connection of the at least one polymer film, most preferably a sealed seam of the at least one polymer film. Alternatively, the opening means could be cuts in the sealed seam, which enable opening the enclosure by rupture.

[0049] Preferably, the opening means has a sealing strength according to ASTM F88-94 in the range from 0.15 to 0.7 N/mm, preferably from 0.15 to 0.5 N/mm, and most preferably from 0.15 to 0.35 N/mm. This ensures that the label cavity and/or the enclosure can be easily opened by peeling or pulling. Preferably, the sealed seam of the opening means extends circumferentially around the label and/or the enclosure. This enables easy opening the whole pharmaceutical product for use.

[0050] In the pharmaceutical product according to the present invention, the container comprised in the enclosure defines a primary headspace, wherein the enclosure and the inner cavity define a secondary headspace. Preferably, the primary headspace and/or the secondary headspace is filled with a gas, preferably with an inert gas, more preferably with a gas selected from nitrogen, noble gases, or oxygen depleted gases. This assures that oxygen sensitive pharmaceutical compounds are protected.

[0051] The secondary headspace can optionally comprise an oxygen absorber to maintain the low oxygen content in the pharmaceutical product.

[0052] Preferably, the pharmaceutical product is sterile, more preferably has been sterilized by heating the pharmaceutical product up to at least 105 °C, and most preferably up to at least 121 °C. The medical device can be in a sterile state before sterilization or can be sterilized together within the pharmaceutical product.

[0053] Preferably, the medical device comprises means for transferring the pharmaceutical compound into the medical device, such as connectors, tubes, syringe tips or needles, and valves.

[0054] The medical device optionally comprised in the inner cavity of the pharmaceutical product of the present invention is preferably a medical device suitable for being filled with the pharmaceutical compound. Thereby, preferably, the medical device comprises means for transferring the pharmaceutical compound from the container into the medical device, such as connectors or needles. Preferably, the medical device this selected from the list consisting of syringes, preferably pre-filled syringes, conventional syringes, or auto-injectors; pumps; topical applicators, preferably transdermal patches, gel applicators, wipes, and ointment/cream dispensers; oral delivery devices, preferably oral dispensers, and capsule/tablet dispensers; injection pens, preferably insulin pens, and multi-dose pens; catheters; needle-free injectors; micro-

needles; and infusion sets; infusion transfer devices; adaptors; connectors.

Uses of the pharmaceutical product

[0055] The present invention is further concerned with the use of a pharmaceutical product according to the present invention for sterile storing the pharmaceutical compound. It is in particular preferred that during storing also oxygen-, water- or light-sensitive pharmaceutical compounds are not degraded.

[0056] Furthermore, the present invention is concerned with the use of a pharmaceutical product according to the present invention for filling the pharmaceutical compound into a medical device, preferably a medical device already comprised by the pharmaceutical product. Thereby the present invention in particular enables the packaging of medical devices, which tend to receive extractables and leachables from a label, preferably a colored label.

Claims

1. A pharmaceutical product, wherein the pharmaceutical product comprises

- a container comprising a pharmaceutical compound and/or a medical device suitable for receiving the pharmaceutical compound from the container,
- an enclosure enclosing the container and/or the medical device, and
- a label comprised by the enclosure,

wherein the enclosure comprises at least one wall enclosing a main cavity,

wherein the main cavity is a closed cavity,

wherein the cavity comprises the container and/or the medical device.

2. The pharmaceutical product according to claim 1, wherein the at least one wall comprises, preferably consists of, at least one polymer film comprising a polymer, preferably a flexible, thermoformable, and/or thermoformed polymer film, more preferably is a flexible polymer film.

3. The pharmaceutical product according to claim 2, wherein the at least one polymer film is a weldable or sealable polymer film.

4. The pharmaceutical product according to claims 2 or 3, wherein the polymer film has a haze value measured according to ASTM D1003, Procedure B, of less than 60%, preferably less than 30%, more preferably less than 25%, and most preferably less than 15%.

5. The pharmaceutical product according to any of the preceding claims 1 to 4, wherein the label is comprised in the main cavity.

6. The pharmaceutical product according to any of the preceding claims 1 to 4, wherein the enclosure further comprises a label cavity, wherein the label cavity is a closed cavity, and wherein the label is comprised in the label cavity.

7. The pharmaceutical product according to claim 6, wherein the label cavity and/or the enclosure comprises an opening means.

8. The pharmaceutical product according to claim 7, wherein the opening means comprises, preferably consists of, a peelable connection, preferably a sealed connection of the at least one polymer film, most preferably a sealed seam of the at least one polymer film.

9. The pharmaceutical product according to claim 8, wherein the peelable connection of the opening means has a sealing strength according to ASTM F88-94 in the range from 0.15 to 0.7 N/mm, preferably from 0.15 to 0.5 N/mm, and most preferably from 0.15 to 0.35 N/mm.

10. The pharmaceutical product according to any of the preceding claims 1 to 9, wherein the label comprises, preferably consists of, a sheet.

11. The pharmaceutical product according to claim 10, wherein the sheet has a thickness in the range of from 10 to 500 μm , preferably 20 to 200 μm .

12. The pharmaceutical product according to claims 10 or 11, wherein one side of the sheet comprises information printed with a colored ink.

13. The pharmaceutical product according to claim 12, wherein the side of the sheet opposite to the side comprising information comprises an adhesive.

14. Use of a pharmaceutical product according to any of the preceding claims 1 to 13 for sterile storing the pharmaceutical compound.

15. Use of a pharmaceutical product according to any of the preceding claims 1 to 13 for filling the pharmaceutical compound into a medical device.



EUROPEAN SEARCH REPORT

Application Number

EP 24 21 2252

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 2019/125627 A1 (MACFARLANE MATTHEW S [US] ET AL) 2 May 2019 (2019-05-02) * page 4, paragraph 56 - page 8, paragraph 90 * * figures 1-23 * -----	1-15	INV. A61J1/03 A61J1/06 A61J1/10 A61J1/16 A61M5/178 B65D1/00
			TECHNICAL FIELDS SEARCHED (IPC)
			A61J B65D A61M
The present search report has been drawn up for all claims			
Place of search		Date of completion of the search	Examiner
The Hague		19 February 2025	Schiffmann, Rudolf
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		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

EPO FORM 1503 03.82 (P34C01)

ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.

EP 24 21 2252

5 This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
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10	Patent document cited in search report	Publication date	Patent family member(s)	Publication date
15	US 2019125627	A1	02-05-2019	NONE
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EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82