Cap for drug delivery devices

This invention relates to a cap for drug delivery devices, in particular of the injector-type comprising a needle and a needle cover, wherein said cap is suitable as a needle safety tool, by comprising a needle cover retaining portion. In particular, the present invention relates to such devices, which are handled by the patients themselves.

Drug delivery devices, which are handled by patients themselves and allow individual dosing of the required amount of drug are well known in the art. Generally, such devices have substantially the same purpose as that of an ordinary syringe. A device of the mechanical pen-type is known, e.g., from US Patent No. 5,226,895.
In such devices, usually a needle assembly comprising a double-ended needle is attached to the device at its distal end. A drug containing cartridge is mounted in a distal end portion of the housing between the needle and a piston rod driving the piston in the cartridge for dispensing the liquid, which is moved by a drive mechanism.
A removable needle cover is mounted on the distal end of the needle to protect the needle from contamination and damage. Further, a removable cap is mounted at the distal end of the housing of the device. The cap is designed to cover and protect the needle and needle cover.

Prior to injection the user (patient, caregiver etc.), must remove the cap from the distal end of the housing and the needle cover from the distal end of the needle. After injection, the needle cover is put back onto the needle and the cap onto the distal end of the housing.

The problem to be solved by instant invention is to reduce the risk of needle related injuries to the user, which may lead to infection of the user of the above-mentioned kind of drug delivery device. In addition, the present invention serves to avoid the loss of the needle cover during drug delivery and therefore provides improved handling of the drug delivery device.

The present invention provides a cap for a drug delivery device having a needle cover retaining portion, designed to retain a needle cover during injection and to assist in

safely attaching/detaching the needle cover from a needle prior to/after injection. Therefore, with the cap of the present invention, a safety tool for retaining a needle cover is provided.

Attaching/detaching a needle cover, e.g. in an axial direction, to/from a needle is achieved by the cap retaining the needle cover by means of the needle cover retaining portion provided on the cap to attach/detach the needle cover.

Definitions

The term "drug delivery device" according to instant invention shall mean a single-dose or multi-dose, disposable or re-useable device designed to dispense a selectable or fixed dose of a medicinal product, e.g. insulin, growth hormones, low molecular weight heparins, their analogues and/or derivatives etc. Said device may be of any shape, e.g. compact format or pen-type. Dose delivery may be provided through a mechanical (optionally manual) or electrical drive mechanism or stored energy drive mechanism, such as a spring, etc. Dose selection may be provided through a manual mechanism or electronic mechanism. Additionally, said device may contain components designed to monitor physiological properties such as blood glucose levels, etc. Furthermore, the said device shall comprise a needle or a needle assembly. In particular, the term "drug delivery device" shall mean a disposable multi-dose pen-type device having mechanical and manual dose delivery and dose selection mechanisms, which is designed for regular use by persons without formal medical training such as patients. Preferably, the drug delivery device is of the injector-type, particularly a pen-type injector.

The term "needle" according to instant invention shall mean a slender hollow instrument designed for introducing material into the body by intravenous, intramuscular, or subcutaneous injection. In particular the term "needle" shall mean a slender hollow instrument having sharp points at both its distal and proximal ends to facilitate its integration with the drug containing cartridge and the injection of the drug into the patient.

The term "proximal end" according to instant invention shall mean the end of the device or a component of the device, which is furthest away from the dispensing end of the device.

The term "distal end" according to instant invention shall mean end of the device or a component of the device, which is closest to the dispensing end of the device.

The term "needle cover" according to instant invention shall mean any component of a drug delivery device designed to protect the needle from physical damage and contamination from environmental factors such as dirt, germs, etc., as well as providing protection for the user of the drug delivery device from needle-stick injuries. Said component can be of any shape and size and manufactured from any suitable material known by a person skilled in the art. In particular, the term "needle cover" shall mean a tubular component of essentially cylindrical shape having a closed distal end and an open proximal end designed to be removably mounted on the distal end of the needle of the drug delivery device.

The term "cap" according to instant invention shall mean a component of a drug delivery device designed to cover the needle assembly and needle cover of the device. Said component can be of any shape and size and manufactured from any suitable material known by a person skilled in the art, e.g., suitable plastic. Additionally, the said component is designed to attach, through any suitable means known by a person skilled in the art, to the distal end of the drug delivery device. Furthermore, the component may comprise a clip designed to allow the whole device to be secured in a pocket in the similar way to a pen. In particular, the term "cap" shall mean a tubular component of cylindrical shape having an open proximal end and a closed distal end designed to be removably mounted on the distal end of the drug delivery device and enclose the needle assembly and needle cover of the device.

According to instant invention the term "needle cover retaining portion" shall mean one or more parts of the cap of a drug delivery device designed to hold a needle cover during injection and assist in the safe attaching/detaching of the needle cover from a needle prior to/after injection. In particular, the term "needle cover retaining portion" shall mean one or more parts of the cap of a drug delivery device designed to hold a

needle cover during injection and assist in the safe attaching/detaching of the needle cover from a needle prior to/after injection formed either;
between the cap body of the device and the elastic clip of the cap, or;
in the distal end of the device cap, or;
integrally molded with the cap, or;
molded as a separate part and then attached to the cap body.

According to instant invention the term "provided on the cap" shall mean that a given functionality, such as needle cover retention or a clip retainer, etc., is present on the cap.

The term "high friction material" according to instant invention shall mean any material having elastic properties, such as rubber or any other suitable material, that allows it to adapt to the shape and size of the outer surface of the needle cover in order to ensure retention of the needle cover in the needle cover retaining portion through frictional forces during the injection process.
The suitable material may be made of any material that is selected from among various elastic (or soft) materials including, for example, natural rubber, synthetic rubbers such as isoprene rubber, silicone rubber, urethane rubber, styrene-butadiene rubber, fluorinated rubber and acrylic rubber, a porous body of polytetrafluoroethylene, polyamide-, polyester- and otherwise-based thermoplastic elastomers, and porous bodies of polyurethane. Said material can be applied to the inner face of the needle cover retaining portion by adhesion, deposition or the like, or molded integrally with the cap (insert molding, 2-color molding et al.) or molded as a separate part and then attached to the cap by adhesion, fitting or the like. Further the material may be a single piece or a multi-part piece.

Examples

The following examples describe embodiments of the cap of instant invention, which shall however, not restrict or limit the underlying inventive concept.

Example 1

An outline of the drug delivery device comprising the cap of the invention is described with reference to FIG. 1.

The device shown is of the pen-type and includes a housing 2, a cartridge holding portion 2a coupled integrally and concentrically to the distal end of the housing. A cartridge 3 containing the drug is mounted in the cartridge holding portion 2a. A needle 5 for injection is mounted at the distal end of the cartridge 3 by a needle assembly 6, which is removable.

A removable needle cover 11 covers and protects the needle 5, e.g., from contamination and damage.

An essentially cylindrical cap 12, which is removable, covers the needle assembly 6 including the needle cover 11. The cap 12 includes an essentially cylindrical cap body 13 and an elastic clip 14. Prior to dispensing the drug, the cap 12 and the needle cover 11 are removed.

Details of the needle cover retaining portion 31 are shown in FIGS. 2 to 3.
The needle cover retaining portion 31 is formed between the cap body 13 of the cap 12 and the elastic clip 14 of the cap (FIG 2).

A recessed portion 32 is formed on the inside face 14c of the clip 14. A high friction material 33 is applied by adhesion to the inner face of the recessed portion 32. The high friction material 33 is made from an elastic material such as synthetic rubber. The inner diameter of the high friction material 33 adapts to the outer diameter of the needle cover 11 in order to retain it.

The needle cover retaining portion 31 as shown in FIG 3, enables the needle cover 11 to be attached/detached to/from the needle 5 safely and easily. When the needle cover 11 is removed from the needle 5, it is retained in the needle cover retaining portion 31 by the tension of the clip 14 of the cap 12. Consequently, the needle cover 11 can be retained safely together with the cap 12 and possible loss of the needle cover 11 can be prevented.

To remove the needle cover 11 from the needle cover retaining portion 31 after injection and when the needle cover 11 has been reattached to the needle 5, the user needs to apply a force to the distal end of the needle cover 11 to overcome the frictional resistance of the high friction material 33.

Example 2

A second embodiment of the cap of the present invention is described in FIGS. 4 to 5.

In this embodiment the needle cover retaining portion 31 is formed along the longitudinal axis of the cap 12 and is located between the cap body 13 and the free end 14e of the clip 14.

The needle cover retaining portion 31 is formed from a pair of upper and lower recessed portions 37 and 38 and a pair of upper and lower elastic high friction materials 39 and 40 (hereinafter referred to simply as "high friction materials"). The high friction materials 39 and 40 are made of synthetic rubber and are applied by adhesion to the inner face of the recessed portions 37 and 38. The recessed portions 37 and 38 are formed on the outer peripheral face 13c of the cap body 13 and an inner face 14g of the free end 14e of the clip 14.

In order to remove the needle cover 11 from the needle cover retaining portion 31 after injection and when the needle cover 11 has been reattached to the needle 5, the user needs to apply a force to the free end 14a of the clip 14 such that the distal free end 14e of the clip 14 is lifted allowing the needle cover 11 to overcome the frictional resistance of the high friction materials 39, 40.

Example 3

A third embodiment of the cap of the present invention is described in FIGS. 6 to 7.

In this embodiment the needle cover retaining portion 31 is formed on the distal outer peripheral face 13c of the cap body 13 of the cap 12. The needle cover retaining portion 31 is formed from an elastic high friction material 43 (hereinafter referred to simply as "high friction material") made of synthetic rubber, which is either molded integrally with the cap body 13 or molded as a separate part and then attached to the cap body 13 by adhesion.

Accordingly, Example 3 of the needle cover retaining portion 31, describes a further alternative by which the needle cover 11 can be attached/detached safely and easily to/from the needle 5.

The cap for a drug delivery device of the present invention is not restricted to the embodiments described in Examples 1, 2 and 3 above, but various, effective alternatives can be envisaged by the person skilled in the art.

Brief Description of the Drawings

[FIG. 1] FIG. 1 is a longitudinal sectional side elevation view of an entire pen-type drug delivery device comprising the cap of instant invention.

[FIG. 2] FIG. 2 is a side elevation view (2A), a plan view (2B) and a plan view partly in section (2C) showing the needle cover retaining portion of the cap of Example 1.

[FIG. 3] FIG. 3 is a plan view illustrating the operation of attaching/detaching the needle cover from the needle, whilst the needle cover is retained by the needle cover retaining portion of the cap of Example 1.

[FIG. 4] FIG. 4 is a side elevation view (4A), a side elevation view partly in section (4B) and an distal end view (4C) showing the needle cover retaining portion of the cap of Example 2.

[FIG. 5] FIG. 5 is a side elevation view illustrating the operation of attaching/detaching the needle cover from the needle, whilst the needle cover is retained by the needle cover retaining portion of the cap of Example 2.

[FIG. 6] FIG. 6 is a side elevation view (6A), a plan view (6B) and an distal end view (6C) showing the needle cover retaining portion of the cap of Example 3.

[FIG. 7] FIG. 7 is a side elevation view illustrating the operation of attaching/detaching the needle cover from the needle, whilst the needle cover is retained by the needle cover retaining portion of the cap of Example 3.

Claims

1. A cap for a drug delivery device comprising
a needle;
a needle cover, which is removably mounted, whereby
said cap is removably mounted on the said drug delivery device to cover said needle cover, characterized in that
the said cap comprises a needle cover retaining portion capable of removably retaining said needle cover in order to assist in attaching/detaching the said needle cover to/from said needle.

2. The cap according to claim 1, characterized in that said needle cover retaining portion is formed
A) between the cap body and the clip of the said cap
or is provided
B) on the cap body of the said cap.

3. The cap according to any of claims 1 to 2, characterized in that said needle cover retaining portion is or comprises an elastic member in order to retain said needle cover.

4. A drug delivery device comprising the cap of any of claims 1 to 3.

5. The drug delivery device according to claim 4, characterized in that said drug delivery device is a pen-type device.

6. The drug delivery device according to any of claims 4 to 5
comprising insulin, low molecular weight heparin, its derivatives and/or analogous.

7. A method of attaching/detaching a needle cover from the needle of a drug delivery device by using the cap according to any of claims 1 to 3.