FIG 1

A drug delivery device comprises a housing (1) with a proximal end (Ia) and an outer surface. A dose dial sleeve (20) comprises a plurality of symbols (7, 32), those symbols representing dosage information during operation of the drug delivery device. A dose dial grip (4) is in operative connection with the dose dial sleeve (20) to select a dosage to be delivered. A dose button (3) is in operative connection with a piston rod (8) to deliver the drug in response to the selected dosage. The drug delivery device comprises a window (5a) in the housing such that at least one symbol (7) corresponding to a selected dosage is visible. The window (5a) is recessed in the housing (1) with respect to the outer surface. The recess distance between the outer surface of the housing (1) and a surface of the window (5a) is 10% to 70% of the housing's (1) thickness.
The present invention relates to a drug delivery device. Particularly, the present invention relates to a drug delivery device with improvements to displaying a scheduled dosage.

Drug delivery devices are generally known for the administration of a medicinal product, for example insulin, growth hormones or other drugs, being suitable for self-administration by a patient.

Some drug delivery devices are configured to deliver a plurality of different doses. One particular example of such drug delivery device is described in EP 1 923 084 A1. The drug delivery device shown therein allows a user to activate the delivery device. For that purpose, the drug delivery device includes a drive mechanism suitable for use in pen-type injectors, where an amount of pre-set doses of medicinal product can be administered. A needle unit can be attached to the drug delivery device for dispensing the medicinal product into a patient's body. After usage of the drug delivery device, the needle unit can be replaced and the distal end of the device can be covered by a cap.

Often, the number of doses stored in a pen-type injector exceeds the dosage of a single treatment. Therefore, some drug delivery devices are configured to allow an adjustment or selection of different dose sizes, which are to be delivered. However, it is generally advisable that the patient or the user is aware of the amount of medicinal product which is selected to be dispensed in the patient's body or which is left in the injection device.

Document US 2001/0053894 shows a dose display for a medicine administration device, in which rotation of the dose setting actuator is transmitted to a display means. The setting actuator comprises a flexible disk carrying numbers in a band along its pe-
rimeter, which numbers are in accordance with the set dosage presented in a window of the device to show that dosage.

Still, the visibility of dosage selected for dispense into the patient's body or the amount of drug still left in the injection device should be guaranteed even if the drug delivery device is frequently used.

It is an aim of the present invention to provide an improved drug delivery device and particularly a drug delivery device with improved visibility of a dosage selected for injection.

For this aim, a drug delivery device comprises a housing having a proximal end and an outer surface. A dose dial sleeve comprises a plurality of symbols that symbols representing dosage information during operation of the drug delivery device. The dose dial sleeve is in operative connection with a dose dial grip to select a dosage to be delivered. Further, the drug delivery device comprises a dose button in operative connection with a piston rod to deliver the drug in response to the selected dosage. To improve visibility of the symbols representing dosage information, the drug delivery device comprises a window aperture in the housing such that at least one symbol representing dosage information is visible, wherein the window aperture is recessed in the housing with respect to the outer surface. Consequently the window is recessed as well with respect to the outer surface of the housing.

The recess distance between the outer surface of the housing and a surface of the window may be 10 % to 70 % of the housing's thickness. The recess may preferably be 10 % to 50 % of the thickness of the housing.

The recess of the window aperture in the housing with respect to the outer surface protects the window and the window material from being scratched or damaged during usage or storing of the drug delivery device. Particularly, sliding, gliding or rolling of the drug delivery device on a surface does not scratch or damage the surface of the window aperture causing abrasion or scratches in the window material.
In an embodiment the at least one symbol shown in the window aperture corresponds to the dosage selected by the dose dial grip and the dose dial sleeve. The user may select the desired amount of dosage by moving or rotating the dose dial grip until the respective symbol corresponding to the desired dosage is visible in the window aperture.

In a further embodiment, the dose dial grip is arranged at the proximal end of the housing. Also, the window aperture may be arranged close to the proximal end of the housing. Consequently, visibility during selection of the dosage to be delivered is improved.

The window aperture may comprise transparent plastic or glass or any other transparent substantially scratch-resistant material on its outer surface. The scratch-resistant material prevents or reduces damage due to gliding or scratching of the drug delivery device along a protrusion able to penetrate the recess.

In another embodiment, the plurality of symbols may comprise consecutive numbers so as to indicate dosage to be delivered or remaining dosages left. To improve visibility and reading of the symbol, the housing of the drug delivery device may comprise markings on its outer surface close to the window aperture to indicate the dosage selected. The numbers may be printed or molded on the dial button sleeve.

In another embodiment, the housing comprises priming information suitable for providing additional information to a user.

In yet another embodiment, the piston rod of the drug delivery device is a linearly movable piston rod. As an alternative, the piston rod is a rotationally movable piston rod.

Other features will become apparent from the following detailed description when considered in conjunction with the accompanying drawings.

In the drawings:
FIG. 1 schematically shows a simplified cross-sectional side view of a drug delivery device according to an embodiment,

FIG. 2 schematically shows a simplified side view of a part of a drug delivery device according to an embodiment,

FIG. 3 shows a simplified side view of a portion of a drug delivery device according to an embodiment,

FIG. 4 schematically shows a simplified top view of the portion of a drug delivery device according to an embodiment.

It should be noted that the description of the drug delivery device as shown in the following figures is merely illustrative. Some portions or parts of the drug delivery device are illustrated enlarged with respect to other parts. However, the dimensions of the portions and parts of the drug delivery device are for illustrational purposes only and do not represent real dimensions or ratios. Similar parts may comprise the same references.

The drug delivery device 100 may be configured to deliver a plurality of fixed or user-settable doses of a drug. The drug delivery device 100 may be a pen-type device, preferably a pen type injector, and comprises a housing 1, which can be formed from a single or multiple pieces.

The term „drug“, as used herein, means a pharmaceutical formulation containing at least one pharmaceutically active compound,

wherein in one embodiment the pharmaceutically active compound has a molecular weight up to 1500 Da and/or is a peptide, a protein, a polysaccharide, a vaccine, a DNA, a RNA, an antibody, an enzyme, an antibody, a hormone or an oligonucleotide, or a mixture of the above-mentioned pharmaceutically active compound,
wherein in a further embodiment the pharmaceutically active compound is useful for
the treatment and/or prophylaxis of diabetes mellitus or complications associated with
diabetes mellitus such as diabetic retinopathy, thromboembolism disorders such as
deep vein or pulmonary thromboembolism, acute coronary syndrome (ACS), angina,
myocardial infarction, cancer, macular degeneration, inflammation, hay fever, athero-
sclerosis and/or rheumatoid arthritis,

wherein in a further embodiment the pharmaceutically active compound comprises at
least one peptide for the treatment and/or prophylaxis of diabetes mellitus or complica-
tions associated with diabetes mellitus such as diabetic retinopathy,

wherein in a further embodiment the pharmaceutically active compound comprises at
least one human insulin or a human insulin analogue or derivative, glucagon-like pep-
tide (GLP-1) or an analogue or derivative thereof, or exedin-3 or exedin-4 or an ana-
logue or derivative of exedin-3 or exedin-4.

Insulin analogues are for example Gly(A21), Arg(B31), Arg(B32) human insulin;
Lys(B3), Glu(B29) human insulin; Lys(B28), Pro(B29) human insulin; Asp(B28) human
insulin; human insulin, wherein proline in position B28 is replaced by Asp, Lys, Leu,
Val or Ala and wherein in position B29 Lys may be replaced by Pro; Ala(B26) human
insulin; Des(B28-B30) human insulin; Des(B27) human insulin and Des(B30) human
insulin.

Insulin derivates are for example B29-N-myhstoyl-des(B30) human insulin; B29-N-
palmitoyl-des(B30) human insulin; B29-N-myhstoyl human insulin; B29-N-palmitoyl
human insulin; B28-N-myhstoyl LysB28ProB29 human insulin; B28-N-palmitoyl-
LysB28ProB29 human insulin; B30-N-myristoyl-ThrB29LysB30 human insulin; B30-N-
palmitoyl-ThrB29LysB30 human insulin; B29-N-(N-palmitoyl-Y-glutamyl)-des(B30)
human insulin; B29-N-(N-lithocholyl-Y-glutamyl)-des(B30) human insulin; B29-N-(ω-
carboxyheptadecanoyl)-des(B30) human insulin and B29-N-(ω-carboxyheptadecanoyl)
human insulin.
Exendin-4 for example means Exendin-4(1-39), a peptide of the sequence H-His-Gly-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Leu-Ser-Lys-Gln-Met-Glu-Glu-Ala-Val-Arg-Leu-Phe-Ile-Glu-Trp-Leu-Lys-Asn-Gly-Gly-Pro-Ser-Ser-Gly-Ala-Pro-Pro-Pro-Ser-NH2.

Exendin-4 derivatives are for example selected from the following list of compounds:

- H-(Lys)₄-des Pro36, des Pro37 Exendin-4(1-39)-NH₂,
- H-(Lys)₅-des Pro36, des Pro37 Exendin-4(1-39)-NH₂,
- des Pro36 [Asp28] Exendin-4(1-39),
- des Pro36 [IsoAsp28] Exendin-4(1-39),
- des Pro36 [Met(O)₁₄, Asp28] Exendin-4(1-39),
- des Pro36 [Met(O)₁₄, IsoAsp28] Exendin-4(1-39),
- des Pro36 [Trp(O₂)₂₅, Asp28] Exendin-4(1-39),
- des Pro36 [Trp(O₂)₂₅, IsoAsp28] Exendin-4(1-39),
- des Pro36 [Met(O)₁₄ Trp(O₂)₂₅, Asp28] Exendin-4(1-39),
- des Pro36 [Met(O)₁₄ Trp(O₂)₂₅, IsoAsp28] Exendin-4(1-39); or

- des Pro36 [Asp28] Exendin-4(1-39),
- des Pro36 [IsoAsp28] Exendin-4(1-39),
- des Pro36 [Met(O)₁₄, Asp28] Exendin-4(1-39),
- des Pro36 [Met(O)₁₄, IsoAsp28] Exendin-4(1-39),
- des Pro36 [Trp(O₂)₂₅, Asp28] Exendin-4(1-39),
- des Pro36 [Trp(O₂)₂₅, IsoAsp28] Exendin-4(1-39),
- des Pro36 [Met(O)₁₄ Trp(O₂)₂₅, Asp28] Exendin-4(1-39),
- des Pro36 [Met(O)₁₄ Trp(O₂)₂₅, IsoAsp28] Exendin-4(1-39),

wherein the group -Lys₆-NH₂ may be bound to the C-terminus of the Exendin-4 derivative;

or an Exendin-4 derivative of the sequence

- H-(Lys)₆-des Pro36 [Asp28] Exendin-4(1-39)-Lys₆-NH₂,
- des Asp₂₈ Pro36, Pro37, Pro38Exendin-4(1-39)-NH₂,
H-(Lys)6-des Pro36, Pro38 [Asp28] Exendin-4(1-39)-NH2,
H-Asn-(Glu)5des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-NH2,
des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-(Lys)6-des Pro36, Pro37, Pro38 [Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-Lys6-des Pro36 [Met(O)14, Asp28] Exendin-4(1-39)-Lys6-NH2,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-Lys6-des Pro36 [Met(O)14, Asp28] Exendin-4(1-39)-Lys6-NH2,
H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-(Lys)6-NH2,
H-Lys6-des Pro36 [Met(O)14, Asp28] Exendin-4(1-39)-Lys6-NH2,
or a pharmaceutically acceptable salt or solvate of any one of the afore-mentioned Exedin-4 derivative.

Hormones are for example hypophysis hormones or hypothalamus hormones or regulatory active peptides and their antagonists as listed in Rote Liste, ed. 2008, Chapter 50, such as Gonadotropine (Follitropin, Lutropin, Chohonggonadotropin, Menotropin), Somatropine (Somatropin), Desmopressin, Terlipressin, Gonadorelin, Triptorelin, Leuprorelin, Buserelin, Nafarelin, Goserelein.

A polysaccharide is for example a glucosaminoglycane, a hyaluronic acid, a heparin, a low molecular weight heparin or an ultra low molecular weight heparin or a derivative thereof, or a sulphated, e.g. a poly-sulphated form of the above-mentioned polysaccharides, and/or a pharmaceutically acceptable salt thereof. An example of a pharmaceutically acceptable salt of a poly-sulphated low molecular weight heparin is enoxaparin sodium.

Pharmaceutically acceptable salts are for example acid addition salts and basic salts. Acid addition salts are e.g. HCl or HBr salts. Basic salts are e.g. salts having a cation selected from alkali or alkaline, e.g. Na+, or K+, or Ca2+, or an ammonium ion N+(R1)(R2)(R3)(R4), wherein R1 to R4 independently of each other mean: hydrogen, an optionally substituted C1-C6-alkyl group, an optionally substituted C2-C6-alkenyl group, an optionally substituted C6-C10-aryl group, or an optionally substituted C6-C10-heteroaryl group. Further examples of pharmaceutically acceptable salts are described in "Remington's Pharmaceutical Sciences" 17. ed. Alfonso R. Gennaro (Ed.), Mark Publishing Company, Easton, Pa., U.S.A., 1985 and in Encyclopedia of Pharmaceutical Technology.

Pharmaceutically acceptable solvates are for example hydrates.

As shown in the embodiment of FIG. 1, housing 1 comprises a proximal end 1a and a distal end 1b.
The term "distal end" of the drug delivery device 100 or a component thereof may refer to that end of the device or the component which is closest to the dispensing end of the device 100, which, for instance, comprises a needle. The term "proximal end" of the drug delivery device 1 or a component thereof may refer to that end of the device or the component which is furthest away from the dispensing end of the device.

On top of the distal end 1b, a needle unit 12 including a needle 13 is attached. The distal end 1b of the housing 1 may serve as a cartridge holder and may be configured to contain a cartridge 11 made of a transparent material. Cartridge 11 contains the drug to be delivered to a patient. Cartridge 11 has a distal end covered by a membrane. For use, the membrane may be pierced by the needle to allow drug to be dispensed from the cartridge through the needle. Bung 9 is retained in the cartridge. Bung 9 is movable to the distal direction with respect to the cartridge using a piston rod 8 connected thereto. Thereby a drug may be dispensed from the cartridge. Piston rod 8 may be driven in the distal direction in order to move bung 9 along the distal direction with respect to the cartridge. A cap 2 is used to cover the distal part 1b of the drug delivery device, when the device is stored.

The proximal part 1a of the drug delivery device comprises a window aperture 5 and markings 6 on housing 1 close to window aperture 5. Through the window, a plurality of different symbols 7, including numbers, are visible. The symbols are printed on a dose dial sleeve 20 which is in operative connection with dose dial grip 4 at the proximal end of housing 1. By rotating dose dial grip 4, dose dial sleeve 20 is rotated to select a dosage to be dispensed during operation of the drug delivery device. The amount of dosage to be dispensed can be seen by the corresponding dosage information 7 displayed through window aperture 5. The drug is delivered by pressing a dose button 3 after the desired dosage is selected using dose dial grip 4.

FIG. 2 shows dose dial sleeve 20 according to an embodiment of the present invention in greater detail. A plurality of symbols 32, each of them corresponding to the amount of dosage to be delivered, is printed or molded upon the surface of dose dial sleeve 20. Dose dial sleeve 20 is rotated using the dose dial grip 4 attached to dose dial slee-
ve 20 at its one end 22. During rotation, symbols 32 on the dose dial sleeve are visible through window aperture 5 of housing 1.

To prevent scratches or abrasion on window 5a, thereby reducing visibility of the symbols printed on dose dial sleeve 4, window 5a is recessed with respect to the surface of the proximal end 1a of the housing.

FIG. 3 shows a schematic side view of the proximal end of the drug delivery device according to an embodiment. Dose dial grip 4 is in operative connection with dose dial sleeve 20, which rotationally moves around piston rod 8. As a result, the symbols representing dosage information, for instance a dosage to be delivered, are shown in window 5 while dose dial sleeve 20 moves along the x-direction as indicated in FIG. 3.

Window 5a in aperture 5 comprises a transparent and scratch-resistant material, particularly plastic or glass, and is recessed with respect to the outer surface of proximal end 1a of the housing. As a result, the outwardly-facing surface of window 5 is below the level of the surface of housing 1.

The recess distance between the outer surface of the housing and the surface of the window may be 10 % to 70 % of the housing's thickness. For instance, if the thickness of the housing is roughly 1 mm, the window may be recessed by up to 0.7 mm with respect to the housing. The window may also protrude with respect to the inner surface of the housing, so the thickness of the window is not or only slightly reduced, thereby providing additional stability. In such cases, the recess may even be greater than 50 % of the housing's thickness.

As a result, window 5a is protected from scratching or grinding when the drug delivery device is moved across a surface like, for instance, a rough table.

FIG. 4 shows the top view of the proximal end 1a of a drug delivery device 100 according to an embodiment.
Window 5a has two symmetrically arranged bulges 5b acting as additional markers. Bulges 5b together with the remaining window 5a are recessed with respect to the surface of housing 1. Numbers or symbols printed on the dose dial sleeve 20 which are displayed in the center of window aperture 5, between bulges 5b, indicate the actual dosage which will be delivered when pressing dose button 3. By rotating dose dial grip 4, the dose dial sleeve is rotated as well and different numbers corresponding to respective dosages to be delivered are shown in window aperture 5.
Reference numerals

1 housing
1a proximal end
1b distal end
2 cap
3 dose button
4 dose dial grip
5 window aperture
5a window
5b bulge
6 markings
7 symbols, numerals
8 piston rod
9 bung
10 window
11 cartridge
12 needle unit
13 needle
20 dose dial sleeve
32 symbols
22 distal end
100 drug delivery device
Claims

1. A drug delivery device, comprising:
   - a housing (1) having a proximal end (1a) and an outer surface;
   - a dose dial sleeve (20) having a plurality of symbols (7, 32), said symbols representing dosage information during operation of the drug delivery device;
   - a dose dial grip (4) in operative connection with the dose dial sleeve (20) during dose selection to select a dosage to be delivered;
   - a dose button (3) in operative connection with a piston rod (8) to deliver the drug in response to the selected dosage;
   - a window (5a) in the housing such that at least one symbol representing dosage information is visible, wherein the window (5a) is recessed in the housing (1) with respect to the outer surface, characterized in that a recess distance between the outer surface of the housing (1) and a surface of the window (5a) is 10 % to 70 % of the housing's (1) thickness.

2. Drug delivery device according to claim 1, wherein the dose dial grip (4) is arranged at the proximal end (1a) of the housing (1).

3. Drug delivery device according to any of claims 1 to 2, wherein the window (5a) is arranged close to the proximal end (1a) of the housing (1).

4. Drug delivery device according to any of claims 1 to 3, wherein the window (5a) comprises transparent plastics.

5. Drug delivery device according to any of claims 1 to 4, wherein the window (5a) comprises glass.

6. Drug delivery device according to any of claims 1 to 5, wherein the window (5a) comprises a transparent substantially scratch-resistant material on its outer surface.
7. Drug delivery device according to any of claims 1 to 6, wherein the plurality of symbols (7, 32) comprises consecutive numbers (32) so as to indicate the dosage which is to be delivered or the dosage still remaining for delivery.

8. Drug delivery device according to any of claims 1 to 7, wherein the housing (1) comprises at least one marking (6) on its outer surface close to the window (5a) to indicate the symbol.

9. Drug delivery device according to any of claims 1 to 8, wherein the window (5a) comprises at least one bulge (5b) acting as a marker to distinguish a symbol shown through window (5a).

10. The drug delivery device according to claim 7, wherein the numbers (32) are printed or moulded on the dose dial sleeve (20).

11. The drug delivery device according to any of claims 1 to 10, wherein the housing (1) comprises priming information suitable for providing additional information to a user.

12. The drug delivery device according to any of claims 1 to 11, wherein the piston rod (8) is a linearly movable piston rod.

13. The drug delivery device according to any of claims 1 to 11, wherein the piston rod (8) is a rotationally movable piston rod.
A CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/24
ADD. A61M5/31 A61M5/315
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>WO 2006/058883 A (NOVO NORDISK AS [DK]; RADMER BO [DK]; MOELLER CLAUS SCHMIDT [DK]; GROT) 8 June 2006 (2006-06-08) abstract figures 1-4 page 3, line 9 - page 6, line 19 page 9, line 25 - page 13, line 18 claims 1,2,11</td>
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Further documents are listed in the continuation of Box C

See patent family annex

* Special categories of cited documents

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Date of the actual completion of the international search
27 April 2010

Date of mailing of the international search report
06/05/2010

Name and mailing address of the ISA/Authorized officer
European Patent Office, P B 5818 Patentlaan 2 NL - 2280 HV Rijswijk
Tel (+31-70) 340-2040, Fax (+31-70) 340-3016

Petersen, Bernhard
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