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Auto-injector

Abstract

An auto-injector for administering a dose of a liquid medicament includes an elongate housing arranged to contain a syringe with a hollow needle and a stopper for sealing the syringe and displacing the medicament, the housing having a distal end and a proximal end with an orifice intended to be applied against an injection site. The syringe is slidably arranged with respect to the housing. A spring capable of, upon activation: pushing the needle from a covered position inside the housing into an advanced position through the orifice and past the proximal end (P), operating the syringe to supply the dose of medicament (M), and retracting the syringe with the needle into the covered position. After delivering the medicament, an activator arranged to lock the spring in a pressurized state prior to manual operation and capable of, upon manual operation, releasing the spring for injection.

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Background/Summary

CROSS REFERENCE TO RELATED APPLICATIONS (1) The present application is a continuation of U.S. patent application Ser. No. 17/453,601, filed Nov. 4, 2021, which is a continuation of U.S. patent application Ser. No. 16/276,366, filed Feb. 14, 2019, now U.S. Pat. No. 11,197,958, which is a continuation of U.S. patent application Ser. No. 14/995,964, filed Jan. 14, 2016, now U.S. Pat. No. 10,232,116, which is a continuation of U.S. patent application Ser. No. 13/579,435, filed Feb. 25, 2013, now U.S. Pat. No. 9,248,245, which is a 35 U.S.C. 371 National Application of PCT/EP2011/052301, filed Feb. 16, 2011, and claims priority to European Patent

Application No. 10153999.7, filed Feb. 18, 2010 and U.S. Patent Application No. 61/412,086, filed Nov. 10, 2010, the entire contents of which are incorporated entirely herein by reference.

TECHNICAL FIELD

(1) The invention relates to an auto-injector for administering a dose of a liquid medicament according to the preamble of claim **1**.

BACKGROUND OF THE INVENTION

(2) Administering an injection is a process which presents a number of risks and challenges for users and healthcare professionals, both mental and physical.

(3) Injection devices (i.e. devices capable of delivering medicaments from a medication container) typically fall into two categories—manual devices and auto-injectors.

(4) In a manual device—the user must provide the mechanical energy to drive the fluid through the needle. This is typically done by some form of button/plunger that has to be continuously pressed by the user during the injection. There are numerous disadvantages to the user from this approach. If the user stops pressing the button/plunger then the injection will also stop. This means that the user can deliver an underdose if the device is not used properly (i.e. the plunger is not fully pressed to its end position). Injection forces may be too high for the user, in particular if the patient is elderly or has dexterity problems.

(5) The extension of the button/plunger may be too great. Thus it can be inconvenient for the user to reach a fully extended button. The combination of injection force and button extension can cause trembling/shaking of the hand which in turn increases discomfort as the inserted needle moves.

(6) Auto-injector devices aim to make self-administration of injected therapies easier for patients. Current therapies delivered by means of self-administered injections include drugs for diabetes (both insulin and newer GLP-1 class drugs), migraine, hormone therapies, anticoagulants etc.

(7) Auto-injectors are devices which completely or partially replace activities involved in parenteral drug delivery from standard syringes. These activities may include removal of a protective syringe cap, insertion of a needle into a patient's skin, injection of the medicament, removal of the needle, shielding of the needle and preventing reuse of the device. This overcomes many of the disadvantages of manual devices. Injection forces/button extension, hand-shaking and the likelihood of delivering an incomplete dose are reduced. Triggering may be performed by numerous means, for example a trigger button or the action of the needle reaching its injection depth. In some devices the energy to deliver the fluid is provided by a spring.

(8) US 2002/0095120 A1 discloses an automatic injection device which automatically injects a pre-measured quantity of fluid medicine when a tension spring is released. The tension spring moves an ampoule and the injection needle from a storage position to a deployed position when it is released. The content of the ampoule is thereafter expelled by the tension spring forcing a piston forward inside the ampoule. After the fluid medicine has been injected, torsion stored in the tension spring is released and the injection needle is automatically retracted back to its original storage position.

(9) US 2007/0112310 A1 discloses an injector being automatic in that the needle is inserted into the injection site (e.g., a patient's skin) with user or caregiver assistance, the delivery is automatically initiated upon needle insertion, and the needle is retracted automatically after the end of delivery. Preferably the needle is not seen by the user prior to, during or after injection. Prior to and after injection, the needle is hidden in the device so as to avoid any potential injury or health risk to the user or health care provider. The injector includes a housing and a shield arranged to slide relative to the housing and a driver moving during drug delivery. The housing and shield form a cartridge enclosure. The cartridge is shielded and locked after delivery is completed. A needle-locking mechanism can be used in any number of pen-like injectors or safety needles.

(10) U.S. Pat. No. 5,267,963 discloses an automatic injection device which, upon activation by the user, automatically extends a syringe with needle, delivers medication through the needle, and retracts the needle, thus keeping the needle hidden from view. All motions are achieved by means

of a tension spring and a cam profile.
(11) WO 2009/081103 A1 discloses an auto-injector for a syringe that is suitable for use in the injected delivery of drug to a patient. The auto-injector comprises a housing defining a housing cavity arranged for receipt of a syringe; and a needle delivery aperture through which a needle tip of the syringe protrudes during dispensing of the liquid drug formulation. The auto-injector further comprises a barrel coupling element that couples to the barrel of the syringe and is movable in tandem therewith; a syringe advancer for moving the syringe and barrel coupling element in tandem therewith from a rest position, in which the hollow needle, is within the housing to a use position, in which the needle tip protrudes through the needle delivery aperture; a syringe actuator for actuating the syringe by plunging said plunger within the barrel of the syringe to dispense the liquid drug formulation; a syringe retractor for retracting the syringe and barrel coupling element in tandem therewith from the use position to a retract position, in which the hollow needle is within the housing; and a syringe lock for locking the barrel coupling element and syringe coupled thereto in the retract position.
(12) WO 2008/155377 discloses an inserter for an infusion set comprising an insertion needle and a spring unit assuring automatic insertion and automatic retraction of the insertion needle. The inserter for a medical device comprises—a housing, —a first body which is movable relative to the housing and comprising penetrating means pointing in the direction of insertion, —a second body which is also movable relative to the housing and—driving means which move respectively the first body and the second body relative to the housing wherein the driving means moves the first body in the direction of insertion and moves the second body in a direction different from the insertion direction.
(13) DE 10 2005 038 933 A1 discloses an inserter for an infusion set comprising an insertion needle and a spring unit assuring automatic insertion and automatic retraction of the insertion needle. The inserter for a medical device comprises—a housing, —a first body which is movable relative to the housing and comprising penetrating means pointing in the direction of insertion, —a second body which is also movable relative to the housing and—driving means which move respectively the first body and the second body relative to the housing wherein the driving means moves the first body in the direction of insertion and moves the second body in a direction different from the insertion direction.
SUMMARY OF THE INVENTION
(14) It is an object of the present invention to provide an improved auto-injector.
(15) The object is achieved by an auto-injector according to claim **1**.
(16) Preferred embodiments of the invention are given in the dependent claims.
(17) According to the invention, an auto-injector for administering a dose of a liquid medicament comprises: an elongate housing arranged to contain a syringe with a hollow needle and a stopper for sealing the syringe and displacing the medicament, the housing having a distal end and a proximal end with an orifice intended to be applied against an injection site, wherein the syringe is slidably arranged with respect to the housing, spring means capable of, upon activation: pushing the needle from a covered position inside the housing into an advanced position through the orifice and past the proximal end, operating the syringe to supply the dose of medicament, and retracting the syringe with the needle into the covered position after delivering the medicament, activating means arranged to lock the spring means in a pressurized state prior to manual operation and capable of, upon manual operation, releasing the spring means for injection.
(18) In the context of this patent application the term proximal refers to the direction pointing towards the patient during an injection while the term distal refers to the opposite direction pointing away from the patient.
(19) According to the invention the spring means is a single compression spring arranged to be grounded at a distal end in the housing for advancing the needle and for injecting the dose of medicament. The force of the compression spring is forwarded to the needle and/or the syringe via

a plunger. The compression spring is arranged to have its ground in the housing switched to its proximal end for retracting the syringe when the injection of the medicament is at least nearly finished.

(20) The single compression spring is used for inserting the needle, fully emptying the syringe and retracting the syringe and needle to a safe position after injection. Thus a second spring for withdrawing the syringe and needle, which is a motion with an opposite sense compared to advancing the syringe and injecting the dose, is not required. While the distal end of the compression spring is grounded the proximal end moves the syringe forward for inserting the needle and carries on to the injection by pushing on the stopper. When the injection is at least nearly finished the compression spring bottoms out at its proximal end, resulting in the proximal end being grounded in the housing. At the same time the distal end of the compression spring is released from its ground in the housing. The compression spring is now pulling the syringe in the opposite direction.

(21) The auto-injector according to the invention has a particularly low part count compared to most conventional auto-injectors. The use of just one compression spring reduces the amount of metal needed and thus consequently reduces weight and manufacturing costs.

(22) In a preferred embodiment of the invention a retraction sleeve is axially movable arranged in the housing. At least one latch is provided for axially fixing the retraction sleeve in a maximum proximal position. The compression spring is arranged inside the retraction sleeve with its distal end bearing against a distal end face of the retraction sleeve and with its proximal end bearing against a thrust face of a decoupling member. The decoupling member is arranged to decouple the latch when being moved in proximal direction nearly into a maximum proximal position. When decoupled the retraction sleeve is allowed to move in distal direction and retract the needle by means of the spring force which is no longer grounded at its distal end.

(23) Preferably the plunger is arranged for pushing the syringe and/or the stopper in proximal direction. At least two resilient decoupling arms are arranged at the decoupling member. The decoupling arms exhibit inner ramped surfaces bearing against a first shoulder of the plunger in proximal direction P. The resilient decoupling arms are supportable by an inner wall of the retraction sleeve in order to prevent the decoupling arms from being flexed outward and slip past the first shoulder. In this state the plunger may be pushed in proximal direction by the decoupling member pushing against the first shoulder in order to insert the needle and inject the dose. At least one aperture is arranged in the retraction sleeve allowing the decoupling arms to be flexed outward by the first shoulder thus allowing the first shoulder to slip through the decoupling arms in proximal direction. This may happen when the injection is at least nearly finished. The decoupled plunger allows the syringe and needle to be retracted since it is no longer bearing against the decoupling member.

(24) The syringe may be arranged for joint axial movement with a syringe holder which is slidably arranged in the retraction sleeve. The syringe holder is provided with at least two resilient syringe holder arms arranged distally, the syringe holder arms having a respective inclined surface for bearing against a second shoulder, which is arranged at the plunger proximally from the first shoulder. The syringe holder arms are supportable by an inner surface of the housing in order to prevent them from being flexed outward. Thus, when the trigger button is pressed the spring force forwarded by the plunger does not yet press against the stopper but against the syringe for forwarding it. Consequently, a so called wet injection is avoided, i.e. the liquid medicament is not leaking out of the hollow needle before the needle is inserted. A widened portion is provided in the housing for allowing the syringe holder arms to flex outwards when the syringe holder has nearly reached a maximum proximal position thus allowing the second shoulder to slip through the syringe holder arms and to switch load of the compression spring from the syringe to the stopper. This allows for defining the moment to start injecting the medicament.

(25) A stud may be arranged at the distal end of the plunger. The retraction sleeve may have two or

more resilient arms distally from the end face for holding the stud. The stud and/or the resilient arms have ramp features. Thus the resilient arms may be pushed apart by the stud when the plunger is moved in proximal direction. The activating means comprise a trigger button arranged at the distal end of the auto-injector. The trigger button is axially moveable and has at least two rigid retainers for preventing the resilient arms from being flexed outward when the trigger button is in a maximum distal position. Upon pushing the trigger button in proximal direction the retainers are moved in proximal direction in a manner to allow the resilient arms to be flexed out by the stud biased by the compression spring in proximal direction. Thus the stud is allowed to slip past the resilient arms in proximal direction under load of the compression spring in order to start a needle insertion/injection/retraction cycle. The main advantages of this trigger mechanism are its simplicity, the low part count and a high reliability.

(26) In order to reduce the risk of unintentionally triggering the auto-injector a safety button may be arranged laterally at the housing. The safety button has an interlock for preventing the trigger button from being pushed. The safety button is arranged to pull the interlock outward when operated thus allowing the trigger button to be pushed. For this purpose the safety button may be pivoted in the housing or it may be cast in one piece with the housing in a manner to be pivoted somewhere in the middle so pushing one end inwards causes the other end to be pulled outwards.

(27) Consequently, in order to operate the trigger button the safety button has to be pushed first so the auto-injector cannot be operated unintentionally. Another advantage of the lateral safety button is that the risk of operating the auto-injector in the wrong orientation and injecting into the thumb is reduced.

(28) In a preferred embodiment of the invention a delay box is arranged for slowing down the motion of the retraction sleeve. The latches are arranged to be disengaged by the decoupling member before the stopper has reached a maximum proximal position in the syringe. The apertures are arranged to meet the decoupling arms after the stopper has reached its maximum proximal position by means of the motion of the retraction sleeve. A gap is provided between a front face of the retraction sleeve and the syringe holder in their respective maximum proximal positions. The gap allows the retraction sleeve to travel a distance before retracting the syringe holder so the syringe holder is retracted after the decoupling arms met the apertures.

(29) Triggering the retraction when the stopper exactly reaches the end of its travel is a problem due to tolerances when manufacturing the syringe and stopper. Due to these tolerances the position of the stopper at the end of its travel is not repeatable. Consequently, in some cases the stopper would prematurely bottom out so the retraction would not be triggered at all. In other cases the retraction would be triggered before the stopper bottomed so residual medicament would remain in the syringe.

(30) Releasing the retraction sleeve from the housing a certain amount of time or travel before the stopper bottoms out in the syringe avoids the risk of stalling the retraction by the stopper hitting the end of the syringe prematurely. The damped backward motion of the retraction sleeve due to the delay box allows the plunger and stopper to finish their forward travel so the syringe is entirely emptied. The apertures of the retraction sleeve and the decoupling arms, which are now moving in opposite directions, meet after the stopper and plunger have stopped in order to decouple the decoupling member from the plunger. Due to the gap between the front face and the syringe holder the retraction sleeve is not immediately dragging the syringe back in distal direction when starting to move back. When the retraction sleeve has travelled back far enough to close the gap the stopper has already bottomed out and the plunger has been decoupled from the decoupling member. As soon as the gap is closed the syringe holder, the syringe, the hollow needle and the plunger are dragged back in distal direction.

(31) Thus both problems are solved, reliably retracting the hollow needle to a safe position and fully emptying the syringe which is particularly desirable with expensive drugs. Emptying the syringe is also important for dosage accuracy.

(32) The delay box may comprise a circumferential outer wall with a back collar attached to the housing and a circumferential inner wall with a front collar attached to the retraction sleeve. A volume is defined between the outer wall and inner wall, the volume sealed by the back collar and front collar and filled with a viscous fluid. At least one hole is arranged in the delay box for allowing the viscous fluid to be pushed out as the volume decreases due to motion of the retraction sleeve. This is a particularly simple and cost-efficient way to damp the backward motion of the retraction sleeve.
(33) Usually the hollow needle is equipped with a protective needle shield for keeping the needle sterile and preventing it from being mechanically damaged. The protective needle shield is attached to the needle when the auto-injector or the syringe is assembled.
(34) Preferably a cap is provided at the proximal end of the housing. A sheet metal clip is attached to the cap for joint axial movement and independent rotation. The sheet metal clip is arranged to extend through an orifice into the housing when the cap is attached to the housing. The sheet metal clip comprises at least two barbs snapped into a circumferential notch or behind a shoulder of the protective needle shield. This allows for automatically engaging the sheet metal clip with the protective needle shield during assembly. When the cap is removed from the housing in preparation of an injection the protective needle shield is reliably removed without exposing the user too high a risk to injure themselves.
(35) The cap may be attachable to the housing by a screw connection. This allows for a low force removal of the protective needle shield.
(36) The housing may have at least one viewing window for inspecting the syringe.
(37) The auto-injector may preferably be used for subcutaneous or intra-muscular injection, particularly for delivering one of an analgetic, an anticoagulant, insulin, an insulin derivate, heparin, Lovenox, a vaccine, a growth hormone, a peptide hormone, a proteine, antibodies and complex carbohydrates.
(38) The term “medicament”, 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 proteine, a polysaccharide, a vaccine, a DNA, a RNA, a 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, atherosclerosis 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 complications 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 peptide (GLP-1) or an analogue or derivative thereof, or exedin-3 or exedin-4 or an analogue or derivative of exedin-3 or exedin-4.
(39) 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.
(40) Insulin derivates are for example B29-N-myristoyl-des(B30) human insulin; B29-N-palmitoyl-des(B30) human insulin; B29-N-myristoyl human insulin; B29-N-palmitoyl human insulin; B28-N-myristoyl 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.

(41) 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-Glu-Ala-Val-Arg-Leu-Phe-Ile-Glu-Trp-Leu-Lys-Asn-Gly-Gly-Pro-Ser- Ser-Gly-Ala-Pro-Pro-Pro-Ser-NH2.

(42) 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 [Trp(O2)25, Asp28] Exendin-4(1-39)-Lys6-NH2, H-des Asp28 Pro36, Pro37, Pro38 [Trp(O2)25] Exendin-4(1-39)-NH2, H-(Lys)6-des Pro36, Pro37, Pro38 [Trp(O2)25, Asp28] Exendin-4(1-39)-NH2, H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Trp(O2)25, Asp28] Exendin-4(1-39)-NH2, des Pro36, Pro37, Pro38 [Trp(O2)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2, H-(Lys)6-des Pro36, Pro37, Pro38 [Trp(O2)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2, H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Trp(O2)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2, H-(Lys)6-des Pro36 [Met(O)14, Asp28] Exendin-4(1-39)-Lys6-NH2, des Met(O)14 Asp28 Pro36, Pro37, Pro38 Exendin-4(1-39)-NH2, H-(Lys)6-desPro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-NH2, H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-NH2, des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-(Lys)6-NH2, H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)14, 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, Trp(O2)25, Asp28] Exendin-4(1-39)-Lys6-NH2, H-des Asp28 Pro36, Pro37, Pro38 [Met(O)14, Trp(O2)25] Exendin-4(1-39)-NH2, H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)14, Asp28] Exendin-4(1-39)-NH2, H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)14, Trp(O2)25, Asp28] Exendin-4(1-39)-NH2, des Pro36, Pro37, Pro38 [Met(O)14, Trp(O2)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2, H-(Lys)6-des Pro36, Pro37, Pro38 [Met(O)14, Trp(O2)25, Asp28] Exendin-4(S1-39)-(Lys)6-NH2, H-Asn-(Glu)5-des Pro36, Pro37, Pro38 [Met(O)14, Trp(O2)25, Asp28] Exendin-4(1-39)-(Lys)6-NH2;

or a pharmaceutically acceptable salt or solvate of any one of the afore-mentioned Exedin-4 derivative.

(43) 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, Choriongonadotropin, Menotropin), Somatropine (Somatropin), Desmopressin, Terlipressin, Gonadorelin, Triptorelin, Leuprorelin, Buserelin, Nafarelin, Goserelin.

(44) 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.
(45) 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.
(46) Pharmaceutically acceptable solvates are for example hydrates.
(47) The delay box may be employed with other types of auto-injectors.
(48) The cap with the sheet metal spring may also be applied with other auto-injectors and injection devices.
(49) Further scope of applicability of the present invention will become apparent from the detailed description given hereinafter. However, it should be understood that the detailed description and specific examples, while indicating preferred embodiments of the invention, are given by way of illustration only, since various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art from this detailed description.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
(1) The present invention will become more fully understood from the detailed description given herein below and the accompanying drawings which are given by way of illustration only, and thus, are not limiting of the present invention, and wherein:
(2) FIG. **1** are two longitudinal sections of an auto-injector with a single compression spring for advancing a syringe with a needle, injecting a dose of medicament and retracting the syringe and needle, the auto-injector as-delivered,
(3) FIG. **2** are two longitudinal sections of the auto-injector with the syringe and needle advanced and the dose expelled from the syringe,
(4) FIG. **3** is a perspective sectional view of the auto-injector in the initial state of FIG. **1**,
(5) FIG. **4** is another perspective sectional view of the auto-injector of FIG. **3**, and
(6) FIG. **5** is a detail view of the distal end of the auto-injector with a delay box,
(7) FIG. **6** is a detailed view of the proximal end of the autoinjector showing the cap and needle shield remover.
(8) Corresponding parts are marked with the same reference symbols in all figures.
DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS
(9) FIG. **1** shows two longitudinal sections in different section planes of an auto-injector **1**, the different section planes approximately 90° rotated to each other. The auto-injector **1** comprises an elongate housing **2**. A syringe **3**, e.g. a Hypak syringe, with a hollow needle **4** is arranged in a proximal part of the auto-injector **1**. When the auto-injector **1** or the syringe **3** is assembled a protective needle shield **5** is attached to the needle **4**. A stopper **6** is arranged for sealing the syringe **3** distally and for displacing a liquid medicament M through the hollow needle **4**. The syringe **3** is held in a tubular syringe carrier **7** and supported at its proximal end therein. A single compression spring **8** is arranged in a distal part of the auto-injector **1**. A plunger **9** is arranged for forwarding the spring force of the compression spring **8**.

(10) Inside the housing **2** a retraction sleeve **10** is slidably arranged. Before the injection is triggered as shown in FIG. **1** the retraction sleeve **10** is in a maximum proximal position and prevented from moving in distal direction D by means of stops **11** caught behind latches **12** in the housing **2**. A distal end of the compression spring **8** bears against an end face **13** of the retraction sleeve **10**. Due to the stops **11** and latches **12** the force of the compression spring **8** is thus reacted into the housing **2**. The proximal end of the compression spring **8** bears against a decoupling member **14** arranged around the plunger **9**. Distally from the end face **13** the retraction sleeve has two or more resilient arms **15** for holding a stud **16** and keeping it from being moved in proximal direction P. The stud **16** is arranged at the distal end of the plunger **9**. The stud **16** and the resilient arms **15** have corresponding ramp features for pushing the resilient arms **15** apart in order to allow the stud **16** and the plunger **9** to move in proximal direction P.

(11) The decoupling member **14** comprises a thrust face **17** for bearing against a proximal end of the compression spring **8**. Proximally from the thrust face **17** two or more resilient decoupling arms **18** are provided at the decoupling member **14**, the decoupling arms **18** having inner ramped surfaces bearing against a first shoulder **19** in the plunger **9** in proximal direction P. The resilient decoupling arms **18** are supported by an inner wall of the retraction sleeve **10** in this situation so they cannot flex outward and slip past the first shoulder **19**.

(12) A trigger button **20** is arranged at the distal end D of the auto-injector **1**. The trigger button **20** may be pushed in proximal direction P in order to start an injection. As long as the trigger button **20** is not pushed the resilient arms **15** are caught between two or more retainers **21** arranged at the trigger button **20** so the resilient arms **15** cannot flex outward and the stud **16** although proximally biased by the compression spring **8** cannot slip through.

(13) The syringe carrier **7** is engaged for joint axial movement with a syringe holder **22** which is slidably arranged in the retraction sleeve **10**. The syringe holder **22** is provided with two or more resilient syringe holder arms **23** arranged distally. The syringe holder arms **23** have a respective inclined surface for bearing against a second shoulder **24** in the plunger **9** arranged proximally from the first shoulder **19**. In the initial position shown in FIG. **1** the syringe holder arms **23** are supported by an inner surface of the housing **2** so they cannot flex outward and the second shoulder **24** cannot slip through. In order to support the syringe holder arms **23** at the housing **2** a respective number of apertures are provided in the retraction sleeve **10**.

(14) FIG. **1** shows the auto-injector **1** as-delivered with a cap **25** screwed onto to the proximal end P of the auto-injector **1**. FIG. **6** shows details of the proximal end P with the cap **25**. The cap **25** comprises a sheet metal clip **26** with two or more barbs **27** extending through an orifice into the proximal end P of the auto-injector **1**. The sheet metal clip **26** is mounted to the cap **25** for joint axial movement with respect to a longitudinal axis of the auto-injector **1**. However, the sheet metal clip **26** may rotate independently from the cap **25**. This may be achieved by attaching the sheet metal clip **26** with a hole in its base onto a pin protruding inwardly from the cap **25** and deforming the pin to form a mushroom-shaped closing head **28** so as to prevent the sheet metal clip **26** from being removed while allowing some clearance for the sheet metal clip **26** to rotate. When the cap **25** is screwed onto the proximal P end of the auto-injector **1** the barbs **27** are pushed down the protective needle shield **5** and snap into a circumferential notch arranged in the protective needle shield **5** or behind a shoulder thereof.

(15) When a user wants to operate the auto-injector **1** the first step is to unscrew the cap **25**. Thus the barbs **27** pull the protective needle shield **5** off the syringe **3** in proximal direction P and through the orifice making the syringe **3** ready to be used.

(16) A safety button **29** is arranged laterally at the distal part of the housing **2**. The safety button **29** serves for interlocking with the trigger button **20** in a manner to prevent the trigger button **20** from being inadvertently operated without the safety button **29** being released from a first blocking position.

(17) Consequently, in order to operate the trigger button **20** the safety button **29** has to be pushed

transversally with respect to the longitudinal axis against the force of a spring element **30** which is formed in the safety button **29**. The safety button **29** is pivoted in the middle so pushing the proximal end of the safety button **29** inward pulls an interlock **31** at its proximal end obstructing the trigger button **20** outward so the trigger button **20** can be pushed.

(18) When the trigger button **20** is pushed the retainers **21** are pushed in proximal direction P so the resilient arms **15** are allowed to flex outward. Under load of the compression spring **8** the inclined surfaces of the stud **16** force the resilient arms **15** apart until the stud **16** can slip through.

(19) The second shoulder **24** pushes the syringe holder **22**, syringe carrier **7** and syringe **3** forward while no load is exerted onto the stopper **6**. The hollow needle **4** appears from the proximal end P and is inserted into an injection site, e.g. a patient's skin.

(20) The forward movement continues until the syringe holder **22** bottoms out at a first abutment **32** in the housing **2** (see FIG. **2**). The travel from the initial position (cf. FIG. **1**) up to this point defines an injection depth, i.e. needle insertion depth.

(21) When the syringe holder **22** has nearly bottomed out the resilient syringe holder arms **23** have reached a widened portion **2.1** of the housing **2** where they are no longer supported by the inner wall of the housing **2**. However, since the force required to insert the needle **4** is relatively low the second shoulder **24** will continue to drive forward the syringe holder **22** until proximal travel is halted at the first abutment **32**. At this point the syringe holder arms **23** are flexed out by the continued force of the second shoulder **24** and allow it to slip through. Now the plunger **9** no longer pushes against the syringe holder **22** but against the stopper **6** for expelling the medicament M from the syringe **3** and injecting it into or through the patient's skin.

(22) When the stopper **6** has nearly bottomed out in the syringe **3** (cf. FIG. **2**) the decoupling member **14** has reached a position where it pushes against the latches **12** in a manner to decouple the retraction sleeve **10** from the housing **2**, so the retraction sleeve **10** may slide in distal direction D. Thus the compression spring **8** is no longer grounded with its distal end in the housing **2**. Instead, as soon as the decoupling member **14** has bottomed out at a second abutment **33** the proximal end of the compression spring **8** gets grounded in the housing while the distal end is pulling the retraction sleeve **10** in distal direction D.

(23) Just before the decoupling member **14** decouples the retraction sleeve **10** from the housing **2** the decoupling arms **18** reach an aperture **34** in the retraction sleeve **10** (see FIG. **4**) so they are no longer kept from being flexed outward. The decoupling arms **18** are thus pushed outward by the first shoulder **19** pushing against its ramped surfaces so the first shoulder **19** slips through in distal direction as soon as the decoupling member **14** has hit the second abutment **33**.

(24) The syringe holder **22** is taken along in distal direction D by the retraction sleeve **10**, e.g. by a front face **35**. Thus the syringe **3** and needle **4** are retracted into a safe position inside the housing **2**, e.g. into the initial position. The plunger **9**, no longer bearing against the decoupling arms **18** is pulled back too.

(25) In the distal part of the auto-injector **1** a delay box **36** is arranged (see FIG. **5** for details). The delay box **36** comprises a circumferential outer wall **37** with a back collar **38** attached to the housing **2** and a circumferential inner wall **39** with a front collar **40** attached to the retraction sleeve **10**. A volume between the outer wall **37** and inner wall **39** is filled with a viscous fluid, such as silicon grease. As the retraction sleeve **10** is moved in distal direction D the inner wall **39** glides along the outer wall **37** wherein the back collar **38** and front collar **40** increasingly reduce the volume. One or more holes (not shown) provided in a part of the delay box **36** allow the viscous fluid to be pushed out as the volume decreases. The force required to do this slows down the motion of the retraction sleeve **10**.

(26) The retraction sleeve **10** is released by the decoupling member **14** from the housing **2** a certain amount of time or travel before the stopper **6** bottoms out in the syringe **3** and the distal motion of the retraction sleeve **10** begins. The motion of the retraction sleeve is slowed down by the delay box **36**. Due to a gap **41** between the front face **35** and the syringe holder **22** the retraction sleeve

10 is not yet dragging the syringe back in distal direction D. The plunger **9** is still pushing against the stopper **6** and expelling residual medicament M. As the stopper **6** hits the proximal end of the syringe **3** the stopper **6** and plunger **9** stop while the retraction sleeve **10** is still slowly moving back in distal direction D. The apertures **34** now meet the decoupling arms **18** allowing them to flex out and the plunger **9** to come clear. The retraction sleeve **10** has now travelled back far enough to close the gap **41** so the syringe holder **22**, syringe carrier **7**, syringe **3**, needle **4** and plunger **9** are dragged back in distal direction D.

(27) The cap **25** and the delay box **36** are not restricted to be used with the auto-injector **1** shown in the embodiments. Instead the cap **25** may be combined with any kind of auto-injector with the needle hidden in the housing prior to an injection. The delay box may be combined with any kind of auto-injector for ensuring full delivery of the syringe's contents and reliable triggering of the retraction, irrespective of the spring means or driving means used in the respective auto-injector.

(28) The housing **2** may have at least one viewing window for inspecting the syringe **3**.

(29) The auto-injector **1** may preferably be used for subcutaneous or intra-muscular injection, particularly for delivering one of an analgetic, an anticoagulant, insulin, an insulin derivate, heparin, Lovenox, a vaccine, a growth hormone, a peptide hormone, a proteine, antibodies and complex carbohydrates.

(30) The aforementioned arrangement for coupling the plunger (**9**) to either, the syringe (**3**) or the stopper (**6**), may be applied in any auto-injector having a plunger for forwarding a force of a drive means to a syringe with a stopper. The primary advantage of this arrangement ensures the load from the drive means is not transferred directly to the stopper until the needle is inserted in the patient, thus avoiding a wet injection. The arrangement comprises the syringe holder (**22**) and associated syringe holder arms (**23**), a shoulder (e.g. the second shoulder **24**) on the plunger (**9**), the support of the holder arms (**23**) by an inner surface in order to prevent them from flexing out in a first position and, a widened portion (**2**.**1**) for allowing them to flex radially and to disconnect from the plunger when in a more proximal position. The spring means or other drive means, the ability to retract the syringe or to forward a needle shroud after injection and other features described herein are not required for the prevention of a wet injection.

LIST OF REFERENCES

(31) **1** auto-injector **2** housing **2**.**1** widened portion **3** syringe **4** hollow needle **5** protective needle shield **6** stopper **7** syringe carrier **8** spring means, compression spring **8**.**1** distal end **8**.**2** proximal end **9** plunger **10** retraction sleeve **11** stop **12** latch **13** end face **14** decoupling member **15** resilient arm **16** stud **17** thrust face **18** decoupling arm **19** first shoulder **20** activating means, trigger button **21** retainer **22** syringe holder **23** syringe holder arm **24** second shoulder **25** cap **26** sheet metal clip **27** barb **28** closing head **29** safety button **30** spring element **31** interlock **32** first abutment **33** second abutment **34** aperture **35** front face **36** delay box **37** outer wall **38** back collar **39** inner wall **40** front collar **41** gap D distal end, distal direction M medicament P proximal end, proximal direction

Claims

1. An auto-injector comprising: a housing defining a longitudinal axis extending from a proximal end of the housing to a distal end of the housing, the proximal end of the housing configured to directly contact an injection site, and at least a portion of the housing being cylindrical; a plunger rod comprising an outer protrusion; a syringe holder configured to retain a syringe containing a medicament, the auto-injector being configured such that the syringe holder remains in one position relative to the housing by an engagement between the syringe holder and the plunger rod as a needle shield is removed from a proximal end of the syringe; a compression drive spring disposed around a distal portion of the plunger rod and biasing the plunger rod via the outer protrusion of the plunger rod in a proximal direction relative to the housing; a cap configured to be releasably

attached to the proximal end of the housing to cover an opening at the proximal end of the housing, the auto-injector being configured such that the syringe holder engages the plunger rod to limit proximal movement of the syringe holder relative to the plunger rod when the cap is attached to the proximal end of the housing, the cap being configured such that removal of the cap from the proximal end of the housing removes the needle shield from the proximal end of the syringe; a button disposed at the distal end of the housing; a safety member disposed at a distal portion of the housing, the safety member configured to (i) limit a proximal movement of the button relative to the housing when the safety member is in a first position relative the housing, and (ii) allow the proximal movement of the button relative to the housing when the safety member is in a second position relative the housing, the auto-injector being configured such that after a user moves the safety member from the first position to the second position the user can move the button proximally relative to the housing; and a collar attached to the housing, the collar containing a viscous substance for delaying retraction of a needle of the syringe into the housing, wherein the housing comprises at least one window for viewing the syringe when the syringe is retained by the syringe holder.

2. The auto-injector of claim 1, comprising a decoupling member configured to release a resilient arm from being engaged to a first protrusion, the collar configured to delay retraction of the needle after the resilient arm has been released from being engaged to the first protrusion.

3. The auto-injector of claim 2, wherein the decoupling member and the plunger rod are separate components of the auto-injector.

4. The auto-injector of claim 2, wherein the compression drive spring is located on a distal side of the decoupling member.

5. The auto-injector of claim 2, wherein the compression drive spring is configured to bias the plunger rod and the decoupling member proximally relative to the housing.

6. The auto-injector of claim 2, comprising a sleeve disposed in the housing, a distal end of the sleeve defining a distal opening for the plunger rod, an axially-extending sidewall of the sleeve defining a longitudinal opening for the decoupling member, and the sleeve being a monolithic structure.

7. The auto-injector of claim 6, wherein the distal opening is located concentrically about the longitudinal axis of the housing, and the longitudinal opening is proximal to the distal opening.

8. The auto-injector of claim 1, wherein the button comprises a proximally-extending portion configured to allow the plunger rod to be released from being held in a distal plunger position within the housing.

9. The auto-injector of claim 1, wherein the auto-injector is configured such that the syringe holder remains in the one position by the engagement between the syringe holder and the plunger rod when the cap is attached to the proximal end of the housing.

10. The auto-injector of claim 1, comprising a sleeve disposed in the housing, the sleeve configured to move in a distal direction relative to the housing during needle retraction.

11. An auto-injector comprising: a housing defining a longitudinal axis extending from a proximal end of the housing to a distal end of the housing, the proximal end of the housing configured to directly contact an injection site, and at least a portion of the housing being cylindrical; a plunger rod comprising an outer protrusion; a syringe holder configured to retain a syringe containing a medicament, the auto-injector being configured such that the syringe holder remains in one position relative to the housing by an engagement between the syringe holder and the plunger rod as a needle shield is removed from a proximal end of the syringe; a compression drive spring disposed around a distal portion of the plunger rod and biasing the plunger rod via the outer protrusion of the plunger rod in a proximal direction relative to the housing; a sleeve disposed in the housing; and a cap configured to be releasably attached to the proximal end of the housing to cover an opening at the proximal end of the housing, the auto-injector being configured such that the syringe holder engages the plunger rod to limit proximal movement of the syringe holder relative to the plunger

rod when the cap is attached to the proximal end of the housing, the cap being configured such that removal of the cap from the proximal end of the housing removes the needle shield from the proximal end of the syringe; a collar attached to the housing, the collar containing a viscous substance for delaying retraction of a needle into the housing, wherein the housing comprises at least one viewing window for viewing the syringe when the syringe is retained by the syringe holder.

12. The auto-injector of claim 11, comprising a button comprising a proximally-extending portion configured to allow the plunger rod to be released from being held in a distal position within the housing.

13. The auto-injector of claim 12, comprising a safety member disposed at a distal portion of the housing, the safety member configured to (i) limit a proximal movement of the button relative to the housing when the safety member is in a first position relative the housing, and (ii) allow the proximal movement of the button relative to the housing when the safety member is in a second position relative the housing.

14. The auto-injector of claim 11, wherein a proximal-facing surface of the sleeve that is inside the sleeve is engaged to a distal end the compression drive spring, and a proximal end of the compression drive spring is coupled to the plunger rod via the outer protrusion of the plunger rod such that the plunger rod is proximally biased relative to the sleeve.

15. The auto-injector of claim 11, wherein the auto-injector is configured such that needle retraction does not begin until after a resilient arm has been released from being engaged to a first protrusion of the sleeve.

16. The auto-injector of claim 15, wherein the auto-injector is configured such that the needle retraction does not begin until after the viscous substance has retarded a relative movement within the auto-injector.

17. The auto-injector of claim 15, comprising a decoupling member configured to release the resilient arm from being engaged to the first protrusion.

18. The auto-injector of claim 17, wherein the decoupling member and the plunger rod are separate components of the auto-injector.

19. An auto-injector comprising: a housing defining a longitudinal axis extending from a proximal end of the housing to a distal end of the housing, the proximal end of the housing configured to directly contact an injection site, and at least a portion of the housing being cylindrical; a plunger rod comprising an outer protrusion; a syringe holder configured to retain a syringe containing a medicament, the auto-injector being configured such that the syringe holder remains in a first position relative to the housing by an engagement between the syringe holder and the plunger rod as a needle shield is removed from a proximal end of the syringe; a compression drive spring disposed around a distal portion of the plunger rod and biasing the plunger rod via the outer protrusion of the plunger rod in a proximal direction relative to the housing; a sleeve disposed in the housing, and a collar attached to the housing, the collar containing a viscous substance for delaying needle retraction, wherein the housing comprises at least one viewing window for viewing the syringe when the syringe is retained by the syringe holder.

20. The auto-injector of claim 19, wherein the syringe holder is configured to (i) slide within the sleeve during needle insertion, and (ii) be slidably coupled to the sleeve during needle retraction.

21. The auto-injector of claim 19, wherein the auto-injector is configured such that the sleeve does not axially move relative to the housing until after the viscous substance has retarded a relative movement within the auto-injector.

22. The auto-injector of claim 19, wherein the auto-injector is configured such that the sleeve does not axially move relative to the housing until after a resilient arm has been released from being engaged to a first protrusion of the sleeve.

23. The auto-injector of claim 22, wherein a distal end of the sleeve defines a distal opening located concentrically about the longitudinal axis of the housing, and an axially-extending sidewall of the

sleeve defines a longitudinal opening.
24. The auto-injector of claim 23, wherein the sleeve is a monolithic structure.
25. The auto-injector of claim 23, wherein the longitudinal opening is sized to allow a decoupling member to extend through the longitudinal opening for allowing a proximal-facing surface of the decoupling member to engage a distally-facing surface of the resilient arm to release the resilient arm from being engaged to the first protrusion.
26. The auto-injector of claim 25, wherein the decoupling member and the plunger rod are distinct components of the auto-injector.
27. The auto-injector of claim 19, comprising a cap configured to be releasably attached to a proximal end of the housing to cover an opening at the proximal end of the housing, the auto-injector being configured such that the syringe holder engages the plunger rod to limit proximal movement of the syringe holder relative to the plunger rod when the cap is attached to the proximal end of the housing.
28. An auto-injector comprising: a housing defining a longitudinal axis extending from a proximal end of the housing to a distal end of the housing, the proximal end of the housing configured to directly contact an injection site; a syringe holder configured to retain a syringe containing a medicament, the auto-injector being configured such that the syringe holder remains in a first position relative to the housing as a needle shield is removed from a proximal end of the syringe; and a collar attached to the housing, the collar containing a viscous substance for delaying needle retraction, wherein the housing comprises at least one viewing window for viewing the syringe when the syringe is retained by the syringe holder.
29. The auto-injector of claim 28, comprising a sleeve configured to releasably hold a plunger rod of the auto-injector in a distal plunger position within the housing against a biasing force of a compression drive spring.
30. The auto-injector of claim 29, comprising a cap configured to be releasably attached to the proximal end of the housing to cover the proximal end of the housing, the cap being configured such that removal of the cap from the proximal end of the housing removes the needle shield from the proximal end of the syringe, and the auto-injector is configured such that the syringe holder engages the plunger rod to limit proximal movement of the syringe holder relative to the plunger rod when the cap is attached to the proximal end of the housing.