Description

Drive mechanism for a drug delivery device and drug delivery device

The present invention relates to a drive mechanism for a drug delivery device, especially for a device that is designed for the delivery of fixed doses.

Portable drug delivery devices are used for the administration of a drug that is suitable for self-administration by a patient. A drug delivery device is especially useful in the shape of a pen, which can be handled easily and kept everywhere available. A drug is delivered by means of a drive mechanism, which may also serve to set the dose to be delivered. A type of drug delivery device is constructed to be refillable and thus reusable many times.

DE 102 37 258 B4 describes a drug delivery device in the shape of an injection pen, which has a drive mechanism with elements that are rotated relatively to one another around a common axis.

It is an object of the present invention to disclose a new drive mechanism for a drug delivery device and a drug delivery device comprising a new drive mechanism.

This object is achieved by a drive mechanism according to claim 1 and a drug delivery device according to claim 10. Further objects are achieved by embodiments according to the dependent claims.

The drive mechanism for a drug delivery device comprises a lead screw, a lead screw nut and a drive member, aligned with an axis defining an axial direction and an opposite axial direction. A coupling between the lead screw and the lead screw nut allows a helical movement of the lead screw with respect to the lead screw nut at least in the axial direction. The lead screw is coupled with the drive member, the coupling generating a helical movement of the lead screw with respect to the drive member when the drive member is moved in the axial direction with respect to the lead screw. The coupling is

overridden to prevent a helical movement of the lead screw with respect to the drive member when the drive member is moved in the opposite axial direction with respect to the lead screw. A dispense stop feature of the lead screw nut and a dispense stop feature of the drive member interact and thereby prevent the generation of the helical movement of the lead screw when a specified end position of the drive member is approached.

In an embodiment of the drive mechanism the dispense stop features have corresponding contact surfaces, which are oblique to the axis.

Preferably, a generation of the helical movement of the lead screw is prevented by an interaction of the oblique contact faces. As an example, an interaction comprises a sliding movement of at least one of the oblique contact faces on the other oblique contact face. In particular, the drive mechanism may be configured such that the oblique contact face of the dispense stop feature of the drive member is enabled to slide along the oblique contact face of the dispense stop feature of the lead screw nut. Thereby, a rotation of the drive member may be caused, in particular a rotation of the drive member relative to the lead screw nut. An inclination of at least one of the oblique contact faces may correspond to the pitch of a thread of the drive member engaging with the lead screw.

In a further embodiment of the drive mechanism the dispense stop features have corresponding contact surfaces, which are provided as end faces and inhibit a rotation of the drive member with respect to the lead screw nut at least in one direction.

In a further embodiment of the drive mechanism the dispense stop feature of the lead screw nut has the shape of a prism or truncated prism.

In a further embodiment of the drive mechanism the dispense stop features guide the drive member with respect to the lead screw nut in a helical movement having the same pitch as the helical movement of the lead screw with respect to the drive member.

As an example, such a movement may be generated by the interaction of oblique contact faces of the dispense stop features, in particular by the interaction of oblique contact faces having an inclination corresponding to a pitch of a thread of the drive member engaging with the lead screw.

A further embodiment of the drive mechanism comprises a flexible guide feature of the lead screw and a screw thread of the drive member. The coupling of the lead screw with the drive member is provided by the flexible guide feature engaging the screw thread. The screw thread has the same pitch as the helical movement of the lead screw with respect to the drive member.

A further embodiment of the drive mechanism comprises stop features of the lead screw, which inhibit the helical movement of the lead screw when the drive member is moved in the opposite axial direction with respect to the lead screw.

In a further embodiment of the drive mechanism the dispense stop feature of the lead screw nut is formed as an integral part of the lead screw nut, and the dispense stop feature of the drive member is formed as an integral part of the drive member.

In a further embodiment of the drive mechanism the drive member and the lead screw nut are rotationally locked.

A drug delivery device that is provided with the drive mechanism may comprise a body, which has a distal end and a proximal end, which are spaced apart in the direction of the axis of the drive mechanism.

The body can be any housing or any component that forms part of a housing, for example. The body can also be some kind of an insert connected with an exterior housing. The body may be designed to enable the safe, correct, and/or easy handling of the device and/or to protect it from harmful liquids, dust or dirt. The body can be unitary or a multipart component of tubular or non-tubular shape. The body may house a

cartridge, from which doses of a drug can be dispensed. The body can especially have the shape of an injection pen.

The term "distal end" refers to a part of the body or housing which is intended to be arranged at a portion of the drug delivery device from which a drug is dispensed. The term "proximal end" refers to a part of the body or housing which is remote from the distal end. The term "distal direction" refers to a movement in the same direction as a movement from the proximal end towards the distal end, not specifying a point of departure nor an end point, so that the movement may go beyond the distal end. The term "proximal direction" refers to a movement in the direction opposite to the distal direction.

The term "lead screw" encompasses any element, whether unitary or of multipart construction, that is provided to transfer a movement to a piston, thus working as a piston rod, especially for the purpose of dispensing a drug. The lead screw may be flexible or not.

The drive mechanism can be used to expel a drug from a receptacle or cartridge inserted in the body of a drug delivery device. The drug delivery device can be a disposable or re-usable device designed to dispense a dose of a drug, especially a liquid, which may be insulin, a growth hormone, a heparin, or an analogue and/or a derivative thereof, for example. The drug may be administered by a needle, or the device may be needle-free. The device may be further designed to monitor physiological properties like blood glucose levels, for example. Each time the lead screw is shifted in the distal direction with respect to the body, a certain amount of the drug is expelled from the drug delivery device.

The term “drug“, as used herein, preferably 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, 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.

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-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.

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.

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.

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.

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.

In the following, a more detailed description of examples and embodiments of the drive mechanism is given in conjunction with the appended figures.

FIG. 1 shows a perspective view of a cross-section of an injection pen comprising an embodiment of the drive mechanism.

FIG. 2 shows a detailed view of the dispense stop features of the drive member and the lead screw nut.

FIG. 3 shows an enlarged view of the distal end of the lead screw.

FIG. 1 shows a cut-away view of an injection pen comprising the drive mechanism. The drive mechanism is arranged in a body 1 having a distal end 2 and a proximal end 3. A lead screw 5 is arranged along an axis 4 of the device. A screw thread 6 of the lead screw 5 is coupled to a drive feature of a lead screw nut 7 engaging the screw thread 6, in order to guide a helical movement of the lead screw 5 with respect to the lead screw nut 7. In further embodiments, the screw thread and the drive feature can be reversed such that the lead screw is provided with discrete drive features and the lead screw nut is provided with a helical screw thread. The lead screw nut 7 is rotationally locked to the body 1.

The embodiment shown in FIG. 1 comprises a drive member 8, which can be operated by the user by means of a button 9, which is arranged at the proximal end 3 and juts out of the body 1. The drive member 8 is coupled or engaged with the lead screw 5. This is achieved, in this embodiment, by means of a screw thread 18 of the drive member 8 and a flexible guide feature 15 of the lead screw 5. The drive member 8 can especially be a drive sleeve of essentially cylindrical shape, the axis of the drive sleeve being arranged parallel to the axis 4 of the device. The lead screw 5 may be disposed to enter the drive member 8.

A removable and attachable part 11 of the body 1 may be provided as a cartridge holder. When this part 11 is removed from the rest of the body 1, a cartridge 12 can be inserted. When the part 11 is attached to the body 1, the lead screw 5 is brought into contact with a piston 13, which is provided to expel a drug from the cartridge 12. A bearing 14 may be arranged between the lead screw 5 and the piston 13 in order to prevent any

damage that might be caused by a relative movement between the lead screw 5 and the piston 13. The lead screw 5 functions as a piston rod to advance the piston 13 in the distal direction.

During a delivery operation, the lead screw 5 is helically moved in the distal direction with respect to the body 1. The lead screw 5 is guided by the lead screw nut 7, which is engaged with the screw thread 6 of the lead screw 5. Stop features 17 (shown in FIG. 3 described below) are provided in the screw thread 6 of the lead screw 5 to enable a set operation, by which a fixed dose that is to be dispensed can be preset. For this purpose, the drive member 8 is drawn in the proximal direction relatively to the body 1 and to the lead screw 5. The drive member 8 is coupled with the lead screw 5. In the embodiment shown in FIG. 1, the coupling is achieved with the screw thread 18 of the drive member 8 and the flexible guide feature 15 of the lead screw 5. During the set operation, the lead screw 5 must not be moved. Therefore, the engagement between the drive member 8 and the lead screw 5 is temporarily released during the set operation. This may be achieved by a deformation of the flexible guide feature 15 to override the screw thread 18 of the drive member 8. In spite of the engagement between the drive member 8 and the lead screw 5, the drive member 8 can therefore be moved without being rotated, while the lead screw 5 stays stationary with respect to the body. Overriding the engagement between the drive member 8 and the lead screw 5 is facilitated by flexible guide features 15, which can be bent towards the central axis 4. A rotation of the drive member 8 with respect to the body 1 may be prevented by guide features 10, which may be protruding elements of the body 1 engaging an axial groove in the outer surface of the drive member 8, for instance.

After the drive member 8 has been moved a distance corresponding to the pitch of the screw thread 18 of the drive member 8, the flexible guide feature 15 of the lead screw 5 reengages the screw thread 18 of the drive member 8, and the user can advance the lead screw 5 by pushing the drive member 8 back in the distal direction. This method of operation by disengaging and reengaging the lead screw 5 with the drive member 8 relies entirely on the lead screw 5 remaining substantially stationary during the setting operation. Should the lead screw 5 rotate or move axially during setting, then the drive

member 8 would very likely not correctly reengage with the lead screw 5 and thus cause dose inaccuracy. Therefore, the lead screw nut 7 guiding the helical movement of the lead screw 5 with respect to the body 1 is rotationally locked to the body 1 at least during the dispense operation and, furthermore, the lead screw 5 is provided with stop features interfering with the rotation of the lead screw 5 in such a manner that the rotation is inhibited in the positions of the lead screw 5 which are obtained after the drug delivery and before the setting of a new dose. The rotation of the lead screw 5 is thus locked with respect to the lead screw nut 7, and the lead screw nut 7 is prevented from rotating relatively to the body 1. Therefore, when the drive member 8 is drawn in the proximal direction, the relative linear motion between the drive member 8 and the lead screw 5 causes the engagement of the drive member and the stationary lead screw 5 to be overridden and thus the engagement between the drive member 8 and the lead screw 5 to be released. The stop features are therefore preferably arranged at least on the distal sidewall of the screw thread 6 of the lead screw 5, while the screw thread 6 may be smooth, forming a helix, on its proximal sidewall. When the drive member 8 is pushed in the distal direction, a guide means of the lead screw nut 7 engaging the screw thread 6 of the lead screw 5 stays in contact with the smooth proximal sidewall of the screw thread 6, thus enabling a smooth helical movement of the lead screw 5 sliding through the opening of the lead screw nut 7. Therefore, the stop features do not interfere with the relative motion of the lead screw 5 with respect to the lead screw nut 7 during the dispense operation.

The stop features may especially be provided by recesses of a helical groove forming the screw thread 6 of the lead screw 5. The recesses can have contact faces arranged transverse to the axis 4 and interrupting the smooth helix of the relevant sidewall of the groove forming the screw thread 6. The contact faces may especially be flat portions, essentially perpendicular to the axis 4 or at least having zero helix angle, but may comprise a rake angle in the radial direction. A drive feature of the lead screw nut 7 may be formed in such a manner that it enters the recesses and stops on the contact face. When the drive feature of the lead screw nut 7 comes into contact with one of the flat portions, the generally perpendicular orientation of the flat portion with respect to the axis 4 causes the guidance of the helical movement of the lead screw 5 with respect to

the body 1 to be stopped. It may be favorable if the drive feature of the lead screw nut 7 that engages with the screw thread 6 of the lead screw 5 and is stopped in the recesses is made up of one or more individual drive features and is not formed by a completely continuous helix. The stop features are arranged in such a fashion that, after a dose of the drug has been fully delivered and the device is ready for the next dose to be set, one of the stop features is in a position ready to stop the rotation of the lead screw 5 when the drive member 8 is pulled in the proximal direction. The axial load exerted on the lead screw 5 is then compensated by the drive feature of the lead screw nut 7 engaging the relevant stop feature, particularly contacting the essentially flat portion of the relevant recess. This acts to lock the rotation of the lead screw 5 rather than rotate it, because the lead screw nut 7 is rotationally locked to the body 1 at least during the operations of setting and dispensing a dose. Essentially, the flat surfaces on the screw thread 6 are designed to prevent a back-driving of the lead screw 5 during a set operation. The motion of the lead screw 5 may thereby be restricted to the distal direction.

FIG. 2 shows an enlarged detailed view of the arrangement of the lead screw nut 7 and the drive member 8. In the embodiment shown in FIG. 2, the dispense stop feature 19 of the lead screw nut 7 has the shape of a truncated prism. A surface of the dispense feature 19 is oblique to the axis 4 and faces a corresponding dispense stop feature 20 of the drive member 8, which is provided with a triangular recess matching the dispense stop feature 19 of the lead screw nut 7. This shape of the dispense stop features 19, 20 is especially favourable, because both a rotation and a purely axial movement of the drive member 8 are inhibited. The dispense stop features 19, 20 thus help to ensure that accurate doses of the drug are dispensed with each device actuation. To achieve accurate doses, it is essential that the axial and rotational position of the drive member 8 relative to the lead screw nut 7 is identical at the end of each dose delivery. The geometry of the dispense stop features 19, 20 is designed to achieve this.

In the embodiment according to FIG. 2, the dispense stop features 19, 20 present the shape of right-angled triangles, with the hypotenuse of each triangle arranged oblique to the axis 4 and matching the helix angle of the internal thread 18 of the drive member 8,

thus forming corresponding contact surfaces 22, which are oblique to the axis 4. The surfaces that correspond to a side of the triangle are arranged along the axis 4 and are provided as end faces 23 to inhibit a rotation of the drive member 8 with respect to the lead screw nut 7 in the direction of rotation of the lead screw 5 during the drug delivery. This means that as the drive member 8 axially engages with the lead screw nut 7 by means of the dispense stop features 19, 20, it is guided along a helical path until the end faces 23 of the triangular dispense stop features 19, 20 engage, thus ensuring that the end position of the drive member 8 is accurately controlled both axially and rotationally. Because the angle of the hypotenuse 22 of the triangular dispense stop features 19, 20 matches the helix angle of the thread 18 of the drive member 8, this also ensures that the lead screw 5 will not be moved by the drive member 8 when the dispense stop features 19, 20 are in contact. When the drive member 8 approaches its specified end position, the dispense stop features 19, 20 force the movement of the drive member 8 into a helix that matches the helix of the thread 18, so that the movement of the drive member 8 does not change the position of the lead screw 5. The end of the drug delivery is thus very precisely determined.

FIG. 2 shows an axial opening of the lead screw nut 7. This opening or gap can be used as a guide feature 21, which may provide the rotational locking of the lead screw nut 7 with respect to the body 1, for example. Instead, other locking means may be provided.

FIG. 3 shows an enlarged detailed view of the distal end of the lead screw 5. In this embodiment the lead screw 5 comprises a screw thread 6 and a further screw thread 16, which are intertwined and are provided with separate entries ("two-start" thread). The lead screw nut 7 engages the screw threads 6, 16 of the lead screw 5. Stop features 17 may be provided on one screw thread 6 or on both screw threads 6, 16. The pitch of the screw threads 6, 16 can be adapted to the pitch of the thread 18 of the drive member 8 in order to provide a desired ratio of the speeds of advancement of the lead screw 5 and the drive member 8.

The dispense stop features 19, 20 of the lead screw nut 7 and the drive member 8 improve the dose accuracy and prevent an incorrect dosage, which might occur

because of mechanical play of the device components. As the dispense stop features 19, 20 can be formed as integral parts of the lead screw nut 7 and the drive member 8, the manufacturing is facilitated and no additional components are necessary.

Reference numerals

1 body
2 distal end
3 proximal end
4 axis
5 lead screw
6 screw thread
7 lead screw nut
8 drive member
9 button
10 guide feature
11 removable and attachable part of the body
12 cartridge
13 piston
14 bearing
15 flexible guide feature
16 dispense stop feature
17 stop feature
18 screw thread
19 dispense stop feature
20 dispense stop feature
21 guide feature
22 contact surface
23 end face

Claims

1. A drive mechanism for a drug delivery device, comprising:
– a lead screw (5), a lead screw nut (7) and a drive member (8), aligned with an axis (4) defining an axial direction and an opposite axial direction,
– a coupling between the lead screw (5) and the lead screw nut (7) allowing a helical movement of the lead screw (5) with respect to the lead screw nut (7) at least in the axial direction,
– the lead screw (5) being coupled with the drive member (8), the coupling generating a helical movement of the lead screw (5) with respect to the drive member (8) when the drive member (8) is moved in the axial direction with respect to the lead screw (5), and the coupling being overridden to prevent a helical movement of the lead screw (5) with respect to the drive member (8) when the drive member (8) is moved in the opposite axial direction with respect to the lead screw (5),
– a dispense stop feature (19) of the lead screw nut (7), and
– a dispense stop feature (20) of the drive member (8),
– the dispense stop features (19, 20) interacting and thereby preventing the generation of the helical movement of the lead screw (5) when the drive member (8) approaches a specified end position.

2. The drive mechanism according to claim 1, wherein
the dispense stop features (19, 20) have corresponding contact surfaces (22), which are oblique to the axis (4).

3. The drive mechanism according to claim 1 or 2, wherein
the dispense stop features (19 ,20) have corresponding end faces (23), which inhibit a rotation of the drive member (8) with respect to the lead screw nut (7) at least in one direction.

4. The drive mechanism according to one of claims 1 to 3, wherein the dispense stop feature (19) of the lead screw nut (7) has the shape of a prism or truncated prism.

5. The drive mechanism according to one of claims 1 to 4, wherein the dispense stop features (19, 20) guide the drive member (8) with respect to the lead screw nut (7) in a helical movement having the same pitch as the helical movement of the lead screw (5) with respect to the drive member (8).

6. The drive mechanism according to one of claims 1 to 5, further comprising:
a flexible guide feature (15) of the lead screw (5), and
a screw thread (18) of the drive member (8),
the coupling of the lead screw (5) with the drive member (8) being provided by the flexible guide feature (15) engaging the screw thread (18), and
the screw thread (18) having the same pitch as the helical movement of the lead screw (5) with respect to the drive member (8).

7. The drive mechanism according to one of claims 1 to 6, further comprising:
stop features (17) of the lead screw (5),
the stop features (17) inhibiting the helical movement of the lead screw (5) when the drive member (8) is moved in the opposite axial direction with respect to the lead screw (5).

8. The drive mechanism according to one of claims 1 to 7, wherein
the drive member (8) and the lead screw nut (7) are rotationally locked.

9. The drive mechanism according to one of claims 1 to 8, wherein
the dispense stop feature (19) of the lead screw nut (7) is formed as an integral part of the lead screw nut (7), and
the dispense stop feature (20) of the drive member (8) is formed as an integral part of the drive member (8).

10. A drug delivery device, comprising:

– a drive mechanism according to one of claims 1 to 9, and

– a body (1) having a distal end (2) and a proximal end (3), which are spaced apart in the direction of the axis (4).