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, which are 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 first axial direction. The drive member is rotationally locked with the lead screw nut. 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. Spline features are arranged on the lead screw in at least one row parallel to the axis with alternatingly small and large gaps between succeeding spline features. The drive member comprises a stop feature, which faces the lead screw and has a dimension in the direction of the axis which is larger than the small gaps and at most as large as the large gaps.

An embodiment of the drive mechanism may comprise a further screw thread of the lead screw, the screw thread and the further screw thread having the same pitch and being intertwined.

In a further embodiment of the drive mechanism the spline features are each arranged adjacent to the screw thread or adjacent to the further screw thread.

In a further embodiment of the drive mechanism the spline features are protruding elements of 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 flexible guide feature of the lead screw and the screw thread of the drive member provide the coupling of the lead screw with the drive member.

A further embodiment of the drive mechanism comprises stop features of the lead screw. The stop features 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 at least some of the spline features are arranged adjacent to the stop features of the lead screw.

In a further embodiment of the drive mechanism the drive member is a drive sleeve, and the lead screw passes through the drive member. The stop feature of the drive member is a protruding element or two separate protruding elements or a plurality of separate protruding elements located on an inner sidewall of the drive member.

In a further embodiment of the drive mechanism the spline features are arranged in at least two rows parallel to the axis. The rows are equi-spaced around the circumference of the lead screw.

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.

In an embodiment of the drug delivery device a guide feature of the drive member prevents a rotation of the drive member with respect to the body. The lead screw nut is rotationally locked with the body, and the drive member is thus rotationally locked with the lead screw nut.

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 cross-section of an injection pen comprising an embodiment of the drive mechanism.

FIG. 2 shows a perspective view of the lead screw.

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

FIG. 4 shows the arrangement of the lead screw and the drive member.

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, 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 rotate 5 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 perspective view of an embodiment of the lead screw 5. The lead screw 5 comprises a screw thread 6 and may comprise at least one further screw thread 16. If a further screw thread 16 is provided, the screw thread 6 and the further screw thread 16 have the same pitch and are intertwined. This means that the lead screw 5 has two co-axial helical features with separate entries at or near the distal end of the lead screw 5. The screw thread 18 of the drive member 8 may also have two separate co-axial helical features, which are intertwined. The shape of the flexible guide feature 15 at the proximal end of the lead screw 5 is adapted to the screw thread 18 of the drive member 8. The flexible guide feature 15 may especially comprise two co-axial helical male thread features provided to engage helical groves, which may form the screw thread 18 of the drive member 8. If there are two co-axial helical features of the screw thread 18, there may be two separate parts of the flexible guide feature 15, each of the parts engaging one of the helical features. The flexible guide feature 15 can be deformed and thus disengaged from the screw thread 18 of the drive member 8. This allows the coupling between the lead screw 5 and the drive member 8 to be temporarily overridden when the drive member 8 is pulled in the proximal direction.

The lead screw 5 is provided with spikes or spline features 25, which are preferably arranged in a regular sequence. In the embodiment according to FIG. 2 there are three rows 20 of spline features 25 arranged parallel to the axis 4. The spline features 25 are located mainly in the region of the screw threads 6, 16 at the distal end of the lead screw 5. The rows 20 are spaced at 120° to each other around the circumference of the lead screw 5. The spacing may instead vary, or there may be another number of rows 20 of spline features 25. The spline features 25 are provided to interact with a stop

feature 19 (shown in FIG. 4 and described below) on an internal surface of the drive member 8 which faces the lead screw 5.

The stop feature 19 may be a single protruding element, for instance, or may instead comprise two or more separate elements. The stop feature 19 helps to prevent the lead screw 5 from rotating when a dose is being set. Each row 20 of spline features 25 may comprise a series of positive protrusions that are positioned between the helical grooves of the screw threads 6, 16. As a result, there are gaps between the spline features 25. Every second gap between the spline features 25 is large enough to allow the corresponding stop feature 19 on the internal surface of the drive member 8 to pass through during dispensing of a dose. The spline features 25 can also serve the further function of extending the line of contact between the lead screw 5 and the lead screw nut 7 at the transition between the helical thread sections and the stop features 17 of the screw threads 6, 16. This reduces the risk of deformation, particularly of the lead screw nut 7, in this region under high dispensing loads.

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. The stop features 17 of the screw threads 6, 16 may be arranged in such a manner that their proximal surfaces extend continuously into the spline features 25 of at least one of the rows 20 of spline features 25, as can be seen from FIG. 3. The screw threads 6, 16 may be arranged at distances from one another that correspond to the different gaps between succeeding spline features 25. The spline features 25 may thus be arranged adjacent to the grooves of the screw threads 6, 16 and may especially be formed integrally with the stop features 17 of the screw threads 6, 16. Instead, only one screw thread 6 or more than two screw threads may be provided on the lead screw 5. In this case the spline features 25 are arranged along the rows 20 with the gaps between succeeding spline features 25 being alternatingly small and large, irrespective of the location of a helical groove of the thread.

The larger gaps are provided to permit the stop feature 19 of the drive member 8 to pass through while a drug is being dispensed and the lead screw 5 is helically moved with respect to the drive member 8. The smaller gaps are sufficiently small to prevent the stop feature 19 of the drive member 8 to pass through when the drive member 8 is pulled in the proximal direction to set a dose. In this case the spline features 25 slide along the stop feature 19 of the drive member 8. This helps to prevent a rotation of the lead screw 5 with respect to the drive member 8, which is rotationally locked with the body 1 and the lead screw nut 7. Consequently the lead screw 5 does not rotate with respect to the body 1 and the lead screw nut 7 either.

FIG. 4 shows the arrangement of the lead screw 5 and the drive member 8, which is a drive sleeve surrounding the lead screw 5 in this embodiment. The distal end of the lead screw 5 juts out of the drive member 8. The stop feature 19 is located on an inner sidewall of the drive member 8 and may be a protruding element, for instance, or two separate protruding elements or a plurality of separate protruding elements. The stop feature 19 is preferably an integral part of the drive member 8 and is formed in the inner sidewall. The axial dimension of each element of the stop feature 19 is sufficiently small to allow the element to pass between two neighbouring spline features 25, if the gap between them is large. In a rest position that is occupied by the drive member 8 with respect to the lead screw 5 after a dose has been dispensed, the stop feature 19 is at a position near two spline features 25 that are separated by a small gap. If the next dose is to be set and the drive member 8 is pulled in the proximal direction with respect to the body 1, the rotation of the lead screw 5 is inhibited by the stop feature 17 of the screw thread 6, which engages with the drive feature of the lead screw nut 7. Therefore the stop feature 19 of the drive member 8 moves axially into a position adjacent to a spline feature 25, comes into contact with the spline feature 25, and slides along the spline feature 25 while the drive member 8 is further moved relatively to the lead screw 5 in the proximal direction. The spline feature 25 prevents the stop feature 19 of the drive member 8 from moving around the circumference of the lead screw 5 transversally to the axis 4 and thus prevents a rotation of the lead screw 5 with respect to the drive member 8. When the stop feature 19 has passed the first spline feature 25, it slides in the same way axially along the following spline feature 25 of the same row 20, because

the gap between the spline features 25 is small and does not allow the stop feature 19 to pass between the spline features 25. After the dose has been set, the stop feature 19 of the drive member 8 is at a position from which it enters the large gap that is present between the neighbouring spline features 25, when the drive member 8 is pushed in the distal direction and a helical movement of the lead screw 5 is generated. An arrangement of a plurality of spline features 25 along the lead screw 5 is preferred because it always provides neighbouring spline features 25 serving the purpose described above, irrespective of the position of the lead screw 5, which is advanced farther in the distal direction each time a dose is dispensed.

The design of the spline features 25 may deviate from the shape that is shown in the figures by way of example. The spline features 25 are arranged according to their purpose of either preventing a rotation of the lead screw 5 or enabling a helical movement of the lead screw 5, depending on the operation of the drive member 8. The embodiment shown in the figures has the advantage that the arrangement of the spline features is adapted to the location of the helical grooves and the manufacturing of the device component is facilitated.

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 further screw thread
17 stop feature
18 screw thread
19 stop feature
20 row of spline features
25 spline feature

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 drive member (8) being rotationally locked with the lead screw nut (7),
– 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),
– spline features (25) of the lead screw (5), the spline features (25) being arranged in at least one row (20) parallel to the axis (4) with alternatingly small and large gaps between succeeding spline features (25), and
– a stop feature (19) of the drive member (8), the stop feature (19) facing the lead screw (5), a dimension of the stop feature (19) in the direction of the axis (4) being larger than the small gaps and at most as large as the large gaps.

2. The drive mechanism according to claim 1, further comprising:
a further screw thread (16) of the lead screw (5), the screw thread (6) and the further screw thread (16) having the same pitch and being intertwined.

3. The drive mechanism according to claim 2, wherein
the spline features (25) are each arranged adjacent to the screw thread (6) or adjacent to the further screw thread (16).

4. The drive mechanism according to one of claims 1 to 3, wherein the spline features (25) are protruding elements of the lead screw (5).

5. The drive mechanism according to one of claims 1 to 4, further comprising:
a flexible guide feature (15) of the lead screw (5), and
a screw thread (18) of the drive member (8),
the flexible guide feature (15) of the lead screw (5) and the screw thread (18) of the drive member (8) providing the coupling of the lead screw (5) with the drive member (8).

6. The drive mechanism according to one of claims 1 to 5, 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).

7. The drive mechanism according to claim 6, wherein
at least some of the spline features (25) are arranged adjacent to the stop features (17) of the lead screw (5).

8. The drive mechanism according to one of claims 1 to 7, wherein
the drive member (8) is a drive sleeve, the lead screw (5) passing through the drive member (8), and
the stop feature (19) of the drive member (8) is a protruding element or two separate protruding elements or a plurality of separate protruding elements located on an inner sidewall of the drive member (8).

9. The drive mechanism according to one of claims 1 to 8, wherein
the spline features (25) are arranged in at least two rows (20) parallel to the axis (4), the rows (20) being equi-spaced around a circumference of the lead screw (5).

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).

11. The drug delivery device according to claim 10, further comprising:
a guide feature (10) of the drive member (8), the guide feature (10) preventing a rotation of the drive member (8) with respect to the body (1), and
the lead screw nut (7) being rotationally locked with the body (1), the drive member (8) thus being rotationally locked with the lead screw nut (7).