Description

The invention relates to a portable appliance for the intradermal or subcutaneous injection of a liquid formulation of an active principle, having a supply vessel for the formulation, an injection needle adapted to communicate with the vessel, pump means for emptying the vessel through the injection needle and securing means for securing the appliance to an appropriate part of the patient's body.

There has for some time clearly been a need for small, compact and portable injection appliances which can be worn on a suitable part of the body and which deliver, preferably subcutaneously, accurately defined quantities of active principles into the body over prolonged periods of time. Various devices of this kind, which have considerable advantages over the conventional subcutaneous syringe, are already known. In conventional subcutaneous injection a so-called bolus of an active principle is introduced into the body and must gradually be adsorbed there and distributed in the body. This distribution depends to a considerable extent on the physiological circumstances of the individual and is therefore uncontrollable. Appliances which deliver an active principle continuously over a prolonged period of time have on the other hand the advantage that an accurate control suited to the body's requirements is possible. Indeed, it is possible to alternate phases of active principle delivery with phases in which no active principle is delivered. A physiologically adapted delivery of this kind is especially advantageous in the case of highly active substances such as, for example, insulin, interferon and the like.

Known appliances of this kind usually have a vessel which contains the active principle and with which an injection needle communicates. The contents of the vessel are delivered to the body by pump means over a predetermined period of time. An example of such an appliance is described in DE 3121888. The appliance contains a supply vessel in the form of a hose which is emptied by a clockwork-driven squeezing roller through an injection needle connected to the end of the hose. The injection needle pierces the skin tissue some distance away from the appliance. The appliance can be worn on the wrist like a wristwatch. A different solution is described in U.S. Patent 4,552,561. This appliance can be stuck to the skin and carries the injection needle on its underside, so that the penetration site is covered while the appliance is in use. In this appliance the needle must also pierce the skin tissue. Not only in the case of the conventional subcuta-

neous bolus injections, but also in the case of the mentioned newer subcutaneous injection appliances the introduction of the injection needle is the primary problem. Medical laymen usually have insufficient experience in placing such a needle correctly and have a fully justified inhibition because of the pain to be expected.

It is the object of the invention to provide a portable injection appliance of the kind mentioned, which does not have the disadvantages associated with known appliances and which can be used readily, especially by medical laymen.

In accordance with the invention this is achieved by an appliance of the kind mentioned earlier, which is characterized by a needle driving means for shooting the needle into the patient's skin.

The appliance can also comprise flow control means with which the delivery of active principle can either be kept constant or can be carried out according to a predetermined profile.

According to a further feature of the invention, the appliance is in two parts, of which one part having the more valuable elements can be used several times and the other part as an expendable item can be discarded after being used once.

The vessel for the active principle or the solution of the active principle can be, for, example, simply a part of the appliance casing, in which case a chamber is separated by an appropriate membrane of elastomers, metals and the like in single or multilayer arrangement. Another possibility for a supply vessel is a closed vessel, again of elastomers, metals and the like, for example in the form of bellows. Another solution for the supply vessel is a squeezable hose as is referred to, for example, in the introduction hereof. Still a further possibility is a plunger syringe whose cylinder is operative as the supply vessel. Finally, an absorbent material like a sponge can be used to take up the active principle. More than one separate supply vessel or chamber can be provided, for example where two active principles have to be injected or when an active principle lyophilizate and a reconstituting solvent are used. Various forms of energy come into consideration for driving the pump means which empties the vessel. Thus, for example, the pump can be gas-operated, in which event the pressure required to empty the can be produced by electrolysis, photolysis or chemical reactions and finally also by propellant vapours such as Freon etc. Another possibility is to

produce the requisite pressure by ordinary osmosis or electro-osmosis. In addition, mechanical drives, for example using springs, bimetals, memory alloys or also clockwork drives, are, of course, also suitable. Finally, electric drives in the form of the known electric pumps, diaphragm pumps, piezoelectric pumps, electric clock drives or magnets also come into consideration.

An adhesive layer on the contact surface of the appliance is particularly suitable for securing the appliance to the appropriate part of the patient's body, and may extend as a plaster beyond the appliance. An alternative thereto is, for example, a securing band or tape like the armband shown in the German Offenlegungsschrift referred to earlier.

A metal spring is preferred as the driving device for the needle.

In the case of constant flow, the constant delivery of the active principle is arranged e.g. by means of capillaries, frits or diaphragms. In addition, the flow can be adjusted by adapting the viscosity of the liquid formulation of the active principle.

Control of the delivered amount of the active principle delivered can also be embodied in various ways. Thus, for example, a squeezable hose, whose diameter is increased or reduced according to requirements, can be disposed between the supply vessel and the needle. A further possibility is to provide a pressure-reducing valve of known type. Another possibility is to select a particular range of the expansion of the driving spring or to use special cup springs in which the force is constant within given limits over a distance. A more elaborate flow control is also possible by feedback using sensors. Finally, flow control can also be on the basis of using a specially programmed pumping mechanism to operate the vessel emptying.

Capillaries which are as thin as possible, i.e. with a diameter of preferably <0.5 mm, are used as injection needles, since pain increases with needle thickness. The depth of penetration and the way in which the needle is ground also have a bearing on pain. Advantageously, therefore, the penetration depth does not exceed 5000 µm. Moreover, the nedle is preferably ground at an inclination, e.g. like a lancet.

Although pain can be avoided on the basis of the needle diameter and the penetration depth, pain or irritation can never-

theless be caused by the formulation itself. This can be counteracted by a local anaesthetic in the formulation.

Embodiments of the invention will be described hereinafter with reference to the accompanying drawings.

Fig. 1 shows a cross-section through an injection appliance according to the invention,
Fig. 2 shows a plan view of the appliance according to Fig. 1, without the safety cap 14,
Fig. 3 shows a cross-section through another embodiment of the invention
Fig. 4 shows a plan view with partial sectioning of the appliance according to Fig. 3,
Fig. 5 shows a cross-section through a further embodiment of the invention,
Fig. 6 shows a section along plane B-B of the appliance according to Fig. 5.
Fig. 7 shows a cross-section through a further embodiment of the invention.
Fig. 8 shows a section along plane A-A of the appliance according to Fig. 7.
Fig. 9 shows a section along a plane perpendicular to the axis of a further embodiment of the invention.

The appliance shown in Figures 1 and 2 comprises a two-part flat cylindrical casing having a lower part 1 and an upper part 2. The two parts of the housing are rigidly interconnected, e.g. by a screw thread (not shown). An annular chamber 3 is formed by annular recesses in the contacting surfaces of the two parts. The annular chamber is divided into two separate compartments by a diaphragm 4. Both compartments communicate with the exterior by way of filling orifices 5 and 6 which are normally closed with stoppers.

An injection needle 7 with driving means suitable for its shooting are disposed in the centre of the discoid casing. The injection needle is a steel capillary having a diameter of 200 µm. Alternatively, a glass capillary could be used. The injection needle 7 is carried by a needle carrier 8. The needle carrier 8 has a lower cylindrical part and an upper flat discoid part. The cylindrical part is disposed for axial movement in a corresponding bore 9 in the lower part of the casing 1. It has a bore 10 which extends perpendicularly to its axis and which communicates with the interior of the hollow needle 7. Its cylindrical outside surface is formed with three peripheral grooves in which

O-ring seals are introduced. Further, a shallow peripheral groove is situated at the level of the bore 10.

In its bottom part the bore 9 is reduced to a diameter which is just large enough to allow the needle to pass through.

The upper discoid part of the needle carrier 8 is disposed for axial movement in a corresponding further concentric bore 11 of the casing upper part 2. Over approximately two-thirds of the thickness of the casing upper part the bore 11 is reduced to approximately half of its diameter. Thereby, an abutment is formed. Disposed between this abutment and the upper part of the needle carrier 8 is a driving spring 12 which serves to drive the needle into the patient's skin.

The needle carrier is also provided with resilient retaining fingers 13 which extend upwards from its surface. These retaining fingers are provided with a pawl-like step or shoulder which engages the edge of a widening of the bore 11. When the retaining fingers 13 are engaged, the needle carrier 8 with the needle 7 is situated in its top position in which the spring 12 is under stress and the needle does not project beyond the bottom surface of the casing.

Disposed between the retaining fingers is a safety cap 14 which prevents accidental compression of the retaining fingers 13 and thereby a triggering of the needle drive. On the other side the cap has a bore14a whose diameter is adapted to appropriate inclined surfaces of the retaining fingers 13 so that these are pressed together when the cap is pressed on and thereby the retaining mechanism is released.

A communicating bore 15 is disposed in the lower part of the casing between the lower compartment of the chamber 3 and the bore 9. This bore is widened over part of its length to receive a restrictor element, which is, for example, a Teflon frit. The bore 15 is arranged to join the bore 9 at a height which corresponds to the bore 10 in the needle carrier when this is in its lower position. In the upper end position the opening where the bore 15 joins the bore 9 is closed by the cylindrical part of the needle carrier 8 and by the bottom two O-rings.

The appliance has an adhesive layer 16 on its underside. Moreover, the appliance is embedded in a correspondingly shaped securing plaster 17. The adhesive layer 16 as well as the adhesive layer of the plaster are covered prior to use by a

protective foil. The adhesive layer 16 on the underside and that of the plaster can contain additional substances such as a local anaesthetic.

In production, after the appliance has been assembled the lower compartment of the chamber 3 is filled via the aperture 5 with a required active principle and the aperture 5 is then closed. Likewise, the upper compartment of the chamber 3 is filled with a propellant via aperture 6. These fillings are in most instances production operations and in that case are not carried out by the user. However, in the case of certain active principles it may be convenient to carry out the filling shortly before use. The appliance is then ready for use.

The mode of operation in use is as follows:

The user removes the protective foil 18 and sticks the appliance to an appropriate part of the body with the aid of the securing plaster 17 and the adhesive foil 16. Then, the user removes the safety cap 14, turns it and presses it on to the inclined surfaces of the retaining fingers 13. These are therefore compressed and release the needle drive. The spring 12 expands and presses the needle carrier with the needle 7 downwards through the predetermined distance and through the adhesive foil into the skin of the user. The needle should penetrate approximately at least 50 µm and at most approximately 5000 µm into the skin. The piercing is painless or nearly so because of the slight depth of penetration, and the small diameter and the inclined grinding of the needle.

Simultaneously with the descent of the needle carrier the cross-bore 10 is moved to the height of the opening of the communicating bore 15 so that the communicating bore communicates with the needle 7. The flow of active principle is put into play and is determined on the one hand by the pressure of the propellant in the upper compartment of the chamber 3 and on the other hand by the restriction effect of the restrictor 15. The volume of the flow of the active principle and at the same time the duration of the injection can be determined by appropriate choice of these factors.

The appliance shown in Figures 3 and 4 is of the same construction as the previously described embodiment with respect to the storage vessel and with respect to the needle-shooting device. A pressure-reducing valve (pressure-limiting valve) is additionally provided in the present embodiment to

compensate for pressure variations of the propellant. The pressure-reducing valve is disposed in a segment of the circular casing. Correspondingly, the chamber 3 extends around only a part of the periphery.

The reducing valve has its own casing which is received in a coresponding recess of the casing of the appliance. Internally it is subdivided by a diaphragm 20, in a manner known in pressure-reducing valves, into a high-pressure compartment 21 and a low-pressure compartment 22. A ram 23 is disposed in the communicating bore between the high-pressure compartment 21 and the low-pressure compartment 22, is secured in the centre of the diaphragm 20 and can close the communicating orifice by axial movement. A spring 24 is disposed on the other side of the diaphragm between the ram 23 and an adjustable abutment 25. This spring basically determines the pressure existing in the low-pressure compartment. The high-pressure compartment 21 communicates by way of a communicating bore 26 with the lower compartment of the chamber 3, i.e. the resevoir of the active principle. The low-pressure compartment communicates by way of a bore 27 with the central bore 9 and, as in the case of the previously described embodiment, opens out at the height of the cross-bore 10 when the needle carrier is at its lower end position.

The pressure-reducing valve enables the maintenance of a substantially constant rate of delivery of the active principle irrespective of pressure variations on the high-pressure side. Such pressure variations can be caused by variations in the vapour pressure of the propellant as a result of temperature variations.

As in the previously described embodiment, this appliance is also provided with an adhesive layer, a securing plaster and protecting foil, and the mode of operation of the appliance in use does not differ practically from the embodiment described previously.

In the appliance shown in Figures 5 and 6 an alternative arrangement for conveying the active principle and a different form of reservoir are provided. The reservoir is provided by two bags, bubbles or bellows 28 having on one side an aperture via which they are secured to a mount 29 formed with a filling aperture 30 and a bore 31 communicating with the central bore 9. The two mounts 29 are connected rigidly to the central part of the casing lower part 1. A rotating member 32 is disposed around

this stationary part and has two inwardly projecting webs 33, each of which engages with the backs of the resevoir bags 28.

Between the rotating member and the outside wall of the casing upper part 2 is a compartment in which a spiral spring 34 is disposed. This spiral spring is secured with its one end in the casing wall and with its other end in the rotating member. When the tight spiral spring expands it brings about a rotation of the rotating member which compresses the reservoir bags 28 with the webs 33 and in this way empties the active principle therein through the orifices 31.

A control effect is achieved by using only some of the usable number of turns of the spiral spring for the rotary movements. Accordingly, in this manner the delivery of the active principle and the control of the flow are simultaneously effected with the aid of the driving spring. In other respects the the function of this embodiment corresponds to that of the embodiment shown in Figures 1 and 2.

In contrast to the hitherto described embodiments, the appliance shown in Figures 7 and 8 has two supply vessels or chambers 35, 36 and two separate needle carriers 39, 40 provided with needles 37, 38 which are driven by a common activating mechanism 41. This embodiment is suitable where two active principles need to be injected simultaneously and separately.

As an alternative to the version shown, a single needle carrier having two needles could be provided in place of the two needle carriers. A more elaborate sealing system would be required for this.

The embodiment shown in section in Figure 9 has an electrically driven conveyance of the active principle. Because of the relatively high cost of the electrical elements in this embodiment the appliance is divided into a discardable part 42 and a reusable part 43. The two parts are connected to each other by resilient clips 56 which engage in corresponding recesses.

The disposable part 42 contains a supply vessel 55 having a filling capability closed by a partition 44. The system is such that the reservoir can, if required, be filled shortly before use. Moreover, the disposable part contains pump means 45 having an intake valve 46 communicating with the supply vessel, a delivery valve 49 controlling a line 47 to the injection needle 48 and a plunger pump 50 disposed between the two valves and connected

thereto. The operation of the pump means 45 is as follows: when the plunger of the pump 50 is drawn back from the shown position a predetermined volume is taken in from the supply vessel through the intake valve 46. The delivery valve 49 is closed during this phase. When the piston is again advanced forward the intake valve 46 closes and the delivery valve 49 opens so that the volume taken in is supplied to the injection needle.

The injection needle with the needle carrier and the piercing mechanism (not shown here) also form part of the discardable part.

The more valuable reusable part 43 contains the electric drive for the pump means. This comprises an electromagnet 51 which brings about the withdrawal of the plunger of the pump 50, while the forward movement is effected by a return spring 52. The electromagnet 51 is controlled by an electronic control facility 53. The electromagnet 51 and the control 53 are supplied with current from a battery 54.

An electrically driven pump is also especially suitable for combination with an electronic control of the delivered quantity. The delivery profile can, e.g., be pre-programmed and stored in a suitable way. The control of the delivery rate can be effected by appropriate sensors.

In the embodiments shown the needle-driving means has been combined with the operation of the valve.These two functions can readily be separated so that, e.g., firstly the needle is shot and then a valve is opened independently. Other skin-piercing movements in place of the simple injection perpendicular to the skin surface are also possible. For example, the vertical piercing movement can be coupled with a rotation of the needle or the needle can be injected into the skin at an inclination to the skin surface.

Claims

1. A portable appliance for the subcutaneous or intradermal injection of a liquid formulation of an active principle, having a supply vessel (3) for the formulation, an injection needle (7) adapted to communicate with the vessel, pump means (4, 32, 34, 50) for emptying the vessel through the injection needle and securing means (16, 17) for securing the appliance to an appropriate part of the patient's body, characterized by a needle

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driving means (12-13) for shooting the injection needle into the patient's skin.

2. An injection appliance according to claim 1, characterized by flow control means (20-25).

3. An injection appliance according to claim 1, characterized in that it is in two parts (42, 43), one of which is reusable and the other of which is discardable.

4. An injection appliance according to claim 3, characterized in that the discardable part (42) comprises the supply vessel and the reusable part comprises means (51-54) for driving the pump means (50).

5. An injection appliance according to claim 1, characterized in that the supply vessel (3) is a chamber in the appliance, which is separated by a diaphragm (4).

6. An injection appliance according to claim 1, characterized in that the supply vessel (3) is in the form of bellows.

7. An injection appliance according to claim 1, characterized in that the supply vessel (3) is in the form of a squeezable hose.

8. An injection appliance according to claim 1, characterized in that the supply vessel (3) is in the form of a plunger syringe whose cylinder is operative as the supply vessel.

9. An injection appliance according to any one of claims 6 to 8, characterized in that an absorbent material is provided to take up the active principle.

10. An injection appliance according to claim 1, characterized in that more than one supply vessel is provided.

11. An injection appliance according to claim 1, characterized in that the pump means comprise a chamber which is separated from the supply vessel by a resilient diaphragm and in which pressure-producing means are provided.

12. An injection appliance according to claim 11, characterized in that the chamber is filled with propellant vapour.

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13. An injection appliance according to claim 11, characterized in that an electrochemical, photochemical or chemical system for producing a pressure is provided in the chamber.

14. An injection appliance according to claim 11, characterized in that an osmosis or electro-osmosis system is provided in the chamber.

15. An injection appliance according to claim 1, characterized in that the pump means comprise a mechanical drive.

16. An injection appliance according to claim 15, characterized in that the mechanical drive comprises a spring, a bimetal, a memory alloy or a clockwork drive.

17. An injection appliance according to claim 1, characterized in that the pump means comprise an electric or magnetic drive.

18. An injection appliance according to claim 17, characterized in that the electric or magnetic drive comprises an electric pump, a diaphragm pump, a piezoelectric pump, an electric clock drive or an electromagnet.

19. An injection appliance according to claim 1, characterized in that the securing means are in the form of an adhesive layer.

20. An injection appliance according to claim 1, characterized in that the securing means comprise a plaster.

21. An injection appliance according to either of claims 19 and 20, characterized in that an adhesive layer containing a local anaesthetic is used.

22. An injection appliance according to claim 1, characterized in that the needle has a diameter of < 0.5 mm.

23. An injection appliance according to claim 1, characterized in that the needle driving means are combined with a valve which controls communication between the supply vessel and the injection needle.

24. An injection appliance according to claim 16, characterized in that only a fraction of the spring deflection of a driving spring is used.

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25. An injection appliance according to claim 1, characterized in that electronic control means for controlling the pump means are provided, the control means having a data memory for a programmed release profile.

26. An injection appliance according to claim 1, characterized in that the pump means are in the form of a squeezable hose pump which is of variable hose cross-section and which enables the release programme to be programmed.

27. An injection appliance according to claim 1, characterized in that the needle driving means are designed for a penetration depth of 0.5-5 mm.

28. An injection appliance according to claim 1, characterized in that the vessel is provided with apertures which are closed by a partition through which the vessel is filled shortly before use.

29. An injection appliance according to claim 1, characterized by the combination with sensors to control or vary the release rate.

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