Inhalation device for powdered drugs

The invention refers to an inhalation device for powdered drugs to be received by a patient by an inhalation-caused air stream, comprising at least one powder reservoir, metering means for repeatedly metering a powder dose from the reservoir, a transportation mechanism for moving said metering means from a filling position for receiving a powder dose into an emptying position for releasing said powder dose into a powder channel, and at least one activating device for manual operation by the patient, said activating device being operatively connected to said transportation mechanism such that upon operation a single powder dose is being metered, said activating device comprising a dosage key acting on said transportation mechanism when pressed by the patient.

A powder inhaler of above-referred kind is for instance disclosed in EP 1 616 592 B9.

In the field of treating bronchial diseases but also other diseases in which medication can be affected by way of the respiratory tract, it is generally known to apply medicaments in powder form. Of course, in the art are also known devices for atomization of solutions of suspensions to provide inhalable aerosols.

The present invention relates to an inhaler for the administration of powdered pharmaceuticals in form of a multi-dose dry powder inhaler, preferably with a dosing counting or indexing means provided in the inhaler or on a cartridge for powdered pharmaceuticals.

As aforementioned, an inhaler of this kind is disclosed in EP 1 616 592 B9. This reference refers to an inhaler for providing a large number of doses of a pharmaceutical powder medicament from a single reservoir space which medicament can be received by the patient by means of an air stream which has to be induced by suction to a mouthpiece by the patient.

An inhalation device for powdered drugs of the above-referred kind is for instance disclosed in US patent 5,840,279. More particularly, this patent refers to a

pharmaceutical powder cartridge for powder inhalers for receiving a medicament depot for a large number of pharmaceutical powder doses, having an integrated metering device which comprises at least one metering cavity for receiving a predetermined quantity of a pharmaceutical powder, the integrated metering device being capable of being moved at least out of a filling position into an emptying position approximately transversely with respect to the flow direction of the pharmaceutical powder, and an inhaler for powdered medicaments, in which inhaler the medicament can be received by a patient by means of an air stream and which has a receptacle for such pharmaceutical powder cartridge.

WO 2006/106367 discloses an inhaler device capable of accepting a plurality of doses of a medicament to be dispensed from the inhaler. The device comprises prevention means for preventing, at least temporarily the dispensing of a dose of medicament and detection means for detecting the inhalation of a previously dispensed dose of medicament.

Another inhalation device of the above-referred kind is disclosed in US 2006/0037612 A1.

For multi-dose inhalers an important design aspect is the metering accuracy of the device.
Another important design aspect of inhalation devices of the above-referred kind are the use properties of the device.

The inhalation device has to be designed such that the user clearly may make out whether the device is ready for inhalation, and whether the device has a certain and sufficient residual amount of powder doses. Moreover, the device has to be sufficient fail-safe and safe against operating errors of the user. For instance double dosing has to be prevented in any event by an appropriate design of the metering technique.

In particular, EP 1 616 592 B9 refers to a locking mechanism, locking an activation device and/or transportation mechanism of the inhaler after a pre-determined number of metering cycles.

This known inhalation device comprises an activating device for manual engagement by the patient for repeatedly metering a dose of medicament to be administered to the patient, an advancing mechanism for advancing a counting or indexing means each time the activating device has been engaged by the patient so that a dose of medicament has been released for administration to the patient, the counting or indexing means comprises an index, the index being detectable by a detection means of the inhaler, and the detection means being coupled to a locking mechanism, the locking mechanism blocking the activation device and/or any transportation mechanism of the inhaler delayed by a pre-determined number of metering cycles since detection of the index. The activating device is arrested in a position different from the operating position indicating the blocking state of the inhaler. This arrangement allows to block further use of the inhaler after removal of a number of doses from the reservoir space or an approximate number of doses left in the reservoir space with a simple, inexpensive and reliable mechanism so that an improved security of the patient using the inhaler can be obtained. In this manner, a patient is prevented from trying to dose from an empty reservoir space causing an inappropriate lack of required medicine. Insofar, the known inhalation device provides an enhanced usability.

As aforementioned, the inhaler comprises an activating device for manual engagement by the patient in form of a dosage-key connected to a transportation mechanism. The transportation mechanism is connected to a metering means which will be transported from a filling position into an emptying position for releasing the dose of medicament powder into a powder channel. From the powder channel the patient can inhale the medicament powder through a mouthpiece via an air stream generated by the patient such that pressing the key for dosing and inhaling of the medicament does not need to be coordinated by the patient. In any event, the patient may receive the metered powder dose via inhalation. The metering and transportation mechanism of the inhaler as disclosed in EP 1 616 592 will only be properly reset if the patient releases the dosage key prior to inhalation.

It might be the case that the patient believes that the dosage key has to be kept depressed in order to fully release the powder dose, as this is generally known from aerosol inhalers.

It also might be the case that the patient is physically and/or mentally not able to release the dosage key.

It is therefore an object of the present invention to provide an inhaler of the above-referred kind which is further enhanced with regard to usability and which is further enhanced in view of eventual mal-operation.

This and other objects are achieved by an inhalation device according to claim 1. Advantageous embodiments of the invention may be derived from the dependent claims.

Particularly, the above-referred objects of the invention are achieved by an inhalation device for powder drugs to be received by a patient by an inhalation-caused air stream, comprising at least one powder reservoir, metering means for repeatedly metering a powder dose from the reservoir, a transportation mechanism for moving said metering means from a filling position for receiving a powder dose into an emptying position for releasing said powder dose into a powder channel and at least one activating device for manual operation by the patient, said activating device being operatively connected to said transportation mechanism such that upon operation a single powder dose will be metered, said activating device comprising a dosage key acting on said transportation mechanism when pressed by the patient, the inhalation device according to the invention being characterized in that said dosage key while being pressed is only temporarily engaged with said transportation mechanism such that a metering cycle will be completed and the transportation and/or the metering means will be reset, even if said dosage key will be held in depressed condition.

The term "reset" in the sense of the present application means that the transportation mechanism and the metering means will independently from the position of the dosage key return to their initial position/starting position and will

be ready for a further metering cycle, regardless of the position of the dosage key after complete actuation of the metering means/transportation mechanism.

Even if the user erroneously keeps the dosage key fully depressed, for instance because he believes it to be necessary to somehow coordinate actuation and inhalation, such operation will not influence the metering cycle as such. Of course, the powder dose upon actuation of the dosage key will be fully released into the powder channel and the mechanism will be properly reset upon inhalation of the powder dose.

In one advantageous embodiment, the inhaler according to the invention is characterized in that said dosage key includes a deflectable element temporarily engaging a dosage lever of the transportation mechanism, the deflectable element being flexible and being disengaged with the dosage lever in a first non-deflected position and being engaged with the dosage lever in a second deflected position. Said deflectable element may be in the form of a bendable and/or flexible peg or pin or spike as well as in the form of an actuator blade or a leaf spring. "Actuator blade" in the sense of the present application means a blade-like bendable and/or flexible element, for instance a kind of leaf spring which may be a metal element or an element made from thermoplastic material. The actuator blade may be integrally formed with the dosage key which in turn may be an injection-molded part. Alternatively, the deflectable element may be in the form of a flexible/bendable metal leaf spring which is attached to the dosage key. Preferably, the actuator blade is a flexible arm or flexible leg.

In other words, upon depression of the dosage key by the user, a flexible arm/leg of the dosage key will be bent such that it engages a dosage lever of the transportation mechanism. Upon further depression of the dosage key, the deflectable element will snap back in its initial position where it is disengaged with the dosage lever, so that the dosage lever can fulfill a reset movement independently from the position of the dosage key.

In a preferred embodiment, the inhaler according to the invention is characterized by a stationary deflection profile, i.e. stationary relative to the dosage key, urging

the deflectable element into the second deflected position during movement of the dosage key from a non-depressed into a depressed position and then releasing the actuator blade into the first non-deflected position during further movement of the dosage key into a fully depressed position. A deflection profile may for instance be provided by a beveled edge or a beveled profile by a stationary part of the inhaler. This could be for instance the valve chamber or another stationary part of the inhaler.

Alternatively, the deflection profile could be provided by a cam profile of a stationary part of the inhaler. The dosage key may be held spring biased in its non-operated position so that the dosage key automatically returns to its starting position if released by the operator/user.

It is particularly advantageous if the transportation mechanism includes a dosage lever acting on said metering means, said dosage lever being locked in the inhalation position of said metering means after the dosage key has been depressed, said dosage lever being releasable by inhalation, regardless of whether the dosage key has been released or not.

The inhaler may include an inhalation-operated valve in an air duct, said valve being operatively connected to said dosage lever so that the dosage lever is releasable by the action of the valve initiated by the suction generated by the patient during inhalation.

The air duct is preferably communicating with the powder channel. Due to this design, the transportation mechanism and/or the metering means are only fully reset after inhalation of the powder dose which has been released into the powder channel. Accordingly, by this design, double dosing will be effectively prevented.

In a particularly preferred embodiment, the dosage lever may assume a first and second locked position subsequently. In order to prevent a mal-operation to that extent that the dosage key will be released too early by the user, said dosage lever is only releasable by inhalation after it has been locked in the second locked position. When the dosage key is not pressed all the way down, the dosage lever

will not return to its starting position, accordingly, no additional dose will be dispensed from the reservoir.

Said dosage lever may assume said second locked position only when said dosage key will be depressed to a certain extent, i.e. until said actuator blade will be released and will snap back on further depression of said dosage key.

Said deflectable element may be formed integrally with said dosage key.

The dosage key may be formed by injection molding of thermoplastic material, the biasing characteristics of the deflectable element being inherently due to its shape and due to the fact that it is made from thermoplastic material.

In the following the invention is disclosed by way of example with reference to accompanying drawings in which:

Figure 1 shows a perspective view of an embodiment of an inhalation device according to the invention with the mouthpiece cap opened,

Figure 2 shows an exploded view of the inhaler according to the invention,

Figure 3 shows a partial longitudinal cross-sectional view through an inhaler according to a first embodiment of the invention,

Figure 4 shows another longitudinal cross-sectional cut through the inhaler according to the first embodiment of the invention,

Figure 5 shows a perspective view of a dosage key according to the invention,

Figure 6 shows a cross-sectional view of the inhaler in a non-actuated state of the dosage key,

Figures 7a, 7b show a cross-sectional view corresponding to the view shown in Figure 6 where the dosage key is partially pressed,

Figure 8a shows a cross-sectional view according to Figures 6 and 7 where the dosage key is fully depressed,

Figure 8b shows a perspective view demonstrating the engagement of the dosage lever into the flap valve,

Figure 9 shows a perspective view of a dosage lever of the inhaler according to the present invention,

Figure 10 shows a perspective view of a first preferred embodiment of an inhalation-operated valve closing the air duct of the inhaler according to the invention,

Figure 11a shows another perspective view of the inhalation-operated valve according to Figure 10,

Figure 11b shows a perspective rear view of an inhalation-operated valve according to a second preferred embodiment,

Figure 12 shows a perspective side view of the inhaler according to the invention without its housing,

Figure 13 shows an enlarged detail of Figure 12 as a rear view,

Figure 14a shows an enlarged detail of the engagement between the dosage lever and an inhalation-operable flap valve of the inhaler according to a first preferred embodiment of the invention,

Figure 14b shows an enlarged detail of the engagement between the dosage lever and the flap valve according to the first preferred embodiment,

Figure 14c shows an enlarged detail of the engagement between the dosage lever and the flap valve according to a second preferred embodiment,

Figure 15 shows another longitudinal sectional view through the inhaler,

Figure 16 shows a perspective view of a powder cartridge of the inhaler according to the invention,

Figure 17 shows a perspective view of the inhaler housing,

Figure 18 shows a detail of the counter slide gliding over the counter ring's tooth,

Figure 19 shows a detail of the cartridge's locking ratchet (locking lever not displayed),

Figure 20 shows a detail of the locking lever and its engagement with the dosage key and the counter ring.

The inhaler 1 shown in Figures 1 to 20 is an inhaler for powdered medicaments, for providing a large number of doses of a pharmaceutical powder medicament from a receptacle in the form of a powder cartridge. The powder cartridge 3 defines a reservoir 2 for receiving a large number of doses of a pharmaceutical powder/powdered drug. In the described embodiment, the typical number of doses which may be obtained from one powder cartridge 3 may be in the range of 30 to 60 doses.

The reservoir 2 is sealingly covered by a lid 4 as can be seen from Figure 2. The lid is secured to the cartridge body 3a in the assembled state of the inhaler in a non-removeable fashion.

The powder medicament can be received by a patient by means of an air stream caused by the user, i.e. induced by suction. Therefore, the inhaler further comprises an activating device for manual engagement by the patient in the form of a dosage key 5 being connected to a transportation mechanism including a dosage lever 6 and a locking lever 7. The dosage lever 6 acts on a dosage slide 8 as a metering means being moveable from a filling position for receiving a powder dose into an emptying position for releasing said powder dose into a powder groove 16a of a cyclone 16 for deagglomeration of the powder in the cyclone 16. From the powder groove 16a the patient can inhale the powdered drug through a mouthpiece 10 via an air stream generated by the patient. If not in use, the mouthpiece 10 is protected from dirt by a mouthpiece cover 11. The mouthpiece cover 11 is secured to the inhaler housing fixedly, i.e. non-detachable.

The powder groove 16a of the cyclone 16 forms a part of a powder channel through the cyclone 16 which functions as a disintegration means as this is known from the art. The powder medicament to be received by the patient may be in form of an adhesive mixture. Adhesive mixtures consist of relatively large crystals, generally α-lactose-monohydrid, carrying the micronised drug particles on their surface. In the disintegration system, the dry powder will be deagglomerated for releasing the drug particles from the powder formulation. The cyclone 16, i.e. the disintegration means, generally includes an air circulation chamber as well as several air supply channels which enter the circulation chamber tangentially so that a circular air flow pattern is created inside the circulation chamber. So the total respiratory flow through the inhaler does include a transportation airflow for traversing the powder dose in the powder groove and dragging the powder into the circulation chamber, a cyclone air flow which tangentially enters the circulation chamber as well as eventually a bypass airflow for creating a so-called sheath flow of clean air. A possible design for the disintegration means is for instance disclosed in the international patent publication WO 03/000325 the disclosure of which is herewith fully incorporated by reference. The disintegration means in the

following in a rather simplified form is referred to as a cyclone. In a also rather simplified form in the following the air path from the powder groove 16a to the mouthpiece opening is referred to as powder channel. It is, however, to be understood that the term "powder channel" does not necessarily refer to one distinct single powder channel but rather to a channel system as explained above.

As this can be taken from Figure 2, the inhaler 1 includes a three-part housing comprising shells 12 and 13 as well as cover 14 received on the shells 12 and 13 via snap-fit connection in a non-releasable fashion.

The heart of the inhaler 1 is formed by a valve chamber 15 including the cyclone 16 and a cartridge body 3a.

Manual operation of the inhaler 1 by a patient functions via dosage key 5 which on depression by the patient against the biasing force of a dosage key spring 17 acts on a dosage lever 6 which is connected to the dosage slide 8 (see Figure 15).

Dosage slide 8 is slidably moveable within dosage slide passage 18 extending below the reservoir 2 within the cartridge body 3a, as this for instance can be seen from Figure 15.

The dosage slide 8 (metering means) includes a dosage cavity 19 for receiving a metered dose of a powdered drug.

It should be mentioned that the cartridge body 3a not only defines the reservoir 2 for receiving the powdered drug but also defines a dosage slide passage 18 extending below the reservoir 2 as well as a housing for receiving counting and indexing means as this is described hereinafter more detailed.

The dosage slide 8 is shown in Figure 15 in its emptying position where the dosage cavity 19 is aligned with an opening 20 in the valve chamber 15 communicating with the powder groove 16a of the cyclone 16. The dosage slide 8 is moveable via dosage lever 6 between a filling position where the dosage cavity 19 is aligned with an opening 21 of the reservoir 2 within the cartridge body 3a

and an inhalation/emptying position. In the filling position, the dosage cavity 19 receives a metered quantity of powder. Upon actuation of the dosage key 5, the dosage slide 8 will be advanced into the position shown in Figure 15, thereby releasing the powder dose into the powder groove 16a through the opening 20.

In this position shown in Figure 15, the inhaler is ready for inhalation. In the event the patient applies suction via mouthpiece 10, this forces a flap valve 22 at the very end of an air duct 9 to swing open so that an air flow can freely circulate from the open end of the air duct 9 into a powder channel defined by the valve chamber 15 and the powder groove 16a of the cyclone, into the mouthpiece. The flap valve 22 includes the flap 22a and a shaft 22b which are in the disclosed embodiment integrally formed.

The flap valve 22 according to a first embodiment in more detail is shown in Figures 10 and 11a. The shaft 22b of the flap valve 22 at its ends is pivot mounted within valve chamber 15.

As this can be seen also from Figure 15, in the inhalation position the flap valve 22 is engaged by a fastening hook 23 of the dosage lever 6.

A rear side view of the flap valve 22 is for instance shown in Figure 10. The flap 22 has an angled/bent profile including three legs 22c, 22d and 22e, the first leg 22c in the mounting position being inclined towards the closing direction of the flap valve 22, the second leg 22d being inclined rearwardly and the third leg 22e extending in forward direction and approximately tangentially to the rotary movement of the flap valve 22.

On the rear side of the first leg 22c of the flap 22a, a latching rib 47 is provided which may be engaged by the fastening hook 23 of the dosage lever 6 in the inhalation position. The fastening hook 23 of the dosage lever 6 at its leading end is provided with a barbed projection 50 which has a sloping face 51. The flap valve 22 includes a flap valve lever 31 integrally formed with said shaft 22b. The distal end of the flap valve lever 31 is provided with a deflector surface 53. Upon actuation of the dosage key 5 and subsequent actuation and downward

movement of the dosage lever 6, a corresponding deflector surface 53' of a latch 29 integrally formed with the hook 23 of the dosage lever 6 gets into abutment with the deflector surface 53 of the flap valve lever 31. The flap valve lever 31 as well as the hook of the dosage lever are thereby both being slightly deflected, i.e. bent aside and snap back in their initial position upon further downward movement of the hook 23 of the dosage lever 6. Upon further downward movement of the hook 23, the sloping face 51 of the barbed projection 50 abuts one edge of the latching rib 47. Thereby the hook 23 is bent aside due to the resilience of its material and snaps back behind the latching rib 47 in its end position thereby engaging the flap valve 22 and being releasable by an inhalation-triggered pivoting movement of the flap valve 22.

As this can particularly seen from Figure 14b, which shows an enlarged longitudinal cut through the flap 22a, the barbed projection 50 of the hook 23 engages the latching rib 47. When the inhaler 1 is ready for inhalation, the latching rib 47 includes a curved bearing surface 54 facing the barbed projection 50. The bearing surface 54 which defines a cam surface almost providing line contact between the barbed projection 50 of the hook 23 and the latching rib 47 so that the contact force between the latching rib 47 and the hook 23 is almost independent from the tolerances of the components. To be more specific, the planar surface of the barbed projection 50 of the hook engages the curved bearing surface 54 only tangentially so that in effect excursion of the contact surface due to tolerances of the parts of the inhaler is only possible in axial direction, which, however, has no impact on the required triggering forces. Due to this design the required triggering forces are only subject to minor variations so that triggering of the flap valve 22 is fairly reproducible. It is readily apparent from Figure 15 that if the flap 22a moves in clockwise direction, the hook 23 is released almost instantaneously. As a result, the dosage lever may swing upwards driven by the force of the dosage lever spring 25. This upward movement will cause the dosage slide 8 to return to its powder receiving position.

Another embodiment of the flap valve 22 is shown in Figures 11b and 14c. Same parts of the flap valve 22 are denoted by the same reference numerals.

The flap valve 22 according to this embodiment comprises a relatively simple flat flap 22a which is not bent or angled in itself.

As this can be taken from Figure 14c, the fastening hook 23 engages the shaft 22b of the flap valve 22 when the inhaler 1 is ready for inhalation.

The shaft 22b of the flap valve 22 (see for instance Figure 11b) has a cut out area 24 which is arranged approximately in the middle of the shaft 22b such that, if the flap 22a swings open (in Figures 14c and 11b in clockwise direction), the fastening hook 23 of the dosage lever 6 tangentially engaging the shaft 22b approximately in the middle of the shaft 22b, will be released so that the dosage lever 6 driven by the force of the dosage lever spring 25 may return to its initial position, thereby moving the dosage slide 8 back into the filling position for receiving a powdered dose from the reservoir/powder cartridge. Upon actuation of the dosage key 5 the dosage lever 6 will be moved downward while partially pivoting the flap 22a by contact of the latch 29 of the dosage lever 6 with the flap valve lever 31. After partially pivoting the flap valve 22 swivels back to its starting position by the force of its molded, integrally formed spring 32. The pivot motion of the flap 22a caused by the contact of the latch 29 with the flap valve lever 31 allows the latch 29 to engage behind the mechanical stop 30 of the flap valve lever 31 upon early release and upward movement of the fastening hook 23.

In the area of the cut out portion 24 of the shaft 22b, the shaft 22b has only a semi-circle cross-section, the leading end of the fastening hook 23 engages the remainder of the cross-section of the shaft only tangentially and only in a very limited surface area (line contact) so that the contact force between the shaft 22b and the fastening hook 23 is almost independent from the tolerances of the components. Due to this design, in particular due to the fact that a planar contact surface of the fastening hook 23 contacts a curved surface area of the remainder of the cross section of the shaft 22b, the required triggering forces are only subject to minor variations so that triggering of the flap valve 22 is fairly reproducible. Only a slight rotation/pivoting movement of the shaft 22b and the flap 22a will set the fastening hook 23 free so that the dosage lever 6 may swing

upwards driven by the force of the dosage lever spring 25, thereby finishing the inhalation cycle.

A perspective view of the dosage key 5 is shown in Figure 5. The dosage key 5 is held in its initial position/starting position by dosage key spring 17 which abuts a tongue member 26 integrally formed with the dosage key 5.

Said dosage key 5 includes an actuator blade 27 being formed as a flexible arm/leg also integrally formed with the dosage key 5 and extending downwards in the mounting position shown in Figure 5. As this can be seen from the operating sequence shown in Figures 6 to 8a, valve chamber 15 is provided with a beveled edge 28 forming a kind of cam surface for the actuator blade 27 upon depression of the dosage key 5.

Figure 6 shows a cross-sectional cut through the inhaler 1 where the dosage key 5 is in its not-operated starting position. The actuator blade 27 in this state is not engaged with the transportation mechanism, i.e. with the dosage lever 6.

Upon depression of the dosage key 5, the actuator blade 27 moves downwards and engages the beveled edge 28 of the valve chamber such that the actuator blade 27 due its inherent flexibility is deflected/bent from a first position shown in Figure 6 to a second position in Figure 7a where it engages at the same time the dosage lever 6. By a further movement of the dosage key 5 and the actuator blade 27, the actuator blade 27 urges the dosage lever 6 downwards against the biasing force of dosage lever spring 25. Upon full depression of the dosage key 5, which is shown in Figure 8a, actuator blade 27 snaps back in its non-deflected and disengaged position. In this position the fastening hook 23 of the dosage lever 6 engages the latching rib 47 of the flap valve 22 as this is also shown in Figure 8a. The device/inhaler is now ready for inhalation.

In the following the double dosing prevention mechanism of the inhaler according to the invention will be described, first referring to the first embodiment of the flap valve 22 according to the invention.

As this has been mentioned before, the dosage lever 6 in the area of its trailing end (left hand side in Figure 9) is provided with latch 29. Upon downward movement of the dosage lever as a result of the actuation of the dosage key 5, first of all the complementary deflection surface 53' of the latch 29 gets into abutment with the deflector surface 53 of the flap valve lever 31. As a result, the flap valve lever 31 is bent aside/deflected while being passed by the fastening hook 23 and snaps back into its initial position upon further downward movement of the dosage lever 6, which ultimately will result in engagement of the hook and the latching rib 47.

It is again referred to Figure 9 which shows a perspective view of the dosage lever 6. In the area of its trailing end (left hand side in Figure 9), the dosage lever 6 is provided with a latch 29 for engaging a mechanical stop 30 of a flap valve lever 31 integrally formed with said shaft 22b on a return movement of the dosage lever 6.

In the event the dosage key 5 will be pressed and released too early, i.e. prior to the engagement of the fastening hook 23 into the latching rib 47 of the flap valve 22, latch 29 of the dosage lever 6 upon upward movement of the dosage lever 6 will abut said mechanical stop 30 of the flap valve lever 31. Accordingly, the dosage lever 6 locks into the flap valve 22 in a middle position. This middle position lock provides a double dosing prevention mechanism. In this middle position lock, i.e. first locked position, the relationship of lever is such that the forces required for releasing the dosage lever 6 can not be brought up simply by inhalation. If the dosage lever 6 does not lock into flap valve 22 in the end position, e.g. when the dosage key 5 is not pressed all the way down, the dosage lever 6 will not return to its initial starting position, i.e. will be locked in the middle position. Accordingly, no additional powder dose will be released from the reservoir 2. The dosage lever 6 and the dosage slide 8 will only return into their starting position after inhalation-triggered actuation of the flap valve 22, thereby releasing the fastening hook 23 of the dosage lever 6.

A double-dosing prevention mechanism is also provided with the design of the flap valve 22 of the second embodiment according to Figure 14c. Upon actuation of the dosage key 5, the dosage lever 6 will be moved downward while partly

pivoting the flap 22a by contact of the latch 29 of the dosage lever with the flap valve lever 31. After partly pivoting the flap upon downward movement of the dosage lever, the flap valve 22 will return into its closed position due to the resilience of a spring 32 integrally molded with the flap valve 22. Latch 29 of the dosage lever 6 upon an early upward movement of the dosage lever 6 will abut the mechanical stop 30 of the flap valve lever 31. Accordingly, the dosage lever 6 locks into the flap valve 22 in a middle position.

Dosage lever 6 includes a cam-like actuating element 33 which upon each actuation moves a counter slide 34 of the cartridge so that a counter ring 35 of the cartridge is moved by one count towards a lower dose. The degree of the cartridge's content is accordingly visible in a display window 36 of the cartridge body 3a indexing the fill status of the cartridge. Details of the counter slide 34 acting on the counter ring 35 may be taken from Figure 18. Counter ring 35 which is designed as a ratchet ring with teeth 37 is rotably inserted into a collar of the cartridge body 3a. Upon actuation of the dosage lever 6, the actuating element 33 moves the counter slide 34, the counter slide engaging the counter ring's teeth 37, thereby moving the counter ring 35 so that the next index number is indicated in the display window 36. The counter ring 35 for instance provides a visual indication of a dose count for each 5^{th} dosing step/metering cycle. The counter ring for instance shows thirteen numbers and indicates a countdown from 60 to 0 upon each metering cycle. Each tooth of the counter ring 35 represents one metering cycle.

As this also can be taken from Figure 4, the counter slide 34 includes a pawl 43 integrally formed with the counter slide 34. The pawl 43 is biased towards the counter ring 35 that it firmly engages the teeth 37 of the counter ring 35. The teeth 37 are unsymmetrical insofar as they have one sloping flank and one vertically extending flank, the sloping flank representing the leading flank with respect to the rotational direction of the counter ring 35.

The counter slide 34 is moveable back and forth within a sliding channel 44 of the cartridge body 3a. The cam-like actuating element 33 of the dosage lever 6 extends into the sliding channel 44 and into a recess 45 of the horizontally

extending part of the counter slide 34. Engagement of the actuating element 33 with the counter slide 34 transforms a pivoting movement of the actuating element 33 into a linear movement of the counter slide 34.

Upon depression of the dosage key 5, the dosage lever will be pivoted such that the actuating element 33 is pivoted towards the left hand side in Figure 4. At the same time, the lower leading end 46 of the dosage lever (see Figures 9 and 12) pushes the dosage slide 8 into its emptying/inhalation position. The counter slide 34 is thereby moved in the opposite direction. While the counter slide 34 fulfills this movement, the pawl 43 engages the vertical flank of the respective tooth 37 of the counter ring, moving the counter ring one count/step. After release of the dosage lever 6, the counter slide 34 will be moved backwards into its starting position. Due to the resilience of the pawl 43, the pawl may glide over the sloping flank of the respective tooth, thereby snapping back behind the tooth. As this can be seen from Figure 19, the counter mechanism includes a locking ratchet 38 engaging the counter ring teeth 37. Due to the geometry of the teeth 37, the locking ratchet 38, which is also a resilient member, blocks an anti-clockwise rotation of the counter ring 35.

As this can be seen from Figure 12, the inhaler 1 includes a locking lever 7 which is pivotably mounted in the valve chamber 15 between dosage key 5 and dosage lever 6. The locking lever 7 includes a blocking arm 39 and a spring leg 40. During assembly of the powder cartridge 3, the locking lever 7 is pushed downwards, the blocking arm 39 and the spring leg 40 thereby being moved backwards. In this position, the dosage key 5 may be freely moved downwards against the biasing force of the spring leg 40 as shown in Figure 12.

The dosage key 5 is also freely moveable against the biasing force of the dosage key spring 17 as shown in Figure 15.

The counter ring 35 includes a notch 41 being engageable by a tongue 42 of the locking lever 7.

The notch is arranged on the counter ring 35 such that, after a pre-determined number of doses has been delivered, the locking lever 7 engages the notch in the counter ring with a pivoting movement caused by the action of spring leg 40 actuated by the dosage key 5. Upon upward movement of the locking lever 7, the blocking arm 39 of the locking lever 7 is pushed forward (towards the mouthpiece 10) and engages the dosage key 5 in its lowest position such that the dosage key 5 stays blocked in its lowest position after the last inhalation. It is impossible to perform another activation of the empty device.

As this can be seen from Figures 5 and 20, the dosage key 5 includes an actuation rib 55 acting on the spring leg 40 only while being in depressed condition in order to avoid fatigue of the spring leg 40. The spring leg 40 is accordingly only biased if the dosage key 5 is being pressed or held downward.

Apart from the indexing means in the form of the counter ring, the device includes another inhalation control window 48 indexing whether the device is ready for inhalation or not. The inhalation control window shows for instance a green-colored flag in the event the device is ready for inhalation. This is because in the activated status of the inhaler 1 a green colored tab 49 of the dosage lever 6 covers a red colored flag in the inhalation control window 48. The reset of the device from the inhalation position into the starting position takes place during inhalation by means of an airflow upon inhalation. Flap valve 22 is deflected thus releasing the dosage lever 6 as this has been described in detail before.

In order to ensure leak tightness of the air duct 9, the shells 12 and 13 may be sealed against valve chamber 15 by means of one or more sealing ribs which extend around valve chamber 15. The sealing rib may be in form of a thermoplastic elastomer which has been co-injection molded with valve chamber 15. Alternatively, the sealing rib 52 may be designed as a resilient ring which has been mounted into a sealing groove during assembly of the inhaler.

In a particularly preferred embodiment of the inhaler according to the invention, the shells 12 and 13 are sealed against the valve chamber by a labyrinth seal which completely extends around the valve chamber 15, so that the valve

chamber 15 including the cyclone 16 and the powder groove 16a is effectively sealed against the dosing compartment of the inhaler. The labyrinth seal is provided by a sealing rib 52 completely extended around the valve chamber 15 and in the assembled state of the inhaler 1 engaging a corresponding sealing groove in the shells 12 and 13. This sealing assists in keeping the triggering forces for the flap valve 22 as reproducible as possible. The bandwidth for the required triggering forces normally corresponds to an air flow variation of 30 l/min for the suction to be applied by the patient. Sealing the valve chamber of the inhaler 1 against the shells 12, 13 remarkably reduces this variation in required air flow for triggering the flap valve 22. Accordingly, this design avoids the possibility of sucking an air flow through the inhaler which bypasses the powder channel and/or the air duct 9.

Reference numerals

1	inhaler
2	reservoir
3	cartridge
3a	cartridge body
4	lid
5	dosage key
6	dosage lever
7	locking lever
8	dosage slide
9	air duct
10	mouthpiece
11	mouthpiece cap
12, 13	shells
14	cover
15	valve chamber
16	cyclone
16a	powder groove
17	dosage key spring
18	dosage slide passage
19	dosage cavity
20	opening
21	opening
22	flap valve
22a	flap
22b	shaft of flap valve
22c	first leg of flap valve
22d	second leg of flap valve
22e	third leg of flap valve
23	fastening hook
24	cut-out portion
25	dosage lever spring
26	tongue member

27 actuator blade
28 beveled edge
29 latch
30 mechanical stop
31 flap valve lever
32 spring of flap valve
33 actuating element
34 counter slide
35 counter ring
36 display window
37 teeth
38 locking ratchet
39 blocking arm
40 spring leg
41 notch
42 tongue
43 pawl
44 sliding channel
45 recess
46 leading end of dosage lever
47 latching rib
48 inhalation control window
49 tab
50 barbed projection
51 sloping face
52 sealing rib
53 deflector surface
53' deflector surface
54 bearing surface
55 actuation rib

Claims

1. Inhalation device for powdered drugs to be received by a patient by an inhalation-caused air stream, comprising at least one powder reservoir, metering means for repeatedly metering a powder dose from the reservoir, a transportation mechanism for moving said metering means from a filling position for receiving a powder dose into an emptying position for releasing said powder dose into a powder channel, at least one activating device for manual operation by the patient, said activating device being operatively connected to said transportation mechanism such that upon operation a single powder dose is being metered, said activating device comprising a dosage key (5) acting on said transportation mechanism when pressed by the patient, characterized in that said dosage key (5) while being pressed is only temporarily engaged with said transportation mechanism such that a metering cycle will be completed and the transportation mechanism and/or the metering means will be reset even if said dosage key (5) will be held in depressed condition.

2. Inhalation device according to claim 1, characterized in that said dosage key (5) includes a deflectable element temporarily engaging a dosage lever (6) of the transportation mechanism, the deflectable element being flexible and being disengaged with the dosage lever (6) in a first non-deflected position and being engaged with the dosage lever (6) in a second deflected position.

3. Inhalation device according to claim 2, characterized in that said deflectable element is in the form of an actuator blade (27).

4. Inhalation device according to claims 2 or 3, characterized by a relative to the dosage key (5) stationary deflection profile urging the deflectable element into the second deflected position during movement of the dosage key (5) from a non-depressed into a depressed position and then releasing the deflectable element into the first non-deflected position during further movement of the dosage key (5) into a fully depressed position.

5. Inhalation device according to claim 4, characterized in that a deflection profile is provided by a beveled edge (28) or a beveled profile of a fixed part of the inhaler (1).

6. Inhalation device according to any of the preceding claims, characterized in that the dosage key (5) is being held spring-biased in its non-operated position.

7. Inhalation device according to any of the preceding claims, characterized in that the transportation mechanism includes a dosage lever (6) acting on said metering means, said dosage lever (6) being locked in the inhalation position of said metering means after the dosage key (5) has been depressed and in that said dosage lever (6) is releaseable by inhalation regardless whether the dosage key (5) has been released or not.

8. Inhalation device according to claim 7, characterized by an inhalation-operated valve in an air duct (9) communicating with said powder channel, said valve being operatively connected to that dosage lever (6) such that the dosage lever is releasable by the action of the valve.

9. Inhalation device according to claim 8, characterized in that said dosage lever (6) may assume a first and a second locked position subsequently and in that said dosage lever (6) is releasable by inhalation only after it has been locked in the second locked position.

10. Inhalation device according to claim 9, characterized in that said dosage lever (6) assumes said second locked position when said dosage key (5) will be depressed until said deflectable element will be released on further depression of the dosage key (5).

11. Inhalation device according to any of the preceding claims, characterized in that said deflectable element is formed integrally with said dosage key (5).