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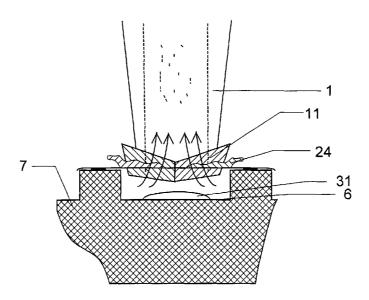
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(54) Title: FOIL CUTTER



(57) Abstract: A foil-cutting device is disclosed for opening a foil protecting a dose of medication power carried by a dosing cassette or the like for an inhaler device. The dosing cassette will in a typical embodiment carry a number of prepared doses (31), which for protection of the medication powder are covered by a metallic or plastic foil (24). The foil-cutter device of the present invention provides a tool (11) for accessing a selected sealed dose of medication powder of the cassette during an inhalation process using a dry powder inhaler (DPI). When a user inhales through the DPI the foil-cutter opens the foil (24) for access to a pre-metered powder dose (31). The foil-cutter arrangement ensures that no access is permitted to the pre-metered dose during any other circumstances. Particularly the present invention is adapted to be applied in an inventive continuous inhaler controlling the release of a powder dose during the inhalation of the medication powder.



VO 02/24266 △



Declaration under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

Published:

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- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Foil cutter

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TECHNICAL FIELD

The present invention relates to dry powder inhalers and more exactly to a foil cutter device for accessing a sealed dose onto a dosing member carrying one or several pre-metered powder doses for a dry powder inhaler.

BACKGROUND

Today supply and distribution of medication powders take place in many different ways. Within health care more and more is focussed on the possibility to dose and distribute powder directly to the lungs of a user by means of an inhaler to obtain an efficient, fast, and user friendly administration of the specific medication substance.

Inhalers have been developed from being very simple to the up-to-date relatively complicated devices. For the up-to-date inhalers some form of dosing process is almost entirely used for preparing the dose to be inhaled. Most often forming of the dose with the amount to be inhaled takes place industrially in advance in a dose package containing of the order 10-50 doses. The inhaler then is loaded with this dose package as the source of each dose. Other inhalers have a magazine from which the powder is dosed by some device for distribution to the inspiration air. In both cases the powder will generally be strongly agglomerated and therefore must be dispersed.

When it comes to a dry powder inhaler (DPI) one aspect that is of great importance is to keep the medication substance free from air humidity, dirt, or any other kind of pollution. In order to achieve this, the dose of powder needs to be kept in a sealed volume during storage and preferably, for as long as possible until the dose on a carrier element is to be inhaled. The material, used for sealing the dose may be for instance aluminum or some polymer foil. Such a foil should prevent all kind of leakage from the surrounding environment, both when it comes to penetration of the film as

such, as well as a leakage between the foil and the edge walls of the carrier element to which the foil is fixed, e.g. by a welding or gluing process.

Therefore there is a demand for a device, which will prepare the dosing member for an immediate access to a selected pre-metered dose of the medication powder at the proper time in connection with an inhalation process for releasing the selected dose of the medication powder by the DPI to a user.

SUMMARY

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A dosing cassette or the like will in a typical embodiment carry a number of prepared doses, which for protection of the medication powder are covered and sealed by e.g. a metallic or plastic foil. The foil-cutter device of the present invention provides a tool for accessing a sealed dose of medication powder of the cassette, which is placed into a dry powder inhaler (DPI). When a user inhales through the DPI the foil-cutter will open the foil for access to a pre-metered powder dose. The foil-cutter arrangement ensures that no access is permitted to the pre-metered dose during any other circumstances. Particularly the present invention is adapted to be applied in an inventive continuous inhaler controlling the release of a powder dose during an inhalation.

A foil-cutter arrangement and device according to the present invention are set forth by the independent claims 1 and 4. Further embodiments of the foil-cutter arrangement and device are set forth by the dependent claims 2 to 3 and 5 to 6 respectively.

DESCRIPTION OF THE DRAWINGS

The invention will be described in the form of a preferred and illustrative embodiment and by means of the attached drawings, wherein like reference numbers indicate like or corresponding elements and wherein:

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- FIG. 1 illustrates in a side-view the mouthpiece suction tube, the cutter, and the cassette member with its pre-metered doses;
- FIG. 2 illustrates in a top-view the mouthpiece, the cutter in an initial position at the cassette member with a foil enclosed pre-metered dose;
 - FIG. 3 illustrates a cross section of the cassette and the cutter cutting the foil for accessing the powder dose;

FIG. 4 illustrates the cassette with its pre-metered doses in motion, whereby the cutter exposes the powder dose to the suction tube nozzle sweeping over the dose bed during an inhalation.

DESCRIPTION OF AN ILLUSTRATIVE EMBODIMENT

In FIG. 1 an illustrative embodiment of the present invention is presented. A cassette 4 serves as a carrier of one or several doses of a medication drug to be administered in the form of a fine powder, which is to be inhaled by a user by means of a dry powder inhaler also referred to as a DPI (not shown). Each dose 31 is placed on a separate dose bed 6 in dose carrying recesses 7 of the cassette 4, Each dose 31 then has been individually sealed by a suitable foil strip 24.

This powder dose **31** has been pre-metered and applied to the cassette **4** in the form of a strip **5** or a series of spots of powder on the dose bed **6**, which is also illustrated in Figure 2 showing the arrangement in a top view. The foil **24** covers the entire strip **5** of powder such that there is formed a closed and sealed volume for each dose of powder **31**, as indicated in Figure. 1. When a cassette **4** to be used is inserted into the DPI, it is in advance prepared in this way.

When an inhalation is performed the cassette 4, at the start of the inhalation, is released from its ready-to-go state by a catch mechanism. The

cassette will then be propelled forward in an appropriate motion, for instance by a spring (not shown). The cassette 4 with the dose 31 to be administered moves towards the foil cutter 11 and the nozzle 1 of the suction tube 33, comprising besides the nozzle 1 a diffuser 2 and a porous tube 3, all of which fitted to the mouthpiece. (not illustrated) At the point where the sharp edge of the cutter 11 comes in contact with the foil 24, which seals the dose 31 in the cassette dose bed 6, the foil is cut open, as indicated in Figure 3. It should be noted that the foil-cutter 11 is not allowed to make contact with the powder on the powder bed 6, but should only open the foil so that the nozzle 1 can get access to the powder without restrictions.

During the continuous motion of the cassette 4 indicated in FIG. 3, the cutter 11 serves two functions; one is to cut the foil 24 open, a continuous action during the cassette motion, and the other is to fold the foil out of the way so it does not interfere with the nozzle 1 during the inhalation process. As the dose strip 5 is continuously transported by the cassette 4 under the nozzle 1 the powder is withdrawn from the dose bed 31 by the flow of air into the nozzle 1 resulting from the inhalation as is further indicated in Figures 3 and 4.

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The powder is dispersed in the air as it goes up the diffuser 2 and porous tube 3 of the suction tube 33 in the mouthpiece 19 and the speed of the air is suitably reduced to make the delivery of the dose 31 to the upper or deep lungs with as little retention as possible in the mouth piece parts or the airways of the user. The mouthpiece suction tube 33 is placed just behind the foil cutter 11.

It will be understood by those skilled in the art that various modifications and changes may be made to the present invention without departure from the scope thereof, which is defined by the appended claims.

CLAIMS

1. Arrangement in a dry powder inhaler for cutting open a foil which protects a selected dose of medication powder carried by a dosing member,

characterized in

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a foil-cutter element (11) having the form of a triangular wedge with a sharp point of knife in front thereby forming a plough positioned in front of a nozzle (1);

a dosing member (4) provided with prepared beds (31) of powder covered by a protective foil (24);

whereby upon an inhalation process the dosing member (4) is propelled towards the foil-cutter element (11) and the protective foil (24) will be cut open to make the nozzle (1) accessing a selected bed of powder (31), the powder content of the selected bed of powder will then be sucked into the inhalation air and transported into the lungs of the user during a controlled time interval of the inhalation process.

- 2. The arrangement according to claim 1, **characterized in** that the foilcutter element (11) and the nozzle (1) are positioned in a close relation to each other.
- 3. The arrangement according to claim 1, **characterized in** that the foil-cutter element forms a triangular wedge having a bottom side positioned at a height relative to the dosing member (4) not to touch the bed of powder (31) but only opening the foil (24) for a free access of the nozzle (1) to the bed of powder (31) during the dosing member motion.
- 4. A foil-cutter element cutting a foil covering a dose of medication powder carried by a dosing member inserted into a dry powder inhaler device, **characterized in** that the element (11) is a triangular wedge forming a plough defined with an upper sharp central edge, whereby the cutter element is placed in the body of the inhaler device in front of a nozzle (1) relative to the movable dosing member (4).

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- 5. The foil-cutter element according to claim 4, **characterized in** that the foil-cutter element (11) is positioned in relation to the dosing member (4) such that, when the dosing member (4) is set in motion the foil-cutter element (11) will open a dose of powder for access by cutting open the foil covering a dose without touching the bed of metered medication powder carried by the dosing member.
- 6. The foil-cutter element according to claim 1, **characterized in** that the element forms a triangular wedge having a bottom side positioned at a height relative to the dosing member (4) not to touch the bed of powder (31) but only opening the foil (24) for a free access of the nozzle (1) to the bed of powder (31) during the dosing member motion.

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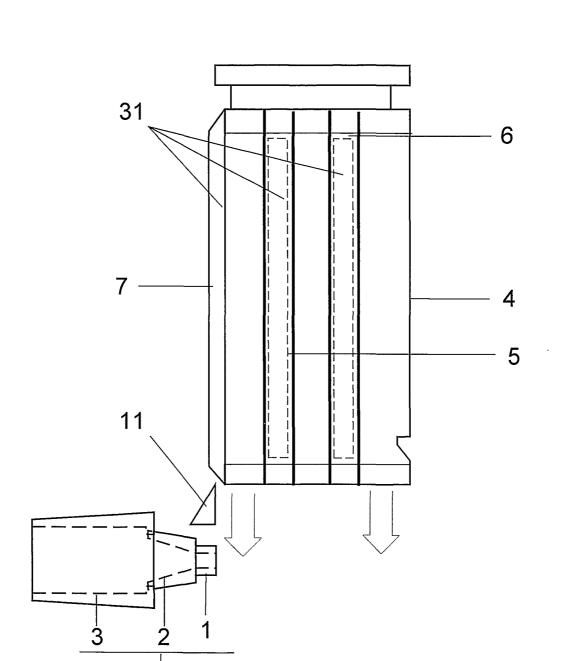
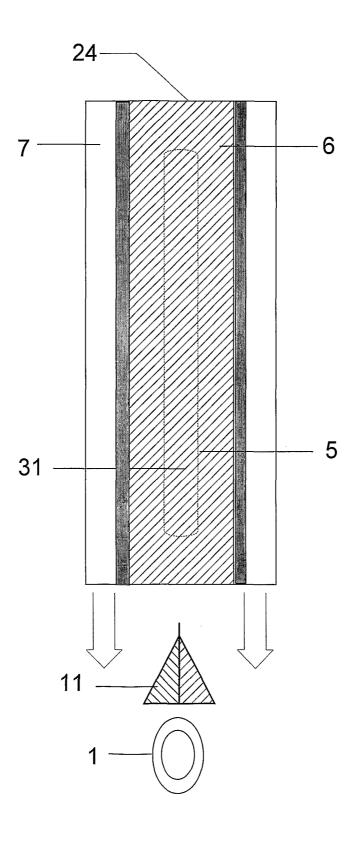


Fig. 1

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Fig. 2

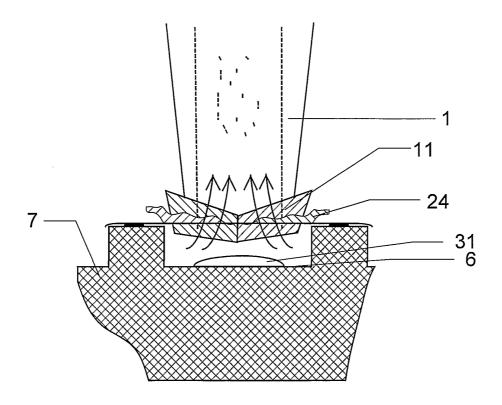


Fig. 3

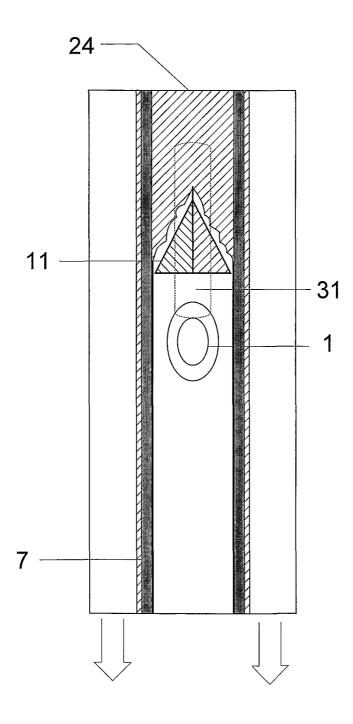


Fig. 4

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 01/01999

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 15/00 According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Y Further documents are listed in the continuation of Box C.

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6116238 A (THOMAS R JACKSON ET AL), 12 Sept 2000 (12.09.00), abstract, fig.	1-6
		
A	US 5875776 A (FARID VAGHEFI), 2 March 1999 (02.03.99), abstract, fig.	1-6
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A	WO 9858695 A1 (CECCHINI, MARCO), 30 December 1998 (30.12.98), abstract, fig.	1-6
	. 	
A	EP 0768094 A2 (UNISIA JECS CORPORATION), 16 April 1997 (16.04.97), abstract, fig.	1-6
		

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*	Special categories of cited documents:	· "T"	later document published after the international filing date or priority		
"A"	document defining the general state of the art which is not considered to be of particular relevance		date and not in conflict with the application but cited to understand the principle or theory underlying the invention		
"E"	earlier application or patent but published on or after the international filing date	"X"	document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive		
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	cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance: the claimed invention cannot be		
″O″	"O" document referring to an oral disclosure, use, exhibition or other means		considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art		
"P"	document published prior to the international filing date but later than the priority date claimed	"&"	document member of the same patent family		
Date	e of the actual completion of the international search	Date	of mailing of the international search report		
22	January 2002		2 4 -0 1- 2002		
Name and mailing address of the ISA/		Authorized officer			
Swedish Patent Office					
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X See patent family annex.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 01/01999

C (Continu	ation). DOCUMENTS CONSIDERED TO BE RELEVANT	
Category*		Relevant to claim No
A ·	WO 9406498 A1 (FISONS PLC), 31 March 1994 (31.03.94), abstract, fig.	1-6
A	WO 9947099 A1 (ASTRA AKTIEBOLAG), 23 Sept 1999 (23.09.99), abstract, fig.	1-6
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INTERNATIONAL SEARCH REPORT

Information on patent family members

27/12/02

International application No.
PCT/SE 01/01999

	ent document n search report		Publication date		Patent family member(s)	Publication date
US	6116238	A	12/09/00	AU CN EP TW	1597499 A 1301185 T 1042025 A 430564 B	16/06/99 27/06/01 11/10/00 00/00/00
	· .			WÖ	9927987 A	10/06/99
US	5875776	A	02/03/99	AU WO	2216097 A 9737708 A	29/10/97 16/10/97
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