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ASTRA AKTIEBOLAG

Inventors:
Elna BERG
Hans NILSSON

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SAS/SK/ÅW/ME

Spacer

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Spacer

Technical field of the invention

The present invention relates to an oblong spacer for children primarily intended to be used in conjunction with a metered dose inhaler (MDI), said spacer being rotationally symmetrical around a central, longitudinal axis and being provided with an opening at each end located centrally in said axis for connection of an MDI respectively a mouth-piece or similar.

Background of the invention

MDI:s are containers with an actuating, metering valve containing a mixture of a pressurized propellant and a drug. When the valve is actuated, a dose of the drug/propellant mixture is ejected into the air and can be inhaled by a patient.

In order to alleviate the problems of a high oral deposition and the coordination difficulties associated with MDI:s, different kinds of spacer devices have been developed, that is a holding chamber connected to the MDI at one end. The other end of the spacer is connected to or provided with a mouthpiece and/or a face mask through which a patient can inhale. When the valve is actuated, the dose of the drug/propellant mixture is sprayed into the spacer, resulting in that a cloud of smaller particles in the respirable range (an aerosol) is contained in the chamber for a certain time, during which time larger particles, that is

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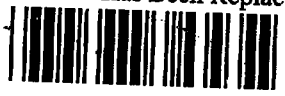
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particles that normally would be deposited orally, are separated from the aerosol dose and deposited in the spacer. The propellant evaporates at the same time. The cloud of particles can be inhaled effortlessly by the patient.

The prior art devices of this kind are however exclusively designed for use in older children and adults. Their volume normally varies from 0.5 to 2 litres and they mostly are made of a polymer material, for instance polycarbonate. They are often adapted for use in younger children. The reproducibility and age-dependency of their dose-delivery when used for the treatment of children is important, but are not yet ascertained. Theoretical models have predicted an increased lung deposition in small children due to the smaller airway calibre and a greater ventilation/kg, but in vivo documentation is sparse. Most of the available documentation in vivo of dose delivery from the prior art devices discusses the clinical response in wheezy children from inhalations of β_2-agonist. In these, the drug has been administered in doses considerably above the minimum effective dose. The response is therefore not critically dependent on reproducible delivery. The results from studies relating to these drugs further can not be extrapolated to the generation of a steroid aerosol, which has other micronizing and solubility characteristics.

Consequently there is a need for spacer delivery systems specially adapted to the treatment of young children. The need is particularly great in systems to be used in the administering of steroids due to the

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stricter demands on the reproducability and dosis accuracy for these drugs. A high utilisation of the substance also is desirable.

The volume of the spacer is critical since the aerosol is emptied from the chamber in an exponential manner. The inspiratory volume required to inhale the total dose of aerosol will be several times the spacer volume. The settling of particles limits the time available for inhalation. Since the inspirational capability of small children is smaller than the inspirational capability of adults, a reduction of the spacer volume might be indicated, for instance in the range of a few tidal breaths of an infant to reduce the time required for administration.

A reduced spacer volume will however contain an increased concentration of aerosols, and, accordingly, will require less time to empty. The fraction of airborne particles is however reduced due to impaction, adsorption, sedimentation and coagulation of the aerosol. This tendency will be aggravated if the spacer is made of a polymer material like polycarbonate, which may be charged by electrostatic forces, since the distance for each particle to the nearest wall will be smaller than in a prior art spacer, and the electrostatic forces will consequently have a greater influence.

The object of the invention consequently is to provide a spacer well adapted to the treatment of small children based on the above considerations.

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Short description of the inventive concept

The above object is achieved in that a spacer as described introductorily is designed to have a small total volume which is in the range between 50 and 400 ml, and in that the material in the spacer has a surface resitivity which is lower than 10^9 Ohm, preferably lower than 10^6 Ohm. In a most preferred embodiment the surface resistivity is lower than 1. Other preferred embodiments are set forth in the dependent claims.

Brief description of the appended drawings

Fig 1 shows a spacer according to the invention in a side view,
Fig 2 illustrates the narrow end of the spacer to which an MDI is to be connected
Fig 3 shows the broad end of the spacer.

Detailed description of a preferred embodiment of the invention

Fig 1 shows the preferred spacer 1 which has an oblong shape with a slightly conically tapering first part 2 with a first end surface 3, a central, cylindrical part 4 and a substantially hemispherical second part 5. The junction between the surface 3 and the tapering part 2 is rounded. The spacer is circular in section and consequently is rotationally symmetrical. The overall length of the spacer is about 130 mm and the length of the tapering part is about 80 mm. The diameter of the end surface 3 is about 40 mm (the round part of the

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junction with the part 2 being disregarded), the diameter of the cylindrical part 4 being about 55 mm. The volume of the spacer is 220 ml. These dimensions are adapted to fit most small children although other dimensions are conceivable. The length of the spacer is adapted to standard MDI:s in that the spacer is long enough to prevent that particles within the respirable range are sprayed onto the opposite walls of the device when the valve of the MDI is actuated.

The hemispherical part 5 is provided with a central opening 6 having a projecting, circumferential flange 7 for the attachment of a standard mouth-piece or a face mask. A two way valve may be connected between spacer and mouth-piece/mask.

The end surface 3 is also provided with a central opening 8 having an elliptical shape adapted to a standard mouth-piece adapter of a standard aerosol dispenser or MDI.

The spacer is made of stainless steel, which is a material having a surface resistivity which is well below the maximum surface resistivity at which the spacer is sufficiently conductive to function properly and at which the risk for electrostatic attraction of the respirable particles to the walls of the spacer is minimized.

The use of stainless steel will also result in a very robust spacer which consequently also in this respect is very well adapted to the use in smaller children.

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In use, the mouth piece adapter of the MDI is connected to the corresponding end of the spacer and the mouth-piece with the two-way valve is connected to the other end. The two-way valve is designed to allow the inspirational air to flow through the spacer from the MDI to the mouthpiece but to prevent the expirational air to flow from the mouth-piece, in this way creating a rectified inspiration through the spacer. The inspirational air is sucked through the mouth piece adapter of the MDI though the standard air openings provided therein for ordinary use without spacer.

The rectified air flow in conjunction with the low risk for electrostatic influence on the respirable particles and the small volume of air which has to be inhaled will contribute to the deposition of a reasonably reproducable and accurate dosage in the desired locations in the lungs of the child, as well as also contributing to the achievement of the utilisation of a larger part of the drug than possible in standard prior art devices.

Possible modifications of the invention

The invention of course can be modified in many ways within the scope of the appended claims.

The desired surface resistivity characteristics can be obtained in several ways.

Thus, it is possible to use most metals, any polymer materials having a surface resistivity below the desired values, polymers containing additives giving

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the desired chacteristics and polymers having been given the desired characteristics by means of a surface treatment.

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CLAIMS

1. Spacer for children primarily intended to be used in conjunction with a metered dose inhaler (MDI), said spacer having a generally oblong shape and being rotationally symmetrical around a central, longitudinal axis and being provided with an opening at each end located centrally in said axis for connection of an meterd dose inhaler respectively of a mouth-piece or similar, c h a r a c t e r i z e d in that said spacer has a small total volume which is in the range between 50 and 400 ml, and in that the material in the spacer has a surface resitivity which is lower than 10^9 Ohm, preferably lower than 10^6 Ohm.

2. Spacer according to claim 1, c h a r a c t e r i z e d in that the surface resistivity is lower than 1.

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ABSTRACT

The present invention relates to a spacer for children primarily intended to be used in conjunction with a metered dose inhaler (MDI), said spacer having a generally oblong shape and being rotationally symmetrical around a central, longitudinal axis and being provided with an opening at each end located centrally in said axis for connection of an meterd dose inhaler respectively of a mouth-piece or similar. The spacer has a small total volume which is in the range between 50 and 400 ml, and the material in the spacer has a surface resitivity which is lower than 10^9 Ohm, preferably lower than 10^6 Ohm.

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Fig. 1

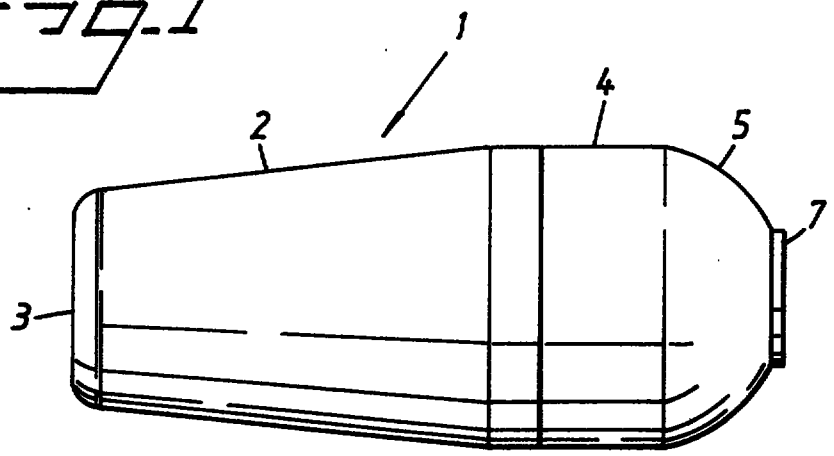


Fig. 2

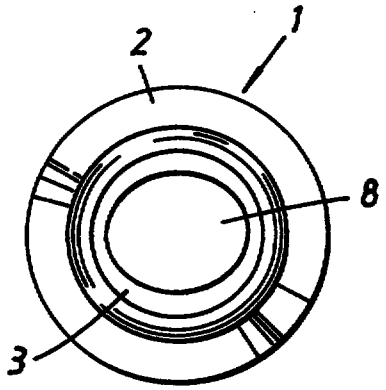
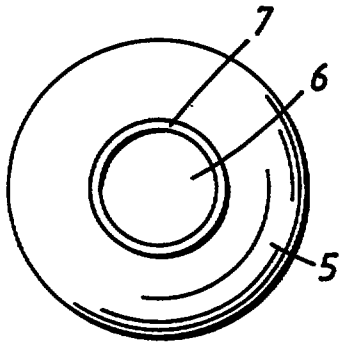


Fig. 3



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24 OCT 1996

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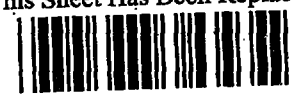
stricter demands on the reproducability and dosis accuracy for these drugs. A high utilisation of the substance also is desirable.

The volume of the spacer is critical since the aerosol is emptied from the chamber in an exponential manner. The inspiratory volume required to inhale the total dose of aerosol will be several times the spacer volume. The settling of particles limits the time available for inhalation. Since the inspirational capability of small children is smaller than the inspirational capability of adults, a reduction of the spacer volume might be indicated, for instance in the range of a few tidal breaths of an infant to reduce the time required for administration.

A reduced spacer volume will however contain an increased concentration of aerosols, and, accordingly, will require less time to empty. The fraction of airborne particles is however reduced due to impaction, adsorption, sedimentation and coagulation of the aerosol. This tendency will be aggravated if the spacer is made of a polymer material like polycarbonate, which may be charged by electrostatic forces, since the distance for each particle to the nearest wall will be smaller than in a prior art spacer, and the electrostatic forces will consequently have a greater influence.

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Short description of the inventive concept

The above object is achieved in that a spacer as described introductorily is designed to have a small total volume which is in the range between 50 and 400 ml, and in that the material in the spacer has a surface resitivity which is lower than 10^9 Ohm, preferably lower than 10^6 Ohm. In a most preferred embodiment the surface resistivity is lower than 1. Other preferred embodiments are set forth in the dependent claims.

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Detailed description of a preferred embodiment of the invention

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junction with the part 2 being disregarded), the diameter of the cylindrical part 4 being about 55 mm. The volume of the spacer is 220 ml. These dimensions are adapted to fit most small children although other dimensions are conceivable. The length of the spacer is adapted to standard MDI:s in that the spacer is long enough to prevent that particles within the respirable range are sprayed onto the opposite walls of the device when the valve of the MDI is actuated.

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The end surface 3 is also provided with a central opening 8 having an elliptical shape adapted to a standard mouth-piece adapter of a standard aerosol dispenser or MDI.

The spacer is made of stainless steel, which is a material having a surface resistivity which is well below the maximum surface resistivity at which the spacer is sufficiently conductive to function properly and at which the risk for electrostatic attraction of the respirable particles to the walls of the spacer is minimized.

The use of stainless steel will also result in a very robust spacer which consequently also in this respect is very well adapted to the use in smaller children.

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In use, the mouth piece adapter of the MDI is connected to the corresponding end of the spacer and the mouth-piece with the two-way valve is connected to the other end. The two-way valve is designed to allow the inspirational air to flow through the spacer from the MDI to the mouthpiece but to prevent the expirational air to flow from the mouth-piece, in this way creating a rectified inspiration through the spacer. The inspirational air is sucked through the mouth piece adapter of the MDI though the standard air openings provided therein for ordinary use without spacer.

The rectified air flow in conjunction with the low risk for electrostatic influence on the respirable particles and the small volume of air which has to be inhaled will contribute to the deposition of a reasonably reproducable and accurate dosage in the desired locations in the lungs of the child, as well as also contributing to the achievement of the utilisation of a larger part of the drug than possible in standard prior art devices.

Possible modifications of the invention

The invention of course can be modified in many ways within the scope of the appended claims.

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the desired chacteristics and polymers having been given the desired characteristics by means of a surface treatment.

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* C L M S *

CLAIMS

1. Spacer for children primarily intended to be used in conjunction with a metered dose inhaler (MDI), said spacer having a generally oblong shape and being rotationally symmetrical around a central, longitudinal axis and being provided with an opening at each end located centrally in said axis for connection of an meterd dose inhaler respectively of a mouth-piece or similar, c h a r a c t e r i z e d in that said spacer has a small total volume which is in the range between 50 and 400 ml, and in that the material in the spacer has a surface resitivity which is lower than 10^9 Ohm, preferably lower than 10^6 Ohm.

2. Spacer according to claim 1, c h a r a c t e r i z e d in that the surface resistivity is lower than 1.

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SPACER

ABSTRACT

The present invention relates to a spacer for children primarily intended to be used in conjunction with a metered dose inhaler (MDI), said spacer having a generally oblong shape and being rotationally symmetrical around a central, longitudinal axis and being provided with an opening at each end located centrally in said axis for connection of an meterd dose inhaler respectively of a mouth-piece or similar. The spacer has a small total volume which is in the range between 50 and 400 ml, and the material in the spacer has a surface resitivity which is lower than 10^9 Ohm, preferably lower than 10^6 Ohm.

FIGURE 1.

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Fig. 1

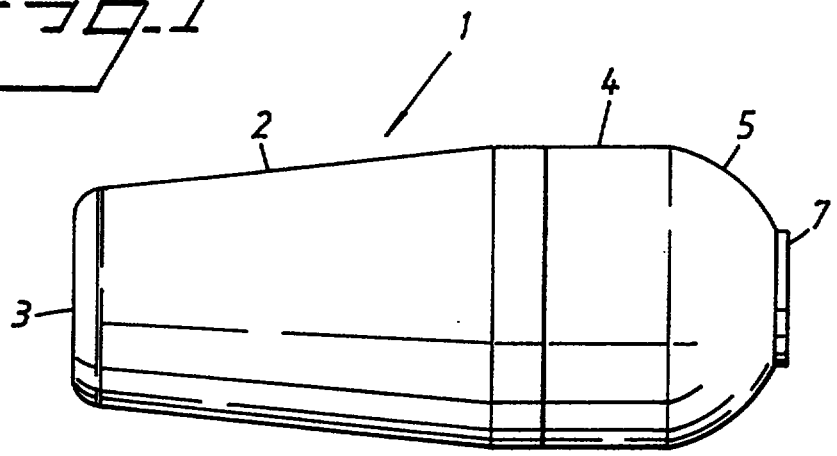


Fig. 2

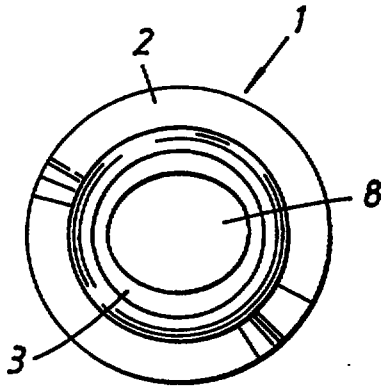
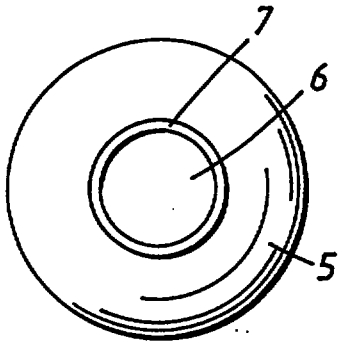


Fig. 3



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The present invention relates to a spacer for use with a metered dose inhaler (MDI).

In order to alleviate the problems of high oral deposition and the coordination difficulties associated with metered dose inhalers, spacers have been developed for use therewith. One end of a spacer is connected to a metered dose inhaler and the other end is connected to or provided with a mouthpiece or face mask through which a patient inhales. When the metered dose inhaler is actuated, gaseous propellant entraining a dose of drug is sprayed into the spacer, thereby providing a cloud of small particles of respirable size in the spacer for a certain period of time, during which time large particles, that is, particles which would normally would deposit orally, settle and deposit in the spacer. The aerosol cloud of small particles can be inhaled effortlessly by a patient.

Prior art spacers of this kind are, however, exclusively designed for use with older children and adults. The volume of such spacers is normally in the range of from 0.5 to 2 litres and such spacers are principally made of a polymeric material, for instance, polycarbonate. Such spacers are often adapted for use in younger children. However, the reproducibility and age-dependency of the dose delivery when used for the treatment of children is important, and as yet has not been ascertained. Theoretical models have predicted an increased lung deposition in small children due to the smaller airways and a greater ventilation per kilogram, but in vivo documentation is sparse. Most of the available in vivo documentation for the dose delivery of prior art spacers relates to the clinical response

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in wheezy children on inhalation of a β_2-agonist. In these studies the drug has been administered in doses considerably above the minimum effective dose and the response is therefore not critically dependent on reproducible delivery. In addition, the results from studies with these drugs cannot be extended to the generation of steroid aerosol systems which exhibit other micronizing and solubility characteristics.

There is therefore a need for a spacer which is adapted to the treatment of young children, particularly for the administration of steroids for which the demands on reproducibility and dose accuracy are stricter and a high utilisation of which is desirable.

The volume of the spacer is critical since it is emptied in an exponential manner. The inspiratory volume required to inhale entirely the aerosol cloud form the spacer will be several times the volume of the spacer, but the fall out of particles from the aerosol cloud limits the time available for inhalation. Since the inspirational capability of small children is less than the inspirational capability of adults, ideally, the volume of the spacer should be reduced, for instance, to the order of a few tidal breaths of an infant so as to reduce the time required for administration. Whilst a spacer of reduced volume will contain an increased concentration of drug and require less time to empty, the fraction of airborne particles will be reduced due to the deposition, settling and agglomeration of particles. This effect will be pronounced if the spacer is made of a polymeric

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material, such as polycarbonate, which may be charged electrostatically.

It is thus an aim of the present invention to provide an improved spacer for use with small children.

Accordingly, the present invention provides a spacer for use with a metered dose inhaler, comprising a body which defines a chamber, wherein the body has a generally oblong shape which is rotationally symmetrical about a longitudinal axis and an opening at each end, one of the openings being adapted for connection to a metered dose inhaler; characterized in that the body is composed of metal having a surface resistivity of less than 1 Ohm, and in that the chamber has a total volume of between 50 and 400 ml.
Preferably, the body is composed of stainless steel.

A preferred embodiment of the present invention will now be described hereinbelow by way of example only with reference to the accompanying drawings, in which:

Figure 1 illustrates a side view of a spacer in accordance with a preferred embodiment of the present invention;

Figure 2 illustrates the end of the spacer of Figure 1 to which a metered dose inhaler is connected; and

Figure 3 illustrates the end of the spacer of Figure 1 to which a mouthpiece or face mask is connected.

The spacer comprises an oblong body 1 which has a rotationally symmetrical circular section. The body 1

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has a slightly tapering frusto-conical part 2, the small end of which is rounded and defines one end 3 of the body 1, a central cylindrical part 4 and a substantially hemi-spherical part 5 which defines the other end of the body 1. The hemi-spherical part 5 includes a central opening 6 having a projecting, circumferential flange 7 for the connection of a mouthpiece or face mask. A two-way valve may be connected between the spacer and the mouthpiece or face mask. The frusto-conical part 2 includes a central opening 8, in this embodiment elliptical in shape, adapted to fit the mouthpiece of a metered dose inhaler.

The spacer has an overall length of about 130 mm, with the length of the frusto-conical part 2 being about 80 mm, the diameter of the one end 3 being about 40 mm (the rounded section of the frusto-conical part 2 being disregarded) and the diameter of the cylindrical part 4 being about 55 mm. In this embodiment the volume of the spacer is 220 ml. The spacer of this embodiment having such dimensions is suited to most small children, although other dimensions are conceivable. The length of the spacer is such that particles of respirable size are not sprayed onto opposing surfaces of the body 1 of the spacer when the metered dose inhaler is actuated.

In this embodiment the spacer is made of stainless steel, which material has a surface resistivity of less than 1 Ohm and is sufficiently low as to minimize the electrostatic attraction of particles of respirable size to surfaces of the body 1 of the spacer. In forming the spacer of stainless steel the spacer is

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also very robust which makes it particularly suitable for use with small children.

In use, the mouthpiece of a metered dose inhaler is fitted into the opening 8 in the frusto-conical part 2 and a mouthpiece or face mask incorporating a two-way valve is fitted into the opening 6 in the hemi-spherical part 5. The two-way valve allows air to be inhaled through the spacer from the metered dose inhaler to the mouthpiece or face mask, but prevents air from being exhaled into the spacer. In this way, air flow through the spacer is rectified.

By forming the spacer of a material of low resitivity and of small volume, the reduction in the volume of air which has to be inhaled enables the delivery of a reasonably reproducible and accurate dose of drug to small children. In addition, the spacer enables the utilisation of a larger fraction of drug than possible in standard prior art spacers.

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* C L M S *

CLAIMS

1. A spacer for use with a metered dose inhaler (MDI), comprising a body (1) which defines a chamber, wherein the body (1) has a generally oblong shape which is rotationally symmetrical about a longitudinal axis and an opening (6, 8) at each end, one of the openings (8) being adapted for connection to a metered dose inhaler; characterized in that the body (1) is composed of metal having a surface resistivity of less than 1 Ohm, and in that the chamber has a total volume of between 50 and 400 ml.

2. The spacer according to claim 1, wherein the body (1) is composed of stainless steel.

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SPACER

ABSTRACT

The present invention relates to a spacer for children primarily intended to be used in conjunction with a metered dose inhaler (MDI), said spacer having a generally oblong shape and being rotationally symmetrical around a central, longitudinal axis and being provided with an opening at each end located centrally in said axis for connection of an meterd dose inhaler respectively of a mouth-piece or similar. The spacer has a small total volume which is in the range between 50 and 400 ml, and the material in the spacer has a surface resitivity which is lower than 10^9 Ohm, preferably lower than 10^6 Ohm.

FIGURE 1.

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SPACER

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In order to alleviate the problems of high oral deposition and the coordination difficulties associated with metered dose inhalers, spacers have been developed for use therewith. One end of a spacer is connected to a metered dose inhaler and the other end is connected to or provided with a mouthpiece or face mask through which a patient inhales. When the metered dose inhaler is actuated, gaseous propellant entraining a dose of drug is sprayed into the spacer, thereby providing a cloud of small particles of respirable size in the spacer for a certain period of time, during which time large particles, that is, particles which would normally would deposit orally, settle and deposit in the spacer. The aerosol cloud of small particles can be inhaled effortlessly by a patient.

Prior art spacers of this kind are, however, exclusively designed for use with older children and adults. The volume of such spacers is normally in the range of from 0.5 to 2 litres and such spacers are principally made of a polymeric material, for instance, polycarbonate. Such spacers are often adapted for use in younger children. However, the reproducibility and age-dependency of the dose delivery when used for the treatment of children is important, and as yet has not been ascertained. Theoretical models have predicted an increased lung deposition in small children due to the smaller airways and a greater ventilation per kilogram, but in vivo documentation is sparse. Most of the available in vivo documentation for the dose delivery of prior art spacers relates to the clinical response