

Ventolin rotacaps.

Contributors

Allen & Hanburys

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Wellcome Collection
183 Euston Road
London NW1 2BE UK
T +44 (0)20 7611 8722
E library@wellcomecollection.org
<https://wellcomecollection.org>

DATA SHEET

VENTOLIN Rotacaps

SALBUTAMOL SULPHATE BP INHALATION CARTRIDGES



VENTOLIN ROTACAPS ▼

Presentation

Ventolin Rotacaps, an alternative inhalation form of salbutamol to Ventolin Inhaler, are especially valuable for treating patients who are unable to use pressurised inhalers effectively or who might use them unwisely.

Ventolin Rotacaps contain a mixture of microfine salbutamol sulphate and larger particle lactose in blue/colourless hard gelatine cartridges. Each Rotacap contains 200 micrograms (light blue) or 400 micrograms (dark blue) of salbutamol (as sulphate) and is marked Ventolin 200 or Ventolin 400. The contents of a Rotacap are inhaled using a specially developed device called a Rotahaler, which cuts the cartridge into halves which rotate and release the drug when the patient inhales. This breath actuation is very sensitive and so the drug is fully available even at the lowest inspiratory flow rates. The Rotahaler is, therefore, a more reliable drug delivery system for many patients, but a rather larger unit dose relative to Ventolin Inhaler is necessary for the same therapeutic effect.

Indications

Salbutamol BP is a beta-adrenergic stimulant which has a highly selective action on bronchial beta-adrenoceptors and little or no effect on cardiac beta-receptors at therapeutic doses.

Salbutamol is also highly active in preventing antigen-induced release of histamine and slow-reacting substance of anaphylaxis, SRS(A), from mast cells in human lung sensitised with IgE antibody. Such Type I hypersensitivity reactions are generally considered to be the primary triggers of the allergic asthma syndrome.

Ventolin Rotacaps are therefore indicated both for the treatment and prevention of bronchial asthma, and also for the treatment of other conditions, such as bronchitis and emphysema, with associated reversible airway obstruction. Inhaled salbutamol has a long duration of action and Ventolin Rotacaps are ideally suited for routine maintenance therapy and prophylaxis in chronic asthma, both to relieve persistent bronchospasm and to suppress the allergic response within the lungs. Their regular use is also indicated for controlling persistent bronchospasm in chronic bronchitis.

Ventolin Rotacaps act rapidly and may be used when necessary to relieve attacks of acute dyspnoea; for this purpose the Rotahaler may be carried with a Rotacap in place. Rotacaps may also be used before exertion to prevent exercise-induced asthma or before exposure to a known unavoidable allergen challenge.

The effective dose of salbutamol from Rotacaps is only one tenth of the usual oral dose and so the skeletal muscle tremor sometimes associated with oral therapy does not occur.

The selective action of salbutamol on the bronchi and its lack of effects on the cardiovascular system make Ventolin Rotacaps particularly suitable for treating patients with co-existing heart disease or hypertension, including those taking beta-blocking drugs which often impair respiratory function.

Dosage and Administration

Ventolin Rotacaps are for inhalation use only, using a Ventolin Rotahaler.

Adults:

For the relief of acute bronchospasm and for managing intermittent episodes of asthma, 200mcg or 400mcg may be administered as a single dose.

The recommended dose for chronic maintenance or prophylactic therapy is 400mcg three or four times a day.

To prevent exercise-induced bronchospasm, 400mcg should be taken before exertion.

Children:

200mcg is the recommended dose for the relief of acute bronchospasm, in the management of episodic asthma or before exercise.

200mcg should be administered three or four times a day for routine maintenance or prophylactic therapy.

For optimum results, in most patients Ventolin Rotacaps should be used regularly.

The bronchodilator effect of these doses of inhaled salbutamol should last for at least four hours, except in patients with relatively severe asthma who require additional treatment with an inhaled and/or systemic glucocorticosteroid.

Contra-Indications, Warnings, etc.

Contra-Indications:

Although intravenous salbutamol and salbutamol tablets are used in the management of premature labour, Ventolin preparations should not be used for threatened abortion during the first or second trimesters.

Precautions:

In the event of a previously effective dose of inhaled Ventolin failing to give relief lasting at least three hours, the patient should be advised to seek medical advice in order that any necessary additional steps may be taken. Ventolin should be administered cautiously to patients suffering from thyrotoxicosis. Unnecessary administration of drugs during the first trimester of pregnancy is undesirable.

Side Effects:

No important side effects have been reported following treatment with Ventolin Rotacaps.

Overdosage:

The preferred antidote for overdosage with salbutamol is a cardioselective beta-blocking agent, but beta-blocking drugs should be used with caution in patients with a history of bronchospasm.

Pharmaceutical Precautions

Ventolin Rotacaps should be stored in a moisture-proof container in a dry place. A convenient supply may be carried in the special container for the Rotahaler.

Legal Category

Prescription only medicine.

Package Quantities

Ventolin Rotacaps 200mcg and 400mcg are supplied in containers of 100.

Further Information

Ventolin does not cause difficulty in micturition because, unlike sympathomimetic drugs such as ephedrine, it does not stimulate alpha-adrenoceptors. Ventolin is not contra-indicated in patients under treatment with monoamine oxidase inhibitors (MAOIs).

Product Licence Numbers

Ventolin Rotacaps 200mcg – 0045/0116

Ventolin Rotacaps 400mcg – 0045/0117

Product Licence Holder

Allen & Hanburys Ltd., London E2 6LA

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