

<div>Patient's Information</div> <div><div>Sultolin®</div><div>Salbutamol</div><div>100 µg/puff</div></div> <div><div>Metered-dose</div><div>HFA Inhaler</div></div> <div></div>	<div>Parts of an Inhaler device</div> <div><div>Metal Canister</div><div>Dust Cap</div><div>Actuator</div><div>Mouthpiece</div></div>	<div><div>1</div><div>SHAKE WELL</div></div> <div>Remove the cap and shake the inhaler vigorously before each use.</div>	<div><div>2</div><div>EXHALE GENTLY</div></div> <div>Holding the inhaler well away from your mouth, breathe out gently (but not fully).</div>	<div><div>3</div><div>PRESS</div><div>PRESS & INHALE (SLOWLY & DEEPLY) SIMULTANEOUSLY</div></div> <div>Place the mouthpiece in your mouth & close your lips around it. After starting to breathe in slowly & deeply through your mouth, press the metal canister firmly to release the powder & continue to breathe in.</div>	<div><div>4</div><div>HOLD BREATH FOR 10 Seconds</div><div>00:00:10</div></div> <div>Remove the inhaler from your mouth & hold your breath for 10 seconds, or as long as it is comfortable, then breathe out slowly.</div>	<div><div>5</div><div>SECOND INHALATION</div><div>Wait 1 minuite</div><div>00:01:00</div></div> <div>If you are to take a second inhalation, you should wait for at least one minute before repeating steps 2, 3 and 4. Replace the dust cap on the mouthpiece after use.</div>	<div><div>Mirror</div></div> <div>NOTE</div> <div>Check your technique in front of a mirror from time to time. If you see a white mist during the inhalation, you may not have closed your lips properly around the mouthpiece, or you may not be breathing in while you press the canister. This indicates failure of technique. If this happens, repeat the procedure from step 2 carefully.</div>	<div><div>Wash actuator regularly & frequently</div></div> <div>IMPORTANT</div> <div>It is very important that the plastic actuator is to be cleaned regularly to prevent build up of spare powder. Remove the metal canister and wash the plastic actuator in warm water at least twice a week. Leave the plastic actuator to dry in a warm place overnight. No harm will come from washing the mouthpiece every day. For further assistance/information, consult your physician.</div>	<div>Children may need assistance of their parents. Consult your physician if needed. Please to follow any other instructions that your doctor may give, as to how to use the inhaler. This may include the use</div> <div>Warning</div> <div>This is a pressurised container. Do not puncture, break or dispose it by burning even when</div> <div>SQUARE</div>
<div>Prescribing Information</div> <div><div>Sultolin®</div><div>Salbutamol</div><div>100 µg/puff</div></div> <div><div>Metered-dose</div><div>HFA Inhaler</div></div> <div></div>	<div>MAIN THERAPEUTIC GROUP</div> <div>Anti Asthmatic.</div> <div>ROUTE OF ADMINISTRATION</div> <div>Inhalation</div> <div>PHARMACOLOGY</div> <div>Sultolin® Inhaler (Salbutamol BP) is a β-adrenergic stimulant which has a highly selective action on the receptors in bronchial muscle and in therapeutic dosage, little or no action on the cardiac receptors. 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 1 hypersensitivity reactions are</div>	<div>generally considered to be the primary triggers of the allergic asthma syndrome. The inhaler drug-delivery system using Salbutamol in microgram dosage, avoids the skeletal muscle tremor sometimes associated with oral therapy.</div> <div>COMPOSITION</div> <div>Each puff delivers Salbutamol 100 µg as Salbutamol Sulfate BP.</div> <div>INDICATIONS</div> <div>Sultolin® Inhaler is indicated both for treatment and prophylaxis of bronchial asthma, and also for the treatment of other conditions, such as bronchitis and emphysema with associated reversible airway obstruction. Sultolin® Inhaler is</div>	<div>ideally suited for routine maintenance therapy in chronic asthma and chronic bronchitis. Sultolin® Inhaler acts rapidly and may be used when necessary to relieve attacks of acute dyspnoea. Doses may be given prophylactically before exertion or to prevent exercise-induced bronchospasm, two inhalations should be taken 10 -15 minuites before exertion. Children (below 4 years of age) : One inhalation is the recommended dose for the relief of acute-bronchospasm, in the maintenance of episodic asthma or before exercise. One inhalation should be administered three or four times a day for routine maintenance or prophylactic therapy. These dosages may be increased to two inhalations if necessary. For optimum results, in most patients, Sultolin® Inhaler</div> <div>DOSAGES AND ADMINISTRATION</div> <div>Adults : For the relief of acute bronchospasm and for managing intermittent episodes of asthma, one</div>	<div>or two inhalations may be administered as a single dose. The recommended dose for chronic maintenance or prophylactic therapy is two inhalations three or four times a day. To prevent exercise-induced bronchospasm, two inhalations should be taken 10 -15 minuites before exertion. Children (below 4 years of age) : One inhalation is the recommended dose for the relief of acute-bronchospasm, in the maintenance of episodic asthma or before exercise. One inhalation should be administered three or four times a day for routine maintenance or prophylactic therapy. These dosages may be increased to two inhalations if necessary. For optimum results, in most patients, Sultolin® Inhaler</div>	<div>should be used regularly.</div> <div>CONTRAINDICATIONS</div> <div>Salbutamol inhaler is contraindicated in patients with a history of hypersensitivity to any of its components.</div> <div>PRECAUTIONS & WARNING</div> <div>In the event of a previously effective dose of Salbutamol inhaler failing to give relief for at least three hours, the patient should be advised to seek medical advice in order that any necessary additional steps may be taken. Salbutamol should be administered cautiously to patients suffering from thyrotoxicosis. Salbutamol and non-selective β-blockers such as</div>	<div>propranolol should not be prescribed together. Inhaled Salbutamol preparations are not appropriate for managing premature labour. Salbutamol presentations should not be used for threatened abortion during the first or second trimesters of pregnancy.</div> <div>PREGNANCY & LACTATION</div> <div>Pregnancy Category C. As with the majority of drugs there is little published evidence of its safety in the early stages of human pregnancy. Lactation: As salbutamol is probably secreted in breast milk, its use in nursing mothers requires careful consideration. It is not known whether salbutamol has a harmful effect on the neonate, and so its use</div>	<div>should be restricted to situations where it is felt that the expected benefit to the mother is likely to outweigh any potential risk to the neonate.</div> <div>SIDE EFFECTS</div> <div>Mild tremor and headache have been rarely reported. They usually disappear with continued treatment. There have been very rare reports of transient muscle cramps. Hypersensitive reactions including angioedema and urticaria, bronchospasm, hypotension and collapse have been reported very rarely. As with other inhalation therapy, the potential for paradoxical bronchospasm should be kept in mind.</div>	<div>If it occurs, the preparation should be discontinued immediately and alternative therapy instituted.</div> <div>DRUG INTERACTION</div> <div>Salbutamol and non-selective β-blocking drugs such as propranolol, should not usually be prescribed together.</div> <div>OVERDOSE, SIGNS, SYMPTOMS & TREATMENT</div> <div>The preferred antidote for overdosage with Salbutamol inhaler is cardioselective β-blocker. But β-blocking drugs should be used with caution in patients with a history of bronchospasm.</div>	<div>STORAGE</div> <div>Store below 30°C. Protect from direct sunlight or heat. Protect from frost. Keep away from contact of eyes. Keep out of children's reach.</div> <div>HOW SUPPLIED</div> <div>Sultolin® 100 Inhaler</div> <div>Each canister contains 20 mg of Salbutamol (at least 200 puffs).</div> <div>Each puff delivers Salbutamol BP 100 µg as Salbutamol Sulfate BP.</div> <div>SQUARE</div>