SEREVENT ACCUHALER

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

SEREVENT ACCUHALER

Powder for Inhalation

COMPOSITION:

Each SEREVENT ACCUHALER blister contains salmeterol xinafoate equivalent to 50 micrograms of salmeterol.

Contains sugar (lactose 12,5 mg/blister).

Excipients: Lactose (which contains milk protein).

PHARMACOLOGICAL CLASSIFICATION:

A 10.2.1 Medicines acting on respiratory system. Bronchodilators. Inhalants

PHARMACOLOGICAL ACTION:

Salmeterol is a selective beta$_2$-adrenoceptor agonist. Salmeterol has been shown to produce long-lasting bronchodilatation of up to at least 12 hours in subjects with reversible airways obstruction.

In vitro tests have shown salmeterol to be a potent and long-lasting inhibitor of the release, from human lung, of mast cell derived mediators, such as histamine, leukotrienes and prostaglandin D2. In man salmeterol inhibits the early and late phase response to inhaled allergen and after single dosing attenuates bronchial hyperresponsiveness.

INDICATIONS:

Adults:

Long-term regular treatment of reversible airways obstruction, in asthma, (including patients with nocturnal asthma and exercise-induced asthma), chronic bronchitis and emphysema.

Children 4 years and older:

Regular treatment of reversible airways obstruction in asthma including long lasting prevention of exercise induced bronchospasm.

SEREVENT is not intended for use in acute attacks of asthma in view of the slow onset of action.

CONTRA-INDICATIONS:

Hypersensitivity to any ingredient of the preparation.

WARNINGS AND SPECIAL PRECAUTIONS:

SEREVENT should not be initiated in patients with significantly worsening or acutely deteriorating asthma.

Sudden and progressive deterioration of asthma is potentially life-threatening and consideration should be given to starting or increasing corticosteroid therapy.

Bronchodilators should not be the only or the main treatment in patients with severe or unstable asthma.

Increasing use of bronchodilators, in particular short-acting inhaled beta$_2$-agonists, to relieve symptoms, indicates deterioration of asthma control. If patients find that short-acting relief bronchodilator treatment becomes less effective or they need more inhalations than usual, medical attention must be sought.

Patients who have to take increasing doses of other beta$_2$-agonists in addition to SEREVENT for relief of symptoms should seek urgent medical advice.

The potential for paradoxical bronchospasm should be kept in mind. If it occurs, SEREVENT should be discontinued immediately and alternative therapy instituted.

Hypokalaemia may occur.

SEREVENT is not a replacement for oral or inhaled corticosteroids.

SEREVENT is not designed to relieve acute asthma symptoms, for which an inhaled short-acting bronchodilator (e.g. salbutamol) is required.

SEREVENT should be administered with caution in patients suffering from thyrotoxicosis.

In patients with impaired renal function there is no need to adjust the dose.

Excipient warnings:

Contains fructose/lactose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not use SEREVENT ACCUHALER. Lactose may have an effect on the glycaemic control of patients with diabetes mellitus.

INTERACTIONS:

Both non-selective and selective beta-blockers should be avoided in patients with reversible obstructive airways disease, unless there are compelling reasons for their use.

PREGNANCY AND LACTATION:

Pregnancy:

Safety in pregnancy has not been established.

Lactation:

There is no experience of the use of salmeterol in nursing mothers.

DOSAGE AND DIRECTIONS FOR USE:

As there may be adverse effects associated with excessive dosing, the dosage or frequency of administration should not be increased. SEREVENT ACCUHALER is for inhalation use only.

Adults:

One SEREVENT ACCUHALER blister (50 micrograms of salmeterol) twice daily.

Children 4 years and older:

One SEREVENT ACCUHALER blister (50 micrograms of salmeterol) twice daily.

There are insufficient clinical data at present to recommend the use of salmeterol in children under 4 years of age.

There is no need to adjust the dose in the elderly.

In order to gain full therapeutic benefit regular usage of salmeterol is recommended in the treatment of reversible airways obstruction. The onset of the bronchodilator effect of salmeterol usually occurs in approximately 10-30 minutes or longer. The full benefits will be apparent after the 1st or 2nd dose of the drug. If symptoms persist, patients should take a short-acting inhaled beta$_2$-agonist for relief but this need is usually an indication that control of their airways obstruction is suboptimal and that further treatment should be considered. This may involve increasing the dose of salmeterol and/or commencing or increasing the dose of prophylactic treatment.

SIDE EFFECTS:

Tremor, headache, palpitations, and muscle cramps have been reported.

Tachycardia may occur in some patients.

Cardiac dysrhythmias (including atrial fibrillation, supraventricular tachycardia and extrasystoles) may occur in some patients.

There have been reports of arthralgia and hypersensitivity reactions, including rash, oedema and angioedema.

The potential for paradoxical bronchospasm should be kept in mind.

Hypokalaemia may occur.

There have been reports of oropharyngeal irritation.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

The symptoms and signs of salmeterol overdosage are tremor, headache and tachycardia. The preferred antidote for overdosage with salmeterol is a cardio-selective beta-blocking agent.

IDENTIFICATION:

The SEREVENT ACCUHALER consists of a plastic inhaler device, containing a foil strip with 60 blisters, each blister containing a white powder.

PRESENTATION:

A carton containing a single SEREVENT ACCUHALER. The SEREVENT ACCUHALER consists of a plastic inhaler device, containing a foil strip with 60 blisters. The device contains a dose counter which shows the number of doses remaining (60 to 1). To show when the last five doses have been reached, the number appears in red.

STORAGE INSTRUCTIONS:

The SEREVENT ACCUHALER provides good protection to the blister contents from the effect of the atmosphere but it should not be exposed to extremes of temperature and should be stored below 30 °C in a dry place. Protect from light.

Keep out of reach of children.

REGISTRATION NUMBER:

29/10.2.1/0350

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

GlaxoSmithKline South Africa (Pty) Ltd

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