Summary of Product Charcteristics

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Salmeterol and Fluticasone Propionate Inhaler

Serocort synchrObreathe SB

1. NAME OF THE MEDICINAL PRODUCT;
Serocort Synchrobreathe SB

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:
Serocort 250 Synchrobreathe SB

Each actuation delivers

Salmeterol (as Salmeterol Xinafoate Ph. Eur.) ..... 25 mcg

Fluticasone Propionate BP ..... 250 mcg

Suspended in Propellant HFA-134a ..... q.s.

Also contains absolute alcohol Ph. Eur.

List of excipients see section 6. 1

3. **PHARMACEUTICAL FORM:** Oral inhalation

4. CLINICAL PARTICULARS:
4.1 Therapeutic indications:
Serocort SB is a combination of Fluticasone propionate, a synthetic corticosteroid and salmeterol; a selective long acting beta2-agonist. Fluticasone propionate is a synthetic, trifluorinated glucocorticoid with potent anti-inflammatory activity. Salmeterol is a selective long-acting beta2-adrenoceptor agonist with duration of action of at least 12 hours.

Serocort SB is indicated in the regular treatment of asthma, where use of a combination (long acting beta2-agonist and inhaled corticosteroid) has been found to be appropriate and in patients with severe chronic obstructive pulmonary disease (COPD).

4.2 Posology and method of administration:
Dosage and Administration

Asthma:

Adults and adolescents 12 years and over

Serocort 50 Synchrobreathe SB: Two inhalations twice daily

Serocort 125 Synchrobreathe SB: Two inhalations twice daily

Serocort 250 Synchrobreathe SB: Two inhalations twice daily

Children 4 years and older

Serocort 50 Synchrobreathe SB: Two inhalations twice daily

Chronic Obstructive Pulmonary Disease (COPD)

Serocort 125 Synchrobreathe SB: Two inhalations twice daily

Serocort 250 Synchrobreathe SB: Two inhalations twice daily

4.3 Contraindications:

Serocort Synchrobreathe SB is contraindicated in patients with a history of hypersensitivity to any of the component of the drug product.

4.4 Special warnings and precautions for use:

Warnings and Precautions

Patients should be made aware that Serocort Synchrobreathe SB must be used daily for

optimum benefit, even when asymptomatic.

Serocort Synchrobreathe SB should not be used to treat acute asthma symptoms for

which a fast and short-acting bronchodilator is required. Patients should be advised to have

their relief medication available at all times.

As with all inhaled medication containing corticosteroids, Serocort Synchrobreathe SB

should be administered with caution in patients with pulmonary tuberculosis.

Serocort Synchrobreathe SB should be administered with caution in patients with severe

cardiovascular disorders, including heart rhythm abnormalities, diabetes mellitus, untreated

hypokalaemia or thyrotoxicosis.

Potentially serious hypokalaemia may result from systemic beta2-agonist therapy but

following inhalation at therapeutic doses plasma levels of salmeterol are very low.

Paradoxical bronchospasm may occur. In such case Serocort Synchrobreathe SB should

be discontinued immediately, the patient assessed and alternative therapy instituted if

necessary.

Systemic effects are much less likely to occur with inhaled corticosteroids than with oral

corticosteroids. Possible systemic effects include adrenal suppression, growth retardation in

children and adolescents, decrease in bone mineral density, cataract and glaucoma. It is

important, therefore, that the dose is titrated to the lowest dose at which effective control is

maintained.

4.5 Interaction with other medicinal products and other forms of interaction

Drug Interactions

Even though plasma levels of salmeterol and fluticasone are very low, potential interactions

with other substrates or inhibitors of CYP 3A4 cannot be excluded.

Both non-selective and selective beta-blockers should be avoided in patients with asthma,

unless there are compelling reasons for their use.

Concomitant use of other beta-adrenergic containing drugs can have a potentially additive

effect.

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4.6 Fertility, pregnancy and lactation

Pregnancy

Use of Serocort Synchrobreathe SB in pregnancy should be considered only if the expected benefit to the mother is greater than any possible risk to the foetus.

Lactation

Use of Serocort Synchrobreathe SB in women who are breastfeeding should only be considered if the expected benefit to the mother is greater than any possible risk to the child.

4.7 Effects on ability to drive and use machines: Not applicable

4.8 Overdose

The signs and symptoms of Serocort Synchrobreathe SB overdose are tremor, headache and tachycardia. The preferred antidotes are cardioselective beta-blocking agents, which should be used with caution in patients with a history of bronchospasm. If higher than recommended dosage is continued over prolonged periods, some degree of adrenal suppression may result. Monitoring of adrenal reserve may be necessary.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org'.

4.9 Overdose Symptoms:

The signs and symptoms of Serocort Synchrobreathe SB overdose are tremor, headache and tachycardia.

5. PHARMACOLOGICAL PROPERTIES:
5.1 Pharmacodynamic properties:
5.2 Pharmacokinetic properties:
5.3 Preclinical safety data:

Side Effects
As Serocort Synchrobreathe SB contains salmeterol and fluticasone propionate, the type
and severity of side effects associated with each of the compounds may be expected. There
is no incidence of additional side effects following concurrent administration of the two
compounds.
Side effects associated with
Salmeterol:
Tremor, palpitations and headache, have been reported, but tend to be transient and reduce with regular therapy. Cardiac arrhythmias muscle cramps and hypersensitivity reactions, including rash, oedema and angioedema may occur in some patients.

Fluticasone propionate:
Hoarseness and candidiasis (thrush) of the mouth and throat can occur in some patients. Cutaneous hypersensitivity reactions have been reported. Both hoarseness and incidence of candidiasis may be relieved by gargling with water after use of Serocort Synchrobreathe SB. Symptomatic candidiasis can be treated with topical anti-fungal therapy whilst still continuing with Serocort Synchrobreathe SB.

6 Pharmaceutical particulars

6.1 List of excipients
Lecithin

Absolute alcohol

Tetrafluoroethane (HFA-134a Propellant)

6.2Incompatibilities; Not Applicable
6.3Nature and contents of container
Serocort 250 Synchrobreathe SB 120 metered doses

7 MARKETING AUTHORISATION HOLDER; Cipla Ltd

8 MARKETING AUTHORISATION NUMBER (S);
SEROCORT 250 Registration No.:

Kenya: H2008/19678/967

Tanzania: TAN 06, 266 R03A CIP

Uganda: NDA/MAL/HDP/3558

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION;
SEROCORT 250

Kenya 07/04/2009

Tanzania 16/06/2006

Uganda 14/03/2009

10 DATE OF REVISION OF THE TEXT ; Not Applicable