Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Asmabec Clickhaler 100 micrograms, Inhalation powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered actuation of 2.6 mg contains 100 micrograms of beclometasone dipropoinate and delivers 90 micrograms of beclometasone dipropionate.

Excipients: includes 2.5 mg of lactose monohydrate per dose.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation powder.

White free-flowing powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Beclometasone Dipropionate is indicated for the control of persistent asthma.

4.2 Posology and method of administration

Posology

For optimum results Asmabec Clickhaler should be used regularly.

The initial dose should be appropriate to the severity of the disease and the maintenance dose titrated to the lowest dose at which effective control of asthma is achieved.

Adults:

The initial dose for patients with mild asthma is 200 to 400 micrograms per day; this may be increased to 800 micrograms per day if required.

For patients with moderate asthma and severe asthma the initial dose can be 800 to 1600 micrograms per day, increased to 2000 micrograms in severe cases. The normal maximum daily for adults is 2000 micrograms.

The maintenance dose is normally 200 to 400 micrograms twice daily. If necessary the dose may be increased to 1600 to 2000 micrograms per day divided into two to four doses and be reduced later when asthma is stabilised.

Special population

There are no special dosage recommendations for elderly patients.

Paediatric population

Children aged 6 - 12 years:

Up to 100 micrograms 2 to 4 times daily according to the clinical response.

Normally the maximum daily dose in children is 400mg. However some cases of severe asthma may not be controlled and higher doses may be required in line with international guidelines. Once the asthma is controlled, the dose of Asmabec Clickhaler should be reduced to the minimum to maintain control.

Children aged under 6 years:

Asmabec Clickhaler is not recommended for children under 6 years of age.

When transferring a patient to Asmabec Clickhaler from other devices, treatment should be individualised taking into consideration the active ingredient and method of administration.

Method of administration

The product is intended for oral inhalation only.

It is important to instruct the patient to:

1. Remove mouthpiece cover from the inhaler

2. Shake the inhaler well

3. Hold the inhaler upright with thumb on the base and finger on the push button.

Press the dosing button down firmly - once only.

4. Breathe out as far as is comfortable.

Note: do not blow into the device at any time.

5. Place mouthpiece in your mouth. Close lips firmly around it (do not bite it).

6. Breathe in through your mouth steadily and deeply, to draw the medicine into your lungs.

7. Hold your breath, take the inhaler from your mouth and continue holding your breath for about 5 seconds.

8. For the second puff, keep the inhaler upright and repeat steps 2-7.

9. Replace the mouthpiece cover.

The patient should be told to refer to the detailed instructions on the use and cleaning of the Clickhaler in the Patient Information Leaflet which is packed with each Clickhaler.

4.3 Contraindications

Asmabec Clickhaler is contra-indicated in patients with hypersensitivity (allergy) to beclometasone dipropionate or to the excipient (see section 6.1).

4.4 Special warnings and precautions for use

Patients should be instructed in the proper use of the inhaler. They should also be made aware of the prophylactic nature of therapy with Asmabec Clickhaler and that they should use it regularly, every day, even when they are asymptomatic. Beclometasone dipropionate is not suitable for the treatment of an acute asthma attack.

Increasing use of bronchodilators, in particular short-acting inhaled β_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. In this situation patients should be reassessed and consideration given to the need for increased anti-inflammatory therapy (e.g. higher doses of inhaled corticosteroids or a course of oral corticosteroids). Severe exacerbations of asthma must be treated in the normal way.

Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract, glaucoma, and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). It is important therefore that the dose of inhaled corticosteroid is titrated to the lowest dose at which effective control of asthma is maintained.

It is recommended that the height of children receiving prolonged treatment with inhaled steroids is regularly monitored. If growth is slowed, therapy should be reviewed with the aim of reducing the dose of inhaled corticosteroid if possible, to the lowest dose at which effective control of symptoms is achieved.

Doses in excess of 1500 micrograms per day may induce adrenal suppression. In such patients the risks of developing adrenal suppression should be balanced against the therapeutic advantages, and precautions should be taken to provide systemic steroid cover in situations of stress or elective surgery.

The transfer to inhaled beclometasone dipropionate of patients who have been treated with systemic steroids for long periods of time, or at high dose, needs special care and subsequent management as recovery from impaired adrenocortical function is slow. With these patients adrenocortical function should be monitored regularly and their dose of systemic steroid reduced cautiously. Gradual withdrawal of the systemic steroid should commence after about one week. Reductions in dosage, appropriate to the level of maintenance systemic steroid, should be introduced at not less than weekly intervals.

Some patients may feel unwell in a non-specific way during withdrawal of the systemic steroid. They should be encouraged to persevere with the inhaled beclometasone dipropionate, unless there are objective signs of adrenal insufficiency.

Patients who have been transferred from oral steroids whose adrenocortical function is impaired should carry a steroid warning card indicating that they may need supplementary systemic steroids during periods of stress, eg. worsening asthma attacks, chest infections, major intercurrent illness, surgery, trauma etc.

Replacement of systemic steroid treatment with inhaled therapy sometimes unmasks allergies such as allergic rhinitis or eczema previously controlled by the systemic drug.

In the case of massive mucus secretion in the respiratory tract, de-obstruction and a short course of oral steroids may be necessary to ensure efficacy of the inhaled beclometasone.

Special care is necessary in patients with active or quiescent pulmonary tuberculosis and in patients with viral, bacterial and fungal infections of the eye, mouth or respiratory tract.

In the case of bacterial infection of the respiratory tract adequate antibiotic co-medication may be required.

Treatment with Asmabec Clickhaler especially at high doses should not be stopped abruptly.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Due to the very low plasma concentration achieved after inhaled dosing, clinically significant drug interactions are in general unlikely. Care should be taken when co-administering known strong CYP 3A4 inhibitors (e.g. ketoconazole, itrazonazole, nelfinavir, ritonavir) as there is a potential for increased systemic exposure to beclomethasone.

4.6 Fertility, pregnancy and lactation

Pregnancy*:*

There are insufficient data regarding the safety of beclometasone dipropionate during human pregnancy. Systemic administration of relatively high doses of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human foetus. Because beclometasone dipropionate is delivered directly to the lungs by the inhaled route it avoids the high level of exposure that occurs when corticosteroids are given by systemic routes.

The use of beclometasone dipropionate in pregnancy requires that the possible benefits of the drug be weighed against the possible hazards. It should be noted that the drug has been in widespread use for many years without apparent ill consequence.

Lactation:

It is reasonable to assume that beclometasone dipropionate is secreted in milk, but at the dosages used for direct inhalation there is low potential for significant levels in breast milk.

The use of beclometasone dipropionate in mothers breast feeding their babies requires that the therapeutic benefits of the drug be weighed against the potential hazards to the mother and baby.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Infections and infestations: candidiasis of the mouth and throat. This may be treated whilst still continuing with Asmabec Clickhaler.

Immune system disorders: easy bruising of the skin, very rarely hypersensitivity including rash and angioedema may occur.

Endocrine disorders: decrease in bone mineral density, adrenal suppression, Cushing's syndrome, growth retardation in children and adolescents

Psychiatric disorders: psychomotor hyperactivity, sleep disorders, anxiety, depression, aggression, behavioural changes (predominantly in children).

Eye disorders: cataract and glaucoma

Respiratory, thoracic and mediastinal disorders: hoarseness, paradoxical bronchospasm. If bronchospasm occurs the preparation should be discontinued immediately and if necessary alternative therapy instituted.

It is recommended to rinse out the mouth thoroughly with water immediately after inhalation in order to reduce the risks of candidiasis and hoarseness.

Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods (see also section 4.4).

4.9 Overdose

Acute Inhalation of a large amount of the drug over a short period may lead to temporary suppression of adrenal function. No emergency action is required. Treatment with beclometasone dipropionate by inhalation should be continued at a dose sufficient to control asthma; adrenal function recovers in a few days and can be verified by measuring plasma cortisol.

Chronic Use of excessive doses of inhaled beclometasone dipropionate over a prolonged period may cause adrenal suppression and a degree of atrophy of the adrenal cortex. Transfer to a maintenance dose of a systemic steroid may be required until the condition is stabilised. Treatment with inhaled beclometasone dipropionate should then be continued at a dose sufficient to control asthma.

If higher than approved doses are continued over prolonged periods, significant adrenal suppression and adrenal crisis are possible. Presenting symptoms of adrenal crisis may initially be non-specific and include anorexia, abdominal pain, weight loss, tiredness, headache, nausea, vomiting.

Hypoglycaemia with decreased consciousness and/or convulsions is a typical symptom. Situations which could potentially trigger acute adrenal crisis include exposure to trauma, surgery, infection or any rapid reduction in dosage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other anti-asthmatics, inhalants, glucocorticoids.

ATC code: R03B A01.

Beclometasone dipropionate given by inhalation has a glucocorticoid anti-inflammatory action within the lungs.

The exact mechanism responsible for this anti-inflammatory effect is unknown.

5.2 Pharmacokinetic properties

Absorption from the gastrointestinal tract is slow and bioavailability is low, suggesting that most of the absorbed drug is metabolised during its first passage through the liver. Since the dose of oral beclometasone dipropionate needed to suppress plasma cortisol is greater than that required by inhalation, this suggests that the portion absorbed from the lungs is mainly responsible for any systemic effects.

5.3 Preclinical safety data

Studies in a number of animal species, including rats, rabbits and dogs, have shown no unusual toxicity during acute experiments. The effects of beclometasone dipropionate in producing signs of glucocorticoid excess during chronic administration by various routes are dose related. Teratogenicity testing has shown cleft palate in mice, as with other glucocorticoids. Beclometasone dipropionate is non-genotoxic and demonstrates no oncogenic potential in lifetime studies with rats

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate (which contains milk proteins**).**

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6 months when removed from the foil pouch.

6.4 Special precautions for storage

Do not store above 30°C. Store in the original package in order to protect from moisture and light.

6.5 Nature and contents of container

A plastic inhaler device incorporating a metering pump and a mouthpiece enclosed within a polyester/aluminium/polyethylene heat-sealed sachet. Each 100 microgram inhaler contains 200 actuations.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

RPH Pharmaceuticals AB
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8 MARKETING AUTHORISATION NUMBER

PA 1638/10/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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August 2011