

Asthmatide

Metered aerosol

Qualitative and quantitative Composition:

Each single actuation of Asthmatide provides:

Salmeterol xinafoate equivalent to 25 micrograms of salmeterol and 50,125 or 250 micrograms of fluticasone propionate.

Mechanism of action:

Asthmatide contains salmeterol and fluticasone propionate which have different modes of action:

- Salmeterol: is a selective long-acting (12 hours) B_2 adrenoceptor agonist with a long side chain which binds to the exo-site of the receptor. Salmeterol produces a longer duration of bronchodilator, lasting for at least 12 hours, than recommended doses of conventional short-acting B_2 -agonists.
- Fluticasone propionate: given by inhalation at recommended doses has a glucocorticoid anti-inflammatory action within the lungs, resulting in reduced symptoms and exacerbations of asthma, without the adverse effects observed when corticosteroids are administered systemically.

Therapeutic Indications:

Asthmatide is indicated in the regular treatment of asthma where use of a combination product (long-acting B_2 -agonist and inhaled corticosteroid) is appropriate:

- Patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting B_2 -agonist.
- Patients already adequately controlled on both inhaled corticosteroid and long acting B_2 -agonist.

Method of administration:

- Asthmatide is for oral inhalation only.
- Patients should be made aware that Asthmatide must be used daily for optimum benefit, even when asymptomatic.
- Patients should regularly reassessed by a doctor, so that the strength of Asthmatide they are receiving remains optimal and is only changed on medical advice. The dose should be titrated to the lowest dose at which effective control of symptoms is maintained.

Dosage:

Adults and adolescences 12 years and older:

- Two inhalations of 25 mcg salmeterol and 50 mcg fluticasone propionate twice daily. OR
- Two inhalations of 25 mcg salmeterol and 125 mcg fluticasone propionate twice daily. OR
- Two inhalations of 25 mcg salmeterol and 250 mcg fluticasone propionate twice daily.
- There are insufficient data currently available to support use of Asthmatide in children aged less than 12 years.

Special patients groups:

- There is no need to adjust the dose in elderly patients.
- There is no need to adjust the dose in patients with renal impairment.
- There are no data available for use of Asthmatide in patients with hepatic impairment.

Contraindications:

Asthmatide is contraindicated in patients with a history of hypersensitivity of any of the ingredients.

Special warnings and Precaution for use:

- The management of asthma should normally follow a stepwise-programmed study, and patient's response should be monitored clinically and by lung functions tests.
- Asthmatide should not be used to treat acute asthma symptoms for which a fast and short acting bronchodilator is required.
- Asthmatide is not intended for the initial management of asthma until the need for an approximate dosage of corticosteroid has been established.
- Treatment with Asthmatide should not be stopped abruptly.
- As with all inhaled medications containing corticosteroids, Asthmatide should be administered with caution in patients with pulmonary tuberculosis.
- Asthmatide should be administered with caution in patients with severe cardiovascular disorders
- Potentially serious hypokalaemia may result from systemic B_2 adrenoceptor agonist therapy, but following inhalation of therapeutic doses plasma levels of salmeterol are very low.
- It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroid is regularly monitored.

Drug Interactions:

- Even though plasma levels of Asthmatide are very low, potential interactions with other substrates or inhibitors of CYP 3A4 cannot be excluded.
- Concomitant use of other beta-adrenergic containing drugs can have a potentially additive effect.

Pregnancy and lactation:

There are insufficient data on the use of salmeterol and fluticasone propionate during pregnancy and lactation in man to assess the possible harmful effects.

Administration of Asthmatide to a pregnant woman should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus. The lowest effective dose of Asthmatide needed to maintain adequate asthma control should be used in the treatment of pregnant woman.

Administration of Asthmatide to women who are breast-feeding should only be considered if the expected benefit to the mother is greater than any possible risk to the child.

Effects on ability to drive or use machines:

The pharmacology of both active ingredients does not indicate any effect.

Undesirable effects:

As Asthmatide contains salmeterol and fluticasone propionate, the type and severity of adverse reactions associated with each of the compounds may be expected. There is no incidence of additional adverse events following concurrent administration of the two compounds. The following undesirable effects were commonly reported:

Hoarseness/dysphonia, throat irritation, headache, candidiasis of mouth and throat and palpitations.

Instructions for use:



- 1- Remove the mouthpiece cover by gently squeezing the sides of the cover
- 2- Shake the inhaler well
- 3- Hold the inhaler upright between fingers and thumb with your thumb on the base below the mouthpiece.
- 4- Breathe out as far as is comfortable and then place the mouthpiece in your mouth between your teeth and close your lips around it.
- 5- Just after starting to breath in through your mouth press down on the top of the inhaler to release Asthmatide, while still breathing in steadily and deeply.
- 6- While holding your breath, take the inhaler from your mouth. Continue holding your breath for as long as possible.
- 7- To take the second puff keep the inhaler upright and wait about half a minute before repeating steps 2 to 6.

How supplied:

Metered aerosol with a special actuator. Each canister provides 120 inhalations of:

- Salmeterol 25 mcg + Fluticasone propionate 50 mcg
- Salmeterol 25 mcg + Fluticasone propionate 125 mcg
- Salmeterol 25 mcg + Fluticasone propionate 250 mcg

This is a medication:

- A medication is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medication.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medications out of reach of children.



Manufactured by K.C.Pharma.
Aleppo- Syria

Council of Arab Health Ministers
Union of Arab Pharmacists

B₂ adrenoceptor

CYP 3A4



.6 2 30

120

50	+	25
125	+	25
250	+	25

إن هذا دواء

- الدواء مستحضر ولكن ليس كثيره من المستحضرات.
- الدواء مستحضر يؤثر على صحتك واستهلاكه خلافا للتعليمات يعرضك للخطر.
- لا تطع مدة العلاج المحددة لك من تلقاء نفسك، ولا تزد عليها بدون استشارة الطبيب.
لا تترك الأدوية أبدا في متناول أيدي الأطفال.



B₂ adrenoceptor

B₂ adrenoceptor

B₂ adrenoceptor

12 12
B₂ adrenoceptor
B₂ adrenoceptor

250 125,50 25

12

50	25
125	25
250	25