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<p>(54) Title: USE OF A COMPOSITION COMPRISING FORMOTEROL AND BUDESONIDE FOR THE PREVENTION OR TREATMENT OF AN ACUTE CONDITION OF ASTHMA</p>		
<p>(57) Abstract</p> <p>The present invention relates to use of a composition for symptomatic relief, when needed, comprising, in admixture (a) a first active ingredient which is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and (b) a second active ingredient which is budesonide; for the manufacture of a medicament for use in the prevention or treatment of an acute condition of asthma and/or intermittent asthma and/or episodes in chronic asthma. The invention further relates to a method for prevention or treatment of an acute condition of asthma and/or intermittent asthma and/or episodes in chronic asthma by administering, by inhalation, a composition comprising the first and second active ingredients as defined previously.</p>		

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USE OF A COMPOSITION COMPRISING FORMOTEROL AND BUDESONIDE FOR THE PREVENTION OR TREATMENT OF AN ACUTE CONDITION OF ASTHMA

FIELD OF THE INVENTION

- 5 The present invention relates to use of a composition for symptomatic relief, when needed, comprising, in admixture
- (a) a first active ingredient which is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and
  - (b) a second active ingredient which is budesonide;
- 10 for the manufacture of a medicament for use in the prevention or treatment of an acute condition of asthma and/or intermittent asthma and/or episodes in chronic asthma. The invention further relates to a method for prevention or treatment of an acute condition of asthma and/or intermittent asthma and/or episodes in chronic asthma by administering, by inhalation, a composition comprising the first and second active ingredients as defined
- 15 previously.

BACKGROUND OF THE INVENTION

Despite recent advances in the awareness of asthma and the introduction of powerful and effective anti-asthma drugs, asthma remains a poorly understood and frequently poorly

20 treated disease. There have been recent advances in the treatment of the disease which result from the recognition that asthma is a chronic inflammatory disease. Therapy is now aimed at both controlling the symptoms and reducing the inflammation. The symptoms may be controlled by  $\beta_2$ -adrenoceptor agonists such as terbutaline, salbutamol, formoterol and salmeterol. Prophylactic therapy is typically provided by steroids such as beclometha-

25 sone dipropionate, fluticasone propionate, mometasone furoate and budesonide.

In spite of modern maintenance treatment too many asthmatic patients are undertreated for a number of reasons with a negative impact on their quality of life. Too complicated

30 therapy with different medications and devices may lead to misunderstanding and commu-

nication problems between patient and doctor. Poor compliance is a common phenomenon. Improved patient education may partly counteract this, but does not completely solve the problem. A new and more simple approach to asthma treatment could thus be of tremendous help for many patients suffering from respiratory disease, particularly asthma. The combination of budesonide and formoterol in the same device as suggested in PCT applications WO 93/11773 and WO 98/15280 (both to Astra AB of Sweden) offers a favorable pathway to improve today's asthma management with an excellent safety profile. However, although having an adequate regular, e.g. bid, treatment with such a combination, many patients will now and then run into acute situations with a higher frequency and severity of exacerbations, when additional medication is needed. Such an additional medication is often a  $\beta_2$ -adrenoceptor agonist with fast onset, normally terbutaline or salbutamol. A second medicament is thus needed, and this can negatively affect the overall compliance of the patient. There is thus need for a neat way of handling maintenance treatment together with the treatment of acute situations which .

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#### SUMMARY OF THE INVENTION

It is an object of the present invention to provide use of a suitable composition for the manufacture of a medicament for the treatment of acute episodes of asthma as a complement to maintenance treatment.

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More specifically, according to the invention there is provided use of a composition for symptomatic relief when needed comprising, in admixture

(a) a first active ingredient which is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and

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(b) a second active ingredient which is budesonide;

for the manufacture of a medicament for use in the prevention or treatment of an acute condition of asthma and/or intermittent asthma and/or episodes in chronic asthma.

Use of the present composition, when needed, relates to use of said composition during one or more of the following conditions:

- i) an acute condition of asthma, i.e. acute asthma attacks,
- ii) intermittent asthma and/or
- 5 iii) short periods (episodes) of acute attacks of bronchospasms in chronic asthma.

Acute asthma attacks may occur on an irregular basis when exposed to an agent e.g. during the pollen season, a virus infection, cold air, perfumes or any other agent(s) triggering an asthma attack in the patient.

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It lies within the scope of the present invention, to use the compositions comprising active compounds (a) and (b) for treating acute conditions of asthma, intermittent asthma and episodes in chronic asthma, in addition to treating chronic asthma on a regular basis, with the same active compounds (a) and (b) or one or more different active compounds,  
15 preferably selected from short-acting  $\beta$ -agonists, long-acting  $\beta$ -agonists and glucocorticosteroids.

We contemplate preventive use when the patient expects to encounter asthma inducing conditions e.g. intends to take exercise or go into smoky conditions.

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According to a further aspect of the invention a method of prevention or treatment of an acute condition of asthma and/or intermittent asthma and/or episodes in chronic asthma, when needed, which comprises administering, by inhalation, to a patient an effective amount of a composition comprising, in admixture:

- 25 (a) a first active ingredient which is formoterol, a pharmaceutically acceptable salt or solvate thereof or a solvate of such a salt; and
- (b) a second active ingredient which is budesonide.

According to the present invention it has surprisingly been found that the medicament can  
30 be administered when needed to a patient with an acute attack of asthma.

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