Summary Public Assessment Report

non-generics

Spiolto Respimat 2.5 microgram/2.5 microgram, inhalation solution

(tiotropium and olodaterol)

NL/H/3157/001/DC

Date: 14 July 2015
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Active substances: tiotropium and olodaterol

This is a summary of the public assessment report (PAR) for Spiolto Respimat. It explains how this medicine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Spiolto Respimat.

For practical information about using this medicine, patients should read the package leaflet or contact their doctor or pharmacist.

What is Spiolto Respimat and what is it used for?
Spiolto Respimat contains two active substances: tiotropium and olodaterol. These substances are also available as separate inhalation solutions marketed under the trade name Spiriva® Respimat® 2.5 microgram (tiotropium) and Striverdi® Respimat® 2.5 microgram (olodaterol).

Spiolto Respimat helps adult patients who have chronic obstructive pulmonary disease (COPD) to breathe more easily. COPD is a long-term lung disease that causes shortness of breath and coughing. The term COPD is associated with the conditions chronic bronchitis and emphysema.

Adult patients who require treatment with tiotropium and olodaterol can use the combination medicinal product Spiolto Respimat instead of two separate products.

How does this medicine work?
Both active substances belong to a group of medicines called long-acting bronchodilators. Tiotropium belongs to the subgroup of anticholinergics; olodaterol belongs to the subgroup of long acting beta₂ agonists. Spiolto Respimat helps to open the patient’s airways and make it easier to get air in and out of the lungs. Regular use of this medicine can also help patients who have on-going shortness of breath related to the disease, and will help to minimise the effects of the disease on everyday life.

How is this medicine used?
The pharmaceutical form of Spiolto Respimat is an inhalation solution. The medicine can only be obtained with a prescription.
Spiolto Respimat is effective for 24 hours, and therefore it has to be administered only once a day, if possible at the same time of the day. Each time the patient needs to inhale two puffs. The medicinal product is supplied with the Respimat soft mist inhaler device. Instructions for use of the Respimat inhaler are provided in the package leaflet.

As COPD is a long-term disease, Spiolto Respimat must be taken every day and not only when the patient experiences breathing problems or other symptoms of COPD.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

How has this medicine been studied?
The two separate active substances have a well known efficacy and safety. The company has conducted a number of clinical studies to investigate the safety and efficacy of the new combination medicine in patients with COPD. In these studies, the administration of Spiolto Respimat showed greater improvement of lung function as well as greater improvements in symptoms than administration of olodaterol or tiotropium alone. Also, exacerbations (increase in the severity of the disease or its signs and symptoms) occurred less often.
In addition, the company conducted three studies in which the endurance exercise time with Spiolto was compared to placebo (dummy treatment). In the special cycling tests patients on the active treatment performed better.

The possible adverse events of olodaterol and tiotropium are well known from experience with the individual products. There is no evidence that there would be additional or different effects when the substances are administered together via the same inhaler.

Overall, the company has provided sufficient proof that the combination of olodaterol and tiotropium, administered via the Respimat inhaler, shows better results in relieving the symptoms of COPD than the individual substances.

**What are the possible side effects from this medicine?**
The most common side effect with Spiolto Respimat (which may affect more than 1 in 10 people) is dry mouth. For the full list of the other side effects, which occur less frequently or with unknown frequency, see section 4 of the package leaflet.

**Why is this medicine approved?**
The Medicines Evaluation Board of the Netherlands decided that the benefits of Spiolto Respimat are greater than its risks and recommended that it be approved for use in patients with COPD.

**What measures are being taken to ensure the safe and effective use of this medicine?**
A risk management plan has been developed to ensure that Spiolto Respimat is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for this medicine, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

**Other information about this medicine**
In the Netherlands, the marketing authorisation for Spiolto Respimat 2.5 microgram/2.5 microgram, inhalation solution was granted on 30 June 2015.

The full PAR for this medicine can be found on the website [http://mri.medagencies.org/Human](http://mri.medagencies.org/Human). For more information about treatment with Spiolto Respimat, read the package leaflet [http://mri.medagencies.org/download/NL_H_3157_001_FinalPl.pdf](http://mri.medagencies.org/download/NL_H_3157_001_FinalPl.pdf) or contact your doctor or pharmacist.

This summary was last updated in July 2015.