Summary Public Assessment Report

Generics

Spironolacton Accord 25 mg, 50 mg and 100 mg film-coated tablets

(spironolactone)

NL/H/3508/001-003/MR

Date: 26 September 2016

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Active substance: spironolactone

This is a summary of the public assessment report (PAR) for Spironolacton Accord film-coated tablets. 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 Spironolacton Accord.

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

What is Spironolacton Accord and what is it used for?
Spironolacton Accord is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Aldactone.

This medicine is used in the treatment of:
- accumulation of fluid in the tissues as a result of heart disorders;
- severe heart failure
- raised blood pressure as an adjunct to a salt-free diet and diuretics;
- certain kidney disorders;
- accumulation of fluid in the tissues in the abdominal cavity.

Spironolactone Accord may also be used during medical investigations (diagnostics) to confirm the presence of disorders in which too high a level of aldosterone is produced in the adrenal cortex (known as Conn's disease) and treatment.

Children should only be treated under guidance of a paediatric specialist.

How does this medicine work?
The active ingredient of the tablets is spironolactone belongs to a particular group of medicines, known as aldosterone antagonists, which inhibit the action of the hormone aldosterone. One of the functions of aldosterone is to ensure that the body retains sodium. It forms part of a system that regulates the balance of fluids and salts in the body ('RAAS', renin angiotensin aldosterone system). Spironolactone promotes the excretion of urine in patients in whom there is an accumulation of fluid in the tissues (oedema) or in the abdominal cavity (ascites) by increasing the amount of sodium (salt) excreted in the urine. Potassium loss as a possible consequence of using certain diuretics is reduced. The antihypertensive effect relies on the excretion of water and salt.

How is this medicine used?
The pharmaceutical form of Spironolacton Accord is a film-coated tablet and the route of administration is oral.

The medicine can only be obtained with a prescription.

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?
Because Spironolacton Accord is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Aldactone. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of this medicine?
Because Spironolacton Accord is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Aldactone, the benefits are greater than its risk and recommended that it can be approved for use.

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 this medicine 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 Spironolacton Accord, 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, Spironolacton Accord has been authorised since 15 February 1999.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human. For more information about treatment with Spironolacton Accord, read the package leaflet (http://mri.medagencies.org/download/NL_H_3508_001_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in September 2016.