LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Abacavir/Lamivudine Medical Valley
lamivudine, abacavir, abacavir sulfate

SE/H/2265/001/DC

This module reflects the scientific discussion for the approval of Abacavir/Lamivudine Medical Valley. The Summary Public Assessment Report was written in July 2019 by the previous RMS NL after initial procedure NL/H/4287/001/DC. RMS transfer from NL to SE was completed 2022-03-10.

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

Abacavir/Lamivudine Medical Valley
lamivudine, abacavir, abacavir sulfate

Film-coated tablet, 600 mg/300 mg

This is a summary of the public assessment report (PAR) for Abacavir/Lamivudine Medical Valley. It explains how Abacavir/Lamivudine Medical Valley 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 Abacavir/Lamivudine Medical Valley.

For practical information about using Abacavir/Lamivudine Medical Valley, patients should read the package leaflet or contact their doctor or pharmacist.

COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Summary Public Assessment Report

Generics

Abacavir/Lamivudine Xiromed 600 mg/300 mg, film-coated tablets

(abacavir and lamivudine)

NL/H/4287/001/DC

Date: 25 July 2019

COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Summary Public Assessment Report

Generics

Abacavir/Lamivudine Xiromed 600 mg/300 mg, film-coated tablets

Active substances: abacavir and lamivudine

This is a summary of the public assessment report (PAR) for Abacavir/Lamivudine Xiromed. 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 Abacavir/Lamivudine Xiromed.

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

What is Abacavir/Lamivudine Xiromed and what is it used for?
Abacavir/Lamivudine Xiromed is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Kivexa.

This medicine is used in combination with at least one other antiviral medicine to treat adults and children weighing at least 25 kg who are infected with human immunodeficiency virus (HIV), the virus that causes acquired immune deficiency syndrome (AIDS).

How does this medicine work?
Both active substances in this medicine, abacavir and lamivudine, are nucleoside reverse transcriptase inhibitors (NRTIs). They both work in similar ways by blocking the activity of reverse transcriptase, an enzyme produced by HIV that allows it to infect cells and make more viruses. Abacavir/Lamivudine Xiromed, taken in combination with at least one other HIV medicine, reduces the amount of HIV in the blood and keeps it at a low level. Abacavir/Lamivudine Xiromed does not cure HIV infection or AIDS, but can delay the damage to the immune system and the development of infections and diseases associated with AIDS.

How is this medicine used?
The pharmaceutical form of Abacavir/Lamivudine Xiromed is a film-coated tablet and the route of administration is oral. Abacavir/Lamivudine Xiromed should be prescribed by a doctor who has experience in the management of HIV infection.
Before starting treatment with abacavir, all patients should have a test to find out if they have a gene called 'HLA-B (type 5701)'. Patients with this gene are at an increased risk of having an allergic reaction to abacavir, so they should not take Abacavir/Lamivudine Xiromed.
This medicine is taken as one tablet once a day. It should only be given to patients who weigh at least 25 kg. Patients who need to adjust the dose of abacavir or lamivudine should take the medicines separately.

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 Abacavir/Lamivudine Xiromed is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Kivexa. 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 Abacavir/Lamivudine Xiromed 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 reference medicine called Kivexa, 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 Abacavir/Lamivudine Xiromed, 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.

Additional risk minimisation measures are required relating to the safe and effective use of this medicine. These have been laid down in line with the reference product. It concerns the following additional risk minimisation measures:

- Educational materials for healthcare professionals to address the risk of abacavir hypersensitivity (website and slide set) covering the key points as stated in Annex II for Kivexa
- Patient Alert Card

Other information about this medicine
In the Netherlands, the marketing authorisation for Abacavir/Lamivudine Xiromed was granted on 19 February 2019.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human. For more information about treatment with

Abacavir/Lamivudine Xiromed, read the package leaflet (https://mri.cts-mrp.eu/Human/Downloads/NL_H_4287_001_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in July 2018.