LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Erlotinib Medical Valley
erlotinib, erlotinib hydrochloride

SE/H/2233/001-003/DC

This module reflects the scientific discussion for the approval of Erlotinib Medical Valley. The Summary Public Assessment Report was written in oktober 2019 by the previous RMS NL after initial procedure NL/H/4407/001-003/DC. RMS transfer from NL to SE was completed 2022-02-14.

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Summary Public Assessment Report

Erlotinib Medical Valley
erlotinib, erlotinib hydrochloride

Film-coated tablet, 25 mg, 100 mg, 150 mg

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

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

COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Summary Public Assessment Report

Generics

Erlotinib Xiromed 25 mg, 100 mg and 150 mg, film-coated tablets

(erlotinib)

NL/H/4407/001-003/DC

Date: 15 October 2019

Summary Public Assessment Report

Generics

Erlotinib Xiromed 25 mg, 100 mg and 150 mg, film-coated tablets
Active substance: erlotinib

This is a summary of the public assessment report (PAR) for Erlotinib Xiromed 25 mg, 100 mg and 150 mg, 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 Erlotinib Xiromed.

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

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

This medicine is used in non-small-cell lung cancer (NSCLC) that is 'advanced' (the cancer has started to spread) or 'metastatic' (it has already spread to other parts of the body). It is used in the following patients:

- Patients whose cancer cells have certain changes ('activating mutations') in the gene for a protein called epidermal growth factor receptor (EGFR) and have not received previous chemotherapy (medicines to treat cancer);
- Patients with EGFR activating mutations whose disease is stable after initial chemotherapy. 'Stable' means that the cancer had neither improved nor worsened during the chemotherapy;
- Patients who have had at least one previous chemotherapy treatment that has failed.

Erlotinib Xiromed has not been shown to be effective in patients whose lung cancer is 'EGFR IHC-negative'. 'EGFR IHC-negative' means that the EGFR receptor protein cannot be detected on the surface of the cancer cells, or can only be detected in small quantities.

Erlotinib Xiromed is also used in patients with metastatic pancreatic cancer, in combination with gemcitabine (another cancer medicine).

For both lung cancer and pancreatic cancer, doctors should take the patient's chances of survival into account when prescribing Erlotinib Xiromed.

How does this medicine work?
The active substance in Erlotinib Xiromed, erlotinib, is a cancer medicine that belongs to the group 'EGFR inhibitors'. Erlotinib blocks EGFRs, which can be found on the surface of some tumour cells. As a result of this block, the tumour cells can no longer receive the messages

needed for growth, progression and spreading (metastasis). As a result, Erlotinib Xiromed helps to stop the cancer from growing, multiplying and spreading through the body.

How is this medicine used?
The pharmaceutical form of Erlotinib Xiromed is a film-coated tablet and the route of administration is oral. The medicine can only be obtained with a prescription.

Treatment with Erlotinib Xiromed should be supervised by a doctor who has experience in the use of cancer medicines. In patients who have not yet received chemotherapy, EGFR mutation testing should be performed before starting Erlotinib Xiromed therapy.
For lung cancer, the recommended daily dose of Erlotinib Xiromed is 150 mg. For pancreatic cancer, it is 100 mg. Erlotinib Xiromed is taken at least one hour before or two hours after food. If needed (for example because of side effects), the dose may be reduced in 50-mg steps. As Erlotinib Xiromed seems to be more effective in patients with pancreatic cancer who develop a rash, treatment should be re-assessed after four to eight weeks if no rash has developed. Patients taking Erlotinib Xiromed should stop smoking, as smoking can decrease the amount of the medicine in the blood.

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 Erlotinib Xiromed is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Tarceva. 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 Erlotinib 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/be comparable to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for the reference medicine, 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 Erlotinib 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.

An additional risk minimisation measure is required relating to Interstitial Lung Disease. This has been laid down in line with the reference product. It concerns educational material for healthcare professionals.

Other information about this medicine

In the Netherlands, the marketing authorisation for Erlotinib Xiromed 25 mg, 100 mg and 150 mg, film-coated tablets was granted on 26 April 2019.

The full PAR for this medicine can be found on the website http://mri.cts-mrp.eu/Human/. For more information about treatment with Erlotinib Xiromed, read the package leaflet (https://mri.cts-mrp.eu/Human/Product/Details/56753) or contact your doctor or pharmacist.

This summary was last updated in April 2018.