COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Summary Public Assessment Report

Generics

Fampridine Intas 10 mg prolonged-release tablets

(fampridine)

NL/H/4942/001/DC

Date: 19 October 2020

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Active substance: fampridine

This is a summary of the public assessment report (PAR) for Fampridine Intas. 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 Fampridine Intas.

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

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

Fampridine Intas is a medicine used to improve walking in adults (18 years and over) with Multiple Sclerosis (MS) related walking disability. In multiple sclerosis, inflammation destroys the protective sheath around the nerves leading to muscle weakness, muscle stiffness and difficulty walking.

How does this medicine work?
Fampridine Intas contains the active substance fampridine which belongs to a group of medicines called potassium channel blockers. They work by stopping potassium leaving the nerve cells which have been damaged by MS. This medicine is thought to work by letting signals pass down the nerve more normally, which allows walking better.

How is this medicine used?
The pharmaceutical form of Fampridine Intas is prolonged-release tablet and the route of administration is oral. The recommended dose is one tablet in the morning and one in the evening (12 hours apart). The tablets should be swallowed whole with a drink of water. They should not be divided, crushed, dissolved, sucked or chewed on.

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 Fampridine Intas is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Fampyra. 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 Fampridine Intas 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 the reference medicine called Fampyra, 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 Fampridine Intas, 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 Fampridine Intas was granted on 1 October 2020.

The full PAR for this medicine can be found on the website http://mri.cts-mrp.eu/Human/. For more information about treatment with Fampridine Intas, read the package leaflet (https://mri.cts-mrp.eu/Human/Downloads/NL_H_4942_001_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in October 2020.