COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Summary Public Assessment Report

Generics

Hydroxychloroquinesulfaat Accord 200 mg, film-coated tablets

(hydroxychloroquine sulfate)

NL/H/4784/001/DC

Date: 18 August 2020

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Active substance: hydroxychloroquine sulfate

This is a summary of the public assessment report (PAR) for Hydroxychloroquinesulfaat Accord. 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 Hydroxychloroquinesulfaat Accord.

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

What is Hydroxychloroquinesulfaat Accord and what is it used for?
Hydroxychloroquinesulfaat Accord is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Plaquenil 200 mg film-coated tablets.

Hydroxychloroquinesulfaat Accord is used in adults:

- for the treatment of a chronic condition with inflammation of joints, muscles, tendons or ligaments (rheumatoid arthritis).
- against certain diseases that manifest themselves by, among other things, skin problems and/or joint complaints (discoid and systemic lupus erythematosus).
- for the treatment of skin problems which are sensitive to sunlight (photodermatoses).
- for the treatment of acute attacks of malaria and to prevent malaria.

This medicine is also used in children (≥ 6 years and ≥ 31 kg):

- For the treatment of childhood rheumatism in combination with other treatments (Juvenile idiopathic arthritis)
- Against certain diseases that manifest themselves by, among other things, skin problems and/or joint complaints (Discoid and systemic lupus erythematosus)
- For the treatment of acute attacks of malaria and to prevent malaria

This medicine does not work against certain types of malaria (chloroquine-resistant).

How does this medicine work?
Hydroxychloroquinesulfaat Accord contains hydroxychloroquine sulfate that works by reducing inflammation in people with autoimmune diseases (this is where the body's immune system attacks itself by mistake). This medicine is also used to prevent and treat

acute attacks of malaria, an infectious disease caused by the presence of parasites in red blood cells, with symptoms such as high fever, shaking, chills, and extreme sweating.

How is this medicine used?
The pharmaceutical form of Hydroxychloroquinesulfaat Accord is a film-coated capsule 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 Hydroxychloroquinesulfaat Accord is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Plaquenil. 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 Hydroxychloroquinesulfaat 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 bio to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Plaquenil, 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 Hydroxychloroquinesulfaat 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, the marketing authorisation for Hydroxychloroquinesulfaat Accord was granted on 20 July 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 Hydroxychloroquinesulfaat Accord, read the package leaflet (https://mri.cts-mrp.eu/Human/Downloads/NL_H_4784_001_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in August 2020.