LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

# Summary Public Assessment Report

# Deferiprone DOC
# (deferiprone)

# SE/H/1687/01-02/DC

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# Summary Public Assessment Report

Deferiprone DOC

(deferiprone)

Film-coated tablet, 500 mg and 1000 mg

This is a summary of the public assessment report (PAR) for Deferiprone DOC. It explains how Deferiprone DOC 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 Deferiprone DOC.

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

## What is Deferiprone DOC and what is it used for?

Deferiprone DOC is a ‘generic medicine’. This means that Deferiprone DOC is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Ferriprox.

Deferiprone DOC is used to treat iron overload caused by frequent blood transfusions in patients with thalassaemia major when current chelation therapy is contraindicated or inadequate.

## How does Deferiprone DOC work?

Deferiprone DOC contains the active substance deferiprone. Deferiprone DOC is a medicine that removes iron from the body.

## How is Deferiprone DOC used?

The pharmaceutical form of Deferiprone DOC is film-coated tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

## What benefits of Deferiprone DOC have been shown in studies?

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

## What are the possible side effects of Deferiprone DOC?

Because Deferiprone DOC 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 restrictions, see the package leaflet.

## Why is Deferiprone DOC approved?

It was concluded that, in accordance with EU requirements, Deferiprone DOC has been shown to have comparable quality and to be bioequivalent to the reference medicine Ferriprox. Therefore, the Medical Products Agency in Sweden decided that, as for Ferriprox, the benefits are greater than its risks and recommended that it can be approved for use.

## What measures are being taken to ensure the safe and effective use of Deferiprone DOC?

A risk management plan has been developed to ensure that Deferiprone DOC 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 Deferiprone DOC, 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 Deferiprone DOC

The marketing authorisation for Deferiprone DOC was granted on 2018-02-05 in Sweden.

The full PAR for Deferiprone DOC can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Deferiprone DOC, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2018-02.