LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Niferex
(iron, ferrous glycine sulfate)

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Gastro-resistant capsule, hard, 100 mg

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

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

What is Niferex and what is it used for?
Niferex is a medicine with 'well-established use'. This means that the medicinal use of the active substance of Niferex is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Niferex is a form of iron that can be taken by mouth to treat or prevent iron deficiency.

How does Niferex work?
Iron is essential for transport of oxygen and for energy transfer in the body. The capsules are called gastro-resistant because they do not release their contents in the stomach. They deliver the iron to your gut where it can be absorbed.

How is Niferex used?
The pharmaceutical form of Niferex is gastro-resistant capsule, hard, 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.

A prescription might be needed for this medicine in Sweden.

What benefits of Niferex have been shown in studies?
As iron, ferrous glycine sulfate is a well-known substance, and its use to treat or prevent iron deficiency is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of Niferex for the approved indication.

What are the possible side effects from Niferex?
For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Niferex approved?
The Swedish Medical Products Agency decided that Niferex's 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 Niferex?
A risk management plan has been developed to ensure that Niferex 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 Niferex, 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 Niferex
The full PAR for Niferex can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Niferex, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2022-06.