LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Vicks Sinex
(oxymetazoline hydrochloride)

SE/H/196/01/E03

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Summary Public Assessment Report

Vicks Sinex

(oxymetazoline hydrochloride)

nasal spray, solution 0,5 mg/ml

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

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

What is Vicks Sinex and what is it used for?

Vicks Sinex is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance. The reference medicine for Vicks Sinex is Iliadin. The marketing authorisation for Iliadin was withdrawn in Sweden in 2013.

Vicks Sinex is a nasal spray used for localised relief of the symptoms of a blocked nose in association with a cold or rhinitis. The effect of the spray starts after several minutes and lasts for 6 – 8 hours.

How does Vicks Sinex work?

Please see section above.

How is Vicks Sinex used?

The pharmaceutical form of Vicks Sinex is nasal spray, solution.

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 be obtained without a prescription.

What benefits of Vicks Sinex have been shown in studies?

Because Vicks Sinex is a hybrid application and is considered to be therapeutically equivalent, to the reference product Iliadin, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects of Vicks Sinex?

For the full list of all side effects reported with Vicks Sinex, see section 4 of the package leaflet.

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

Why is Vicks Sinex approved?

It was concluded that, in accordance with EU requirements, Vicks Sinex has been shown to have comparable quality and to be similar to the reference medicine Iliadin. Therefore, the Medical Products Agency in Sweden decided that, as for Iliadin, 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 Vicks Sinex?

A risk management plan has been developed to ensure that Vicks Sinex 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 Vicks Sinex, 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 Vicks Sinex

The marketing authorisation for Vicks Sinex was granted on 1997-08-22 in Sweden.

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

This summary was last updated in 2015-01.