LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Damigra
(sumatriptan)

SE/H/2710/001-002/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

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sumatriptan

Nasal spray, solution, 10 mg, 20 mg

This is a summary of the public assessment report (PAR) for Damigra. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Damigra and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Imigran.

The product is used in the treatment of migraine headache.

How does Damigra work?

Damigra contains sumatriptan, which belongs to a group of medicines called triptans (also known as 5-HT1 receptor agonists).

Migraine symptoms may be caused by the temporary widening of blood vessels in the head. Sumatriptan is believed to reduce the widening of these blood vessels. This in turn helps to take away the headache and relieve other symptoms of a migraine attack, such as feeling or being sick (nausea or vomiting) and sensitivity to light and sound.

How is Damigra used?

The pharmaceutical form is nasal spray, solution, for nasal administration.

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 in Sweden.

What benefits of Damigra have been shown in studies?

No additional studies were needed as the product is a generic medicine considered to be bioequivalent to the reference medicine, Imigran. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Damigra?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

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 Damigra approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Imigran, 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 Damigra?
A risk management plan has been developed to ensure that the product 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, 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 Damigra
The full PAR for Damigra can be found on the following website: MRI - Home. For more information about treatment with Damigra, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-07.