LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Nocdurna
(desmopressin acetate)

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Summary Public Assessment Report

Nocdurna

(desmopressin acetate)

Oral lyophilisate, 25micrograms and 50 micrograms

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

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

What is Nocdurna and what is it used for?

Nocdurna reduces urine production and is used for the treatment of nocturia (frequent need to get up to urinate at night) due to nocturnal polyuria (overproduction of urine during night) in adults.

How does Nocdurna work?

Nocdurna contains desmopressin which is a synthetic analogue of a naturally occurring hormone called arginine vasopressin (AVP). Desmopressin causes reabsorption of water in the kidneys. This reabsorption in turn decreases night-time urine production.

How is Nocdurna used?

The pharmaceutical form of Nocdurna is oral lyophilisate for oral (sublingual) 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 Nocdurna have been shown in studies?

Desmopressin has been marketed since 1972, and has been available as nasal drops, nasal spray, in an injectable form and as tablets for oral use for many years. The first regulatory approval (2001) of desmopressin for the treatment of night-time urine production was based on the NOCTUPUS study program.

A battery of non-clinical studies has also been conducted on desmopressin.

What are the possible side effects of Nocdurna?

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

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

Why is Nocdurna approved?

Desmopressin is a widely used, well-known active substance, and has been marketed since 1972. Therefore, the Medical Products Agency in Sweden decided that Nocdurna's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Nocdurna?

A risk management plan has been developed to ensure that Nocdurna 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 Nocdurna, 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 Nocdurna

The marketing authorisation for Nocdurna was granted on 2016-06-16 in Sweden.

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

This summary was last updated in 2016-07.