LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Desmopressin Newbury
(desmopressin acetate, desmopressin)

SE/H/2788/001-003

This module reflects the scientific discussion for the approval of Desmopressin Newbury. The Summary Public Assessment Report was written in August 2023 by the previous RMS IS after initial procedure IS/H/0502/001-003/DC. RMS transfer from IS to SE was completed 01 June 2025.

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Summary Public Assessment Report

Generics

IS/H/0502/001-003/DC: Desmopressin Newbury

desmopressin acetate

IS/H/0502/001-003/DC

Date: 01.08.2023

Summary Public Assessment Report

Generics

Desmopressin Newbury 60, 120 and 240 micrograms sublingual tablets from Newbury Newbury Pharmaceuticals AB.

Active substance: desmopressin acetate

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

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

What is Desmopressin Newbury and what is it used for?

Desmopressin Newbury is a ‘generic medicine’. This means that Desmopressin Newbury is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Minirin Melt.
Desmopressin Newbury is used to treat:
- Central diabetes insipidus (pituitary disorder leading to severe thirst and the emission of a large quantity of urine, usually pale and resembling water).
- Bed wetting in children from 5 years of age with normal ability to concentrate urine (involuntary nightly urination during sleep).
- Nocturia (a condition when a person wakes up frequently during the night to urinate) in adults below 65 years of age.

How does Desmopressin Newbury work?

The product belongs to the Pharmacotherapeutic group: Pituitary and hypothalamic hormones and analogues, vasopressin and analogues ATC code: H01BA02.

Desmopressin, the active substance of this product, acts like the natural hormone vasopressin and regulates the kidneys' ability to concentrate urine.

How is Desmopressin Newbury used?

The pharmaceutical form of Desmopressin Newbury is sublingual tablet and the route of administration is oral use.

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

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The dose is established by your doctor, who will adjust it individually for you.
Desmopressin Newbury should always be taken at the same time.

The sublingual tablet must be placed under the tongue where it dissolves without water.

Diabetes insipidus
The usual dose for adults and children is 1-2 tablets under the tongue (60 micrograms tablet) 3 times daily.

Bedwetting
The usual dose is 1-2 tablets (120 micrograms tablet) under the tongue at night. You should take this medicine at bedtime. Liquids intake should be limited.

Your doctor will check every three months to see if the treatment should be continued. Your doctor may set a treatment-free period of at least one week.

Nocturia in adults
The usual dose is 1 tablet (60 micrograms tablet) under the tongue at bedtime.
Liquids intake should be limited.

Use in children
This medicine is used for treating diabetes insipidus and nocturnal bedwetting (see dosage for different treatment conditions above). Dosage is the same for children and adults only for diabetes insipidus.

The medicine can only be obtained with a prescription.

What benefits of Desmopressin Newbury have been shown in studies?
Because Desmopressin Newbury is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Minirin Melt. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.
The company provided data from the published literature on desmopressin acetate.

What are the possible side effects of Desmopressin Newbury?

Because Desmopressin Newbury 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 Desmopressin Newbury approved?

It was concluded that, in accordance with EU requirements, Desmopressin Newbury has been shown to have comparable quality and to be bioequivalent to reference medicine Minirin Melt. Therefore, the Icelandic Medicines Agency decided that, as for reference medicine called Minirin Melt, the benefits are greater than its risk and recommended that it can be approved for use.

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

A risk management plan has been developed to ensure that Desmopressin Newbury 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 Desmopressin Newbury, 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 Desmopressin Newbury

End of procedure for Desmopressin Newbury was in June 2023.

The full PAR for Desmopressin Newbury can be found on the website Human MRIndex. For more information about treatment with Desmopressin Newbury, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in August 2023.