LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

# Summary Public Assessment Report

# Clonazepam Vital Pharma Nordic (clonazepam)

# SE/H/2122/01/DC

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# Summary Public Assessment Report

Clonazepam Vital Pharma Nordic
clonazepam

Concentrate for solution for injection/infusion, 1 mg/ml

This is a summary of the public assessment report (PAR) for Clonazepam Vital Pharma Nordic. 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 Clonazepam Vital Pharma Nordic and what is it used for?**

The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but is available as concentrate for solution for injection/infusion.

The reference medicine for the product is Iktorivil, 1 mg/ml, concentrate for solution for injection/infusion Roche AB, 1974-0017.

**How does Clonazepam Vital Pharma Nordic work?**

Clonazepam Vital Pharma Nordic contains the active substance clonazepam, which belongs to a group of medicines known as benzodiazepines. These medicines have anticonvulsant and relaxing effects.

This medicine is used for various forms of epilepsy, including status epilepticus, for adults and adolescents from 12 years of age.

**How is Clonazepam Vital Pharma Nordic used?**

The pharmaceutical form is concentrate for solution for injection/infusion.

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 Clonazepam Vital Pharma Nordic have been shown in studies?**

Because the product is a hybrid application and is considered to be similar to the reference product Iktorivil 1 mg/ml, concentrate and solvent for solution for injection or infusion, the benefits and risks are taken as being the same as those of the reference medicine.

**What are the possible side effects from Clonazepam Vital Pharma Nordic?**

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 Clonazepam Vital Pharma Nordic approved?

The Swedish Medical Products Agency decided that 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 Clonazepam Vital Pharma Nordic?

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 Clonazepam Vital Pharma Nordic

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

This summary was last updated in 2023-01.