LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

# Summary Public Assessment Report

# Betolvan
# (cyanocobalamin)

# SE/H/2607/001/MR

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# Summary Public Assessment Report

Betolvan
cyanocobalamin

Film-coated tablet, 1 mg

This is a summary of the public assessment report (PAR) for Betolvan. 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 Betolvan 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 Betolvex.
Betolvan is administrated at vitamin $B_{12}$ deficiency or when there is a risk for vitamin $B_{12}$ deficiency to occur.

For example, vitamin $B_{12}$ deficiency can develop if the vitamin cannot be absorbed normally by the body from foods. This can be due to a gastrointestinal disease but can also result from a stomach ulcer operation or other intestinal surgery. Vitamin $B_{12}$ deficiency can also occur due to longterm medicinal treatment of gastrointestinal inflammation.

**How does Betolvan work?**
Betolvan contains the active substance cyanocobalamin, vitamin $B_{12}$. This is a vital vitamin which is needed e.g. for normal production of blood and normal neurological function.

**How is Betolvan used?**
The pharmaceutical form is film-coated tablet for oral 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 be obtained without a prescription in Sweden.

**What benefits of Betolvan 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, Betolvex. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

**What are the possible side effects from Betolvan?**

Because the product isa 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 Betolvan approved?**
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Betolvex, 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 Betolvan?**
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.

For more details, please see the full PAR for Betolvan on the following website: MRI - Home.

**Other information about Betolvan**
The full PAR for Betolvan can be found on the following website: MRI - Home. For more information about treatment with Betolvan, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-05.