LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Bevione
(thiamine hydrochloride)

SE/H/2406/01/DC

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Summary Public Assessment Report

Bevione
thiamine hydrochloride

solution for injection, 50 mg/mL

This is a summary of the public assessment report (PAR) for Bevione. 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 Bevione and what is it used for?

The product is a medicine with ‘well-established use’. This means that the medicinal use of the active substance of the product is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

The product contains the active substance thiamine (vitamin B1). This is a water-soluble vitamin that belongs to a group of medicines called “vitamins B”.

Sometimes a human body requires a supplement of vitamin B1. This could be due to a diet that does not contain enough thiamine or due to ineffective absorption of thiamine from the diet. It is also used if there is a special need for extra thiamine as in cases of quick excretion from the body (e.g. via urine).

Bevione is used to treat or prevent vitamin B1 deficiencies (when the body has too low amounts of the vitamin) like beriberi disease and Wernicke-Korsakoff syndrome.

How does Bevione work?

The main physiological role of thiamine is as a co-enzyme in the metabolism of carbohydrates, where the so called ´thiamine pyrophosphate´, also known as ´TPP´, is required for several stages in the breakdown of glucose (sugar) in the process where energy is produced.

Thiamine deficiency affects mainly the nervous, cardiovascular, muscular and gastrointestinal organ systems.

How is Bevione used?

The pharmaceutical form is solution for injection.

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 Bevione have been shown in studies?

As *thiamine* is a well-known substance, and its use in the treatment of *vitamin B1 deficiencies like beriberi disease and Wernicke-Korsakoff syndrome* is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of *thiamine* in the treatment of the above-mentioned indication.

What are the possible side effects from Bevione?

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 Bevione 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 Bevione?

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 Bevione

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

This summary was last updated in 2024-11.