

Summary Public Assessment Report

Hydroxocobalamin Pharmexon (hydroxocobalamin acetate)

SE/H/2207/01/DC

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Hydroxocobalamin Pharmexon
hydroxocobalamin acetate, hydroxocobalamin

Solution for injection, 1 mg/ml

This is a summary of the public assessment report (PAR) for Hydroxocobalamin Pharmexon. 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 Hydroxocobalamin Pharmexon 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 is used for prevention and treatment of pernicious anaemia (anemia due to vitamin B₁₂ deficiency) and other types of vitamin B₁₂ deficiency when tablets are not considered sufficient or appropriate.

How does Hydroxocobalamin Pharmexon work?

Hydroxocobalamin Pharmexon contains the active substance hydroxocobalamin (vitamin B₁₂). Hydroxocobalamin Pharmexon is used for prevention and treatment of pernicious anaemia (anemia due to vitamin B₁₂ deficiency) and other types of vitamin B₁₂ deficiency when tablets are not considered sufficient or appropriate.

How is Hydroxocobalamin Pharmexon used?

The pharmaceutical form is Solution for injection, for Intramuscular or subcutaneous 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 in Sweden.

What benefits of Hydroxocobalamin Pharmexon have been shown in studies?

As hydroxocobalamin is a well-known substance, and its use in the treatment of *pernicious anaemia, and other conditions with vitamin B12 deficiency where oral supplementation is not considered sufficient or else appropriate* is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of hydroxocobalamin in the treatment of the above-mentioned indication.

What are the possible side effects from Hydroxocobalamin Pharmexon?

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 Hydroxocobalamin Pharmexon 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 Hydroxocobalamin Pharmexon?

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 Hydroxocobalamin Pharmexon

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

This summary was last updated in 2023-03.