LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Dexamfetamin Sea Pharma (dexamfetamine sulfate)

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Summary Public Assessment Report

Dexamfetamin Sea Pharma
dexamfetamine sulfate

Tablet, 5 mg, 10 mg, 20 mg

This is a summary of the public assessment report (PAR) for Dexamfetamin Sea Pharma. 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 Dexamfetamin Sea Pharma 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.

Dexamfetamin Sea Pharma is used to treat attention-deficit/hyperactivity disorder (ADHD).

- It is used in children and adolescents aged 6-17 years.
- It is not indicated in all children with ADHD
- It is used only after when another medicine called methylphenidate was not sufficiently effective.
- It should be used as part of a treatment programme which typically includes psychological, educational and social measures.

Dexamfetamin Sea Pharma treatment must only be initiated by, and used under the supervision of a specialist in childhood or adolescent behavioural disorders.

How does Dexamfetamin Sea Pharma work?

Dexamfetamin Sea Pharma is a psychostimulant. It improves activity in parts of the brain. This medicine can help to improve attention span, concentration, and reduce impulsive behaviour.

How is Dexamfetamin Sea Pharma used?

The pharmaceutical form is tablets 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 only be obtained with a prescription in Sweden.

What benefits of Dexamfetamin Sea Pharma have been shown in studies?

As dexamfetamine is a well-known substance, and its use in the treatment of ADHD is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of dexamfetamine in the treatment of the above-mentioned indication.

What are the possible side effects from Dexamfetamin Sea Pharma?

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 Dexamfetamin Sea Pharma approved?

The Swedish Medical Products Agency decided that the benefits are greater than its risks and recommended that it can be approved for use.

The product has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below “What measures are being taken to ensure the safe and effective use of Dexamfetamin Sea Pharma?”

What measures are being taken to ensure the safe and effective use of Dexamfetamin Sea Pharma?

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.

Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: Specific adverse reaction follow-up questionnaires for adverse events, abuse/dependence/misuse/diversion, and pregnancy.

Legal status: Prescription only medicine. Treatment must be under the supervision of a specialist in childhood and/or adolescent behaviour disorders.

Additional risk minimisation measures (including educational material):
The educational material should contain the following key elements:

The potential for abuse and misuse and related complications are known and appropriate warnings are in the SmPC and PL. To avoid/reduce abuse/misuse and associated events, educational material for treating physicians, pharmacists, and carers will be developed. The products are only claimed to be authorised for children and adolescents.

To observe the prescription pattern, a Drug utilisation study (DUS) is planned to be performed within relevant EU countries. The objectives of the study will be to describe how the products are prescribed in Europe, to evaluate off-label use in Europe, and to collect data on abuse, misuse, overdose, diversion, and dependence related to the products.

Other information about Dexamfetamin Sea Pharma

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

This summary was last updated in 2024-05.