Annex III

Amendments to the summary of product characteristics and package leaflet

Note: These amendments are to be incorporated to the valid Summary of Product Characteristics, labelling and package leaflet which are the final versions achieved during the Coordination group procedure

SUMMARY OF PRODUCT CHARACTERISTICS

[The below wording should be inserted at the top of the document]

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

[…]

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

[The wording of this section should read as follows]

Dexamfetamine is indicated as part of a comprehensive treatment programme for attentiondeficit/hyperactivity disorder (ADHD) in children and adolescents aged 6 to 17 years when response to previous methylphenidate treatment is considered clinically inadequate. A comprehensive treatment programme typically includes psychological, educational and social measures.

Diagnosis should be made according to DSM-5 criteria or the guidelines in ICD-10 and should be based on a comprehensive multidisciplinary evaluation of the patient.

Dexamfetamine is not indicated in all children with ADHD and the decision to use dexamfetamine must be based on a very thorough assessment of the severity and chronicity of the child's symptoms in relation to the child's age and potential for abuse, misuse or diversion.

Treatment should be under the supervision of a specialist in childhood and/or adolescent behavioural disorders.

[…]

4.4 Special warnings and precautions for use

[…]

Abuse, misuse, and diversion

[…]

[The wording below should be deleted]

Dexamfetamine possesses a high potential to cause dependency and has been/is frequently abused.

[The following sentence should be added in its place]

The risk is generally greater for short acting stimulants than for corresponding long-acting products (see section 4.1).

[…]

4.8 Undesirable effects

[…]

[The following wording should be added at the end of this section]

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V

PACKAGE LEAFLET

Package leaflet: Information for the patient

Dexamed 5 mg tablets

Dexamfetamine sulphate

[The below wording should be inserted at the top of the document]

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

1. WHAT DEXAMED IS AND WHAT IT IS USED FOR

[…]

What it is used for

[These bullet points should read as follows]

Dexamed 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.

[…]

4. POSSIBLE SIDE EFFECTS

[…]

[The following wording should be added at the end of this section]

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.