Annex IV

Amendments to relevant sections of the summary of product characteristics and package leaflet

Note:

The amendments to the Summary of Product Characteristics, labelling and package leaflet may need to be subsequently updated by the national competent authorities, in liaison with the Reference Member State if appropriate

Summary of Product Characteristics of Numeta G16%E, and associated names

[This wording should be inserted at the top of the SmPC]

▼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.

Section 4.4 Special warnings and precautions for use

Renal

[This wording should be inserted]

[…]

Use with caution in patients with renal insufficiency. Fluid and electrolyte status including magnesium (see Hypermagnesaemia) should be closely monitored in these patients.

Severe water and electrolyte equilibration disorders, severe fluid overload states, and severe metabolic disorders should be corrected before starting the infusion. (see 4.3 Contraindications).

[…]

[This wording should be inserted at the end of the section]

[…]

Hypermagnesaemia

<Invented Name> provides 0.3 mmol/kg/d of magnesium when administered at maximum dose (see section 4.2). There is a possibility that this may lead to hypermagnesaemia. The signs of hypermagnesaemia include generalised weakness, hypo-reflexia, nausea, vomiting, hypocalcaemia, respiratory failure, hypotension and arrhythmias. As signs of hypermagnesaemia may not be detected, monitoring of magnesium levels is advised at baseline and at appropriate intervals thereafter, in accordance with routine clinical practice and the needs of the individual patient. This is especially important in those patients at increased risk of developing hypermagnesaemia including patients with impaired renal function, patients receiving other medicinal products which place them at risk of developing hypermagnesaemia or patients receiving magnesium from other sources, including neonates whose mother's recently received magnesium in the antepartum period.

If serum magnesium levels are elevated (above reference range normal values) the infusion of <Invented Name> should be stopped or infusion rate reduced as deemed clinically appropriate and safe.

4.8 Undesirable effects

[The wording below should be added to 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*.

*[*For the printed material, please refer to the guidance of the annotated QRD template.]*

Package Leaflet of Numeta G16%E, and associated names

[This wording should be inserted at the top of the PL]

▼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.

Section 2

[The wording below should be added to this section]

[…]

Elevated levels of Magnesium in blood

The amount of magnesium in <Invented Name>, may cause elevated levels of magnesium in blood. The signs of this could include weakness, slow reflexes, nausea, vomiting, low calcium levels in blood, breathing difficulties, low blood pressure and irregular heartbeat. As these signs may be difficult to detect, your child´s blood values may be monitored by their doctor, in particular if your child has risk factors for elevated levels of magnesium in blood, including impaired renal function. If blood magnesium levels are elevated, the infusion will be stopped or reduced.

[…]

Section 4

[The wording below should be added to this section]

[…]

Reporting of side effects
If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. 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.

*[*For the printed material, please refer to the guidance of the annotated QRD template.]*

Annex V

Conditions to the marketing authorisations