

Sundhedsstyrelsen Axel Heides Gade 1 2300 København S Att.: Rapidalert 25-09-2013

Numeta G16E – Potential risk of hypermagnesaemia

Following the CMDh position dated September 18, 2013 for Numeta G13E and Numeta G16E emulsions for infusion (procedure number EMEA/H/A-107i/1373 under Article 107i of Directive 2001/83/EC), you will find attached the translation of the agreed upon DHPC and Communication plan for Numeta G16E.

As mentioned in the communication plan endorsed by the CMDh and in order to disseminate the translated approved DHPC to healthcare professionals by October 07, 2013, we would be grateful if you could send us any additional comment by October 02, 2013.

Should you have any question, do not hesitate to contact me.

Yours sincerely, Baxter A/S

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