



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

13 June 2013  
EMA/367009/2013  
Patient Health Protection

## Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states for Numeta G13%E and Numeta G16%E emulsions for infusion

Article 107i of Directive 2001/83/EC

Procedure number: EMEA/H/A-107i/1373

Please note that this draft Annex I will be updated to reflect information on concerned products/MAHs in MS(s) not providing info requested in time for initial publication



Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Austria	Baxter Healthcare GmbH Stella-Klein-Löw-Weg 15 1020 Wien Austria	Numeta G 13 % E Emulsion zur Infusion	13%	Emulsion for infusion	Intravenous use
Belgium	BAXTER S.A. Bd. René Branquart 80 7860 Lessines Belgium	NUMETZAH G13%E	13%	Emulsion for infusion	Intravenous use
Belgium	Baxter SA Boulevard d'Angleterre 2-4 1420 Braine-l'Alleud Belgium	NUMETZAH G16%E	16%	Emulsion for infusion	Intravenous use
Czech Republic	BAXTER CZECH spol. s r.o. Karla Engliše 3201/6 150 00 Praha 5 Czech Republic	NUMETA G13%E	13%	Emulsion for infusion	Intravenous use
Denmark	Baxter A/S Gydevang 43 DK-3450 Allerød Denmark	Numeta G13E	13%	Solution for infusion	Intravenous use
Denmark	Baxter A/S Gydevang 43 DK-3450 Allerød Denmark	Numeta G16E	16%	Solution for infusion	Intravenous use
Finland	Baxter Oy Tammasaarenkatu 1 PL 119 00181 HELSINKI Finland	NUMETA G13E	13%	Emulsion for infusion	Intravenous use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Finland	Baxter Oy Tammasaarencatu 1 PL 119 00181 HELSINKI Finland	NUMETA G16E	16%	Emulsion for infusion	Intravenous use
France	Baxter S.A.S. 6 Avenue Louis Pasteur 78310 Maurepas France	NUMETAH G13%E, émulsion pour perfusion	13%	Emulsion for infusion	Intravenous use
Germany	Baxter Deutschland GmbH Edisonstr. 4 85716 Unterschleißheim Germany	Numeta G 13 % E Emulsion zur Infusion	13%	Emulsion for infusion	Intravenous use
Germany	Baxter Deutschland GmbH Edisonstr. 4 85716 Unterschleißheim Germany	Numeta G 16 % E Emulsion zur Infusio	16%	Emulsion for infusion	Intravenous use
Greece	Baxter HELLAS Ltd Metsovou 3 Neo Hrakleio 14121, Athens Greece	NUMETA (G13)	13%	Emulsion for infusion	Intravenous use
Greece	Baxter HELLAS Ltd Metsovou 3 Neo Hrakleio 14121, Athens Greece	NUMETA (G16)	16%		Intravenous use
Ireland	Baxter Healthcare Limited Caxton Way Thetford Norfolk IP24 3SE United Kingdom	Numeta G13% E Emulsion for Infusion	13%	Emulsion for infusion	Intravenous use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Ireland	Baxter Healthcare Limited Caxton Way Thetford Norfolk IP24 3SE United Kingdom	Numeta G16% E Emulsion for Infusion	16%	Emulsion for infusion	Intravenous use
Italy	Baxter S.p.A. Piazzale dell' Industria, 20 00144 ROMA Italy	NUMETA	13%	Solution for infusion	Intravenous use
Italy	Baxter S.p.A. Piazzale dell' Industria, 20 00144 ROMA Italy	NUMETA	16%	Solution for infusion	Intravenous use
Luxembourg	Baxter S.A Bd Rene Branquart, 80 7860 Lessines Belgium	Numetzah G13%E	13%	Emulsion for infusion	Intravenous use
Luxembourg	Baxter S.A. Bd Rene Branquart, 80 7860 Lessines Belgium	Numetzah G16%E	16%	Emulsion for infusion	Intravenous use
Malta	Baxter Healthcare Limited Caxton Way, Thetford, Norfolk IP24 3SE, United Kingdom	Numeta Emulsion for Infusion G13%E	13%	Emulsion for infusion	Intravenous use
Malta	Baxter Healthcare Limited Caxton Way, Thetford, Norfolk IP24 3SE, United Kingdom	Numeta Emulsion for Infusion G16%E	16%	Emulsion for infusion	Intravenous use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Norway	Baxter AS Gjerdrumsvei 11 0468 Oslo Norway	Numeta 13	13%	Emulsion for infusion	Intravenous use
Norway	Baxter AS Gjerdrumsvei 11 0468 Oslo Norway	Numeta G16E	16%	Emulsion for infusion	Intravenous use
Poland	Baxter Polska Sp. z o.o. ul. Kruczkowskiego 8 00-380 Warszawa Poland	Numeta G13%E	13%	Emulsion for infusion	Intravenous use
Poland	Baxter Polska Sp. z o.o. ul. Kruczkowskiego 8 00-380 Warszawa Poland	Numeta G16%E	16%	Emulsion for infusion	Intravenous use
Portugal	Baxter Médico-Farmacêutica, Lda. Zona Industrial da Abrunheira Edifício 10 - Sintra Business Park 2710-089 Sintra Portugal	Numeta G13%E	13%	Emulsion for infusion	Intravenous use
Spain	Baxter S.L. Poligono Industrial Sector 14 Pouet de Camilo, 2 46394 Ribarroja del Turia (Valencia) Spain	MUMETA G13%E, emulsión para perfusión	13%	Emulsion for infusion	Intravenous use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Spain	Baxter S.L. Poligono Industrial Sector 14 Pouet de Camilo, 2 46394 Ribarroja del Turia (Valencia) Spain	MUMETA G16%E, emulsión para perfusión	16%	Emulsion for infusion	Intravenous use
Sweden	Baxter Medical AB Box 63 164 94 Kista Sweden	Numeta G13E	13%	Emulsion for infusion	Intravenous use
The Netherlands	Baxter B.V. Kobaltweg 49 3542 CE Utrecht The Netherlands	NUMETA G13%E emulsie voor infusie	13%	Emulsion for infusion	Intravenous use
United Kingdom	Baxter Healthcare Limited Caxton Way, Thetford Norfolk IP24 3SE United Kingdom	Numeta G13%E Emulsion for Infusion	13%	Emulsion for infusion	Intravenous use
United Kingdom	Baxter Healthcare Limited Caxton Way, Thetford Norfolk IP24 3SE United Kingdom	Numeta G16%E Emulsion for Infusion	16%	Emulsion for infusion	Intravenous use