Norwegian Medicines Agency

Chemi S.p.A
Via dei Lavoratori, 54
Cinisello Balsamo
Italia

Your ref.:	Date:	Our ref.:	Officer:
	11 June 2018	15/03122-53	Ida Tufte Sogn

MARKETING AUTHORISATION

Ghemaxan 2000 IE (20 mg)/0,2 ml injeksjonsvæske, oppløsning i ferdigfylt sprøyte «Chemi», MTnr. 17-11897
Ghemaxan 4000 IE (40 mg)/0,4 ml injeksjonsvæske, oppløsning i ferdigfylt sprøyte «Chemi», MTnr. 17-11898
Ghemaxan 6000 IE (60 mg)/0,6 ml injeksjonsvæske, oppløsning i ferdigfylt sprøyte «Chemi», MTnr. 17-11899
Ghemaxan 8000 IE (80 mg)/0,8 ml injeksjonsvæske, oppløsning i ferdigfylt sprøyte «Chemi», MTnr. 17-11900
Ghemaxan 10 000 IE (100 mg)/1 ml injeksjonsvæske, oppløsning i ferdigfylt sprøyte «Chemi», MTnr. 15-10636
Ghemaxan 12 000 IE (120 mg)/0,8 ml injeksjonsvæske, oppløsning i ferdigfylt sprøyte «Chemi», MTnr. 17-11901
Ghemaxan 15 000 IE (150 mg)/1 ml injeksjonsvæske, oppløsning i ferdigfylt sprøyte «Chemi», MTnr. 15-10637

UK/H/5798/001-007/DC

According to the Norwegian Medicinal Product Regulation (Forskrift om legemidler 18. desember 2009 nr. 1839) § 5-8 the Norwegian Medicines Agency grants marketing authorisation of 11.06.2018 for the above mentioned medicinal products.

The marketing authorisation is valid until 11.06.2023.

The Summary of Product Characteristics as approved by the Norwegian Medicines Agency is enclosed with this document.

General classification for supply

- Reseptgruppe: C.

This marketing authorisation gives the holder the right to market the above mentioned medicinal products in Norway in accordance with the authorisation and other relevant legislation in force.

Norwegian Medicines Agency (NoMA)
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Application for renewal of the marketing authorisation must be submitted to The Norwegian Medicines Agency no later than 9 months prior to the expiry date of the marketing authorisation. Regarding submission of Periodic Safety Update Reports (PSURs), please refer to the final Assessment Report (under the section “Scientific overview and discussion”) in the authorisation procedure.

Yours sincerely
Norwegian Medicines Agency

Marianne Borge (b.a.)
Head of Unit
Safe use

This document is electronically approved and sent without signature.

Attachments: SmPC, PIL, mock-ups and General information on marketing authorisations