

Research and Development/Unmet Medical Need

DG PRE/R&D/UMN

Tel. : +32 (0)2 528 40 00
Fax : +32 (0)2 524 80 01
e-mail : umn@fagg-afmps.be

*Teva Pharma Belgium N.V./S.A.
Laarstraat 16
2610 Wilrijk*

Your letter from	Your reference	Our reference	Annex	Date
		FAGG/R&D/UMN <i>1219725</i>	1	

Onderwerp
Titre de l'objet
Subject

Opzetten van een medisch noodprogramma op 20/03/2020
Mise sur pied d'un programme médical d'urgence le 20/03/2020
Set up of a medical need program dated 20/03/2020

Medicinal product : Ajovy (fremanezumab) (225 mg and 675 mg solution for injection in pre-filled syringe)

Indication : Prophylaxis of migraine in adult patients who suffer from at least 8 monthly migraine days and who previously failed on at least 2 preventive treatment classes and cannot be satisfactorily treated with the other approved and commercially available alternative treatments, in accordance with clinical guidelines, because of efficacy and/or safety issues

Ethics Committee designated: Jessa Ziekenhuis
Reference: MNP-201930

Pharmacovigilance report cut-off date: 20/03/2021

Pharmacovigilance report deadline submission: 20/04/2021

Chère Madame, Cher Monsieur,

Conformément à l'article 6quater de la loi du 25 mars 1964, relative aux médicaments, j'ai décidé de mettre sur pied le programme ci-dessus mentionné selon les conditions précisées dans l'annexe I.

Salutations sincères,

Pour la Ministre des Affaires sociales et de la Santé publique

Geachte Mevrouw, Geachte Heer,

In overeenstemming met artikel 6quater van de wet van 25 maart 1964 inzake geneesmiddelen, heb ik besloten het hierboven vermelde programma op te zetten onder de voorwaarden zoals gepreciseerd in de bijlage I.

Met de meeste hoogachting,

Voor de Minister van Sociale Zaken en Volksgezondheid



Dr. Greet Musch
Unofficial translation

In accordance with article 6quater of the Law of 25 March 1964 concerning medicinal products, I have decided to set up the above mentioned medical need program following the conditions stated in annex I.