

26 April 2020

Dear Dr. Oved,

This letter is in response to your inquiry regarding treatment with Aimovig and COVID-19 (MI-GM.IL.20/091).

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Erenumab is a fully human IgG2 monoclonal antibody produced using recombinant DNA technology in Chinese hamster ovary (CHO) cells.

**Therapeutic indications**

Aimovig is indicated for prophylaxis of migraine in adults who have at least 4 migraine days per month when initiating treatment with Aimovig .

**For further information please refer to the attached Aimovig Israeli Prescribing Information (PI).**

Novartis Israel does not recommend or suggest using Aimovig otherwise then mentioned in the Israeli Prescribing Information (approved by the Israeli MoH and attached for your convenience).

Attached a document that summarizes the updated information on **Risk of COVID-19 in patients treated with erenumab.**

Based on the attached GGD:

### Risk of COVID-19 in patients treated with erenumab:

- There are no data to inform incidence or severity of COVID-19 in patients receiving erenumab. Physicians and other healthcare professionals need to use their best clinical judgement when evaluating patients and making treatment decisions.
- Concerning the known mechanism of action and safety profile of erenumab, it should be noted that:
  - Erenumab is not an immunomodulator and is not expected to have an effect on B or T cell function.<sup>4</sup>
  - The use of erenumab is not associated with adverse events linked to increased risk of infections or immunosuppression, nor are such events important identified or potential risks in the risk management plan for erenumab.<sup>4</sup>
- Patients who think may have been exposed to COVID-19 and patients with protracted flu-like symptoms, particularly shortness of breath, are advised to contact a healthcare professional immediately, in line with local health agency recommendations.<sup>1-3</sup>

בתרגום לעברית:

- סיכון ל COVID-19 בחולים המטופלים ב-Aimovig:
- אין נתונים שמראים על שכיחות או חומרת COVID-19 בקרב חולים שקיבלו Aimovig רופאים ואנשי מקצוע אחרים בתחום הבריאות צריכים להשתמש במיטב שיקול הדעת הקליני שלהם בהערכת חולים ולקבל החלטות טיפול.
- בנוגע למנגנון הפעולה הידוע ופרופיל הבטיחות של Aimovig יש לציין כי:
- Aimovig אינו אימונומודולטור ואינו צפוי להשפיע על תפקוד תאי B או T.
- שימוש ב Aimovig אינו מקושר לתופעות לוואי המשויכות לעלייה בסיכון לזיהומים או לדיכוי חיסוני, וגם אירועים כאלה אינם מזוהים או סיכונים פוטנציאליים בתוכנית ניהול הסיכונים עבור Aimovig.
- חולים הסבורים שנחשפו ל COVID-19 ולחולים עם תסמינים דמויי שפעת ממושכים, במיוחד קוצר נשימה, מומלץ לפנות באופן מיידי למוקד מד"א או לרופא המטפל בהתאם להמלצות משרד הבריאות.

### References

1. World Health Organization. Current novel coronavirus (2019-nCoV) outbreak. Accessed 10-Mar-2020. <https://www.who.int/health-topics/coronavirus>
2. European Centre for Disease Prevention and Control. Novel coronavirus. Accessed: 10-Mar-2020. <https://www.ecdc.europa.eu/en/novel-coronavirus-china>
3. US Centers for Disease Control and Prevention. Coronavirus Disease 2019 (COVID-19). Accessed: 10-Mar-2020. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html#clinical-management-treatment%3C>

4. Novartis Data on File.

I hope this information helps.

Should you have any additional questions with which I can be of assistance, please contact us at [il.medinfo@novartis.com](mailto:il.medinfo@novartis.com).

Sincerely,

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Enclosures:

- AIM 70 API MAR20 V2.pdf
- Erenumab \_ 2019 Novel Coronavirus Disease \_COVID-19\_.pdf

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