



Drug Market Withdrawal for Makena (hydroxyprogesterone caproate injection)

The U.S. Food and Drug Administration (FDA) announced on April 6, 2023 the final decision to withdraw approval of Makena and its generics, which had been approved under the FDA's accelerated approval pathway. Makena and its generics were initially approved to reduce the risk of preterm birth in women pregnant with one baby who have a history of spontaneous preterm birth. As a result of this withdrawal of approval, Makena and its generics are now unapproved products. Approvals of the medications have been withdrawn because Makena and its generics are no longer shown to be effective, and the benefits do not outweigh the risks for the indication for which they were approved.

Please carefully review the impacted medication, and talk to your doctor about it right away.

What this means for you:

- If you take Makena or its generic, talk to your doctor or healthcare provider
- To determine if your medication is affected, you should look at the drug name and company name on the label of your prescription. If the information is not on the container, you should contact the pharmacy that dispensed the medication.
- Please refer to the Food and Drug Administration website for the most current updates to this drug withdrawal at: [FDA Commissioner and Chief Scientist Announce Decision to Withdraw Approval of Makena | FDA](#) and [Makena \(hydroxyprogesterone caproate injection\) Information | FDA](#)

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either by online, regular mail or fax.

- **Online:** Complete and submit the report: <https://www.accessdata.fda.gov/scripts/medwatch/>
 - o Select **Consumer/Patient (FDA Form 3500B)**
- **Regular mail or fax:** Download form at www.fda.gov/media/85598/download
 - o **Form FDA-3500B: Consumer Voluntary Reporting** will automatically download

Note: A reporting form also may be requested by calling **800-332-1088 (TTY:711)**. Complete and return to the address on the pre-addressed form, or submit by fax to **800-FDA-0178**.

If you have questions about this medicine or the recall, please talk to your doctor or pharmacist. You may also call the number on the back of your Humana member ID card.

For 24-hour service, you can sign into MyHumana, your personal, secure online account on Humana.com, to search for other medicine that your plan covers.

As your partner in health, we want to make sure that you are informed about issues that may affect your health and overall well-being.



Important!

At Humana, it is important you are treated fairly.

Humana Inc. and its subsidiaries do not discriminate or exclude people because of their race, color, national origin, age, disability, sex, sexual orientation, gender, gender identity, ancestry, marital status or religion. Discrimination is against the law. Humana and its subsidiaries comply with applicable Federal Civil Rights laws. If you believe that you have been discriminated against by Humana or its subsidiaries, there are ways to get help.

- You may file a complaint, also known as a grievance:
Discrimination Grievances, P.O. Box 14618, Lexington, KY 40512-4618
If you need help filing a grievance, call the number on your ID card or if you use a **TTY**, call **711**.
- You can also file a civil rights complaint with the **U.S. Department of Health and Human Services**, Office for Civil Rights electronically through their Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or at **U.S. Department of Health and Human Services**, 200 Independence Avenue, SW, Room 509F, HHH Building, Washington, DC 20201, **1-800-368-1019**, **800-537-7697 (TDD)**. Complaint forms are available at <https://www.hhs.gov/ocr/office/file/index.html>.
- **California residents:** You may also call California Department of Insurance toll-free hotline number: **1-800-927-HELP (4357)**, to file a grievance.

Auxiliary aids and services, free of charge, are available to you. Call the number on your ID card (TTY: 711)

Humana provides free auxiliary aids and services, such as qualified sign language interpreters, video remote interpretation, and written information in other formats to people with disabilities when such auxiliary aids and services are necessary to ensure an equal opportunity to participate.

Language assistance services, free of charge, are available to you. Call the number on your ID card (TTY: 711)

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call the number on your ID card (**TTY: 711**)... **ATENCIÓN:** Si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al número que figura en su tarjeta de identificación (**TTY: 711**)... **注意：**如果您使用繁體中文，您可以免費獲得語言援助服務。請致電會員卡上的電話號碼 (**TTY: 711**)... **CHÚ Ý:** Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số điện thoại ghi trên thẻ ID của quý vị (**TTY: 711**)... **주의：**한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. ID 카드에 적혀 있는 번호로 전화해 주십시오 (**TTY: 711**)... **PAUNAWA:** Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tawagan ang numero na nasa iyong ID card (**TTY: 711**)... **ВНИМАНИЕ:** Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Наберите номер, указанный на вашей карточке-удостоверении (**телетайп: 711**)... **ATANSYON:** Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele nimewo ki sou kat idantite manm ou (**TTY: 711**)... **ATTENTION:** Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le numéro figurant sur votre carte de membre (**ATS: 711**)... **UWAGA:** Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Proszę zadzwonić pod numer podany na karcie identyfikacyjnej (**TTY: 711**)... **ATENÇÃO:** Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para o número presente em seu cartão de identificação (**TTY: 711**)... **ATTENZIONE:** In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero che appare sulla tessera identificativa (**TTY: 711**)... **ACHTUNG:** Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Wählen Sie die Nummer, die sich auf Ihrer Versicherungskarte befindet (**TTY: 711**)... **注意事項：**日本語を話される場合、無料の言語支援をご利用いただけます。お手持ちの ID カードに記載されている電話番号までご連絡ください (**TTY: 711**)...

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با شماره تلفن روی کارت شناسایی تان تماس بگیرید (**TTY: 711**)...

Díí baa akó nínízin: Díí saad bee yáníłti'go Diné Bizaad, saad bee áká'ánída'áwo'déé', t'áá jiik'eh, éí ná hólq, námboo ninaaltsoos yézhí, bee nées ho'dółzin bikáá'ígíí bee hólne' (**TTY: 711**)...

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم الهاتف الموجود على بطاقة الهوية الخاصة بك (**TTY: 711**)...