

Drug Recall for Irbesartan Tablets and Irbesartan-HCTZ Tablets

Lupin Pharmaceuticals, Inc. is voluntarily recalling all batches of Irbesartan (75mg, 150mg and 300mg) Tablets USP and Irbesartan and Hydrochlorothiazide (150mg/12.5mg and 300mg/12.5mg) Tablets USP. Irbesartan used to treat hypertension, to lower blood pressure, diabetic nephropathy, an elevated serum creatinine, and proteinuria. Irbesartan and Hydrochlorothiazide is a combination used to treat patients whose blood pressure is not adequately controlled with monotherapy, or for patients likely to need multiple drugs to achieve their blood pressure goals.

Lupin Pharmaceuticals decided to recall these drugs because certain test batches were above the acceptable limit for the impurity, N-nitrosoirbesartan. However, none of the final product batches have tested above the acceptable limit. Due to the N-nitrosoirbesartan impurity being classified as a possible carcinogen to humans, there are multiple possible side effects. To date, Lupin has no known reports of adverse events related to this recall.

What this means for you:

- It is important that you do not abruptly stop taking your medication. Talk to your doctor or healthcare provider about switching to another medicine or obtaining the same medicine that is not part of the recall.
- To determine if your medicine 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 bottle, you should contact the pharmacy that dispensed the medicine.
- Please refer to the FDA website for the most current updates to this drug recall <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lupin-pharmaceuticals-inc-issues-voluntarily-nationwide-recall-all-irbesartan-tablets-and-irbesartan>
- You can also contact Inmar Rx Solutions, Inc. with any questions regarding this recall or for instructions on how to return your affected drug by calling **(855) 769-3988** or **(855) -3989**, Monday -Friday, 9 a.m. – 5 p.m. EST.

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

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

Note: A reporting form also may be requested by calling **1-800-332-1088(TTY:711)**. Complete and return to the address on the pre-addressed form, or submit by fax to **1-800-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 nínizin: 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**)...