COMPANY ANNOUNCEMENT

Gilead Issues A Voluntary Nationwide Recall of Two Lots of Veklury® (Remdesivir) Due to Presence of Glass Particulates

Summary

Company Announcement Date:

December 03, 2021

FDA Publish Date:

December 03, 2021

Product Type:

Drugs

Reason for Announcement:

Presence of glass particulates

Company Name:

Gilead Sciences Inc.

Brand Name:

Gilead

Product Description:

Veklury® (remdesivir 100 mg for injection)

Company Announcement

Foster City, CA, Gilead Sciences Inc. (Nasdaq: GILD) today announced it is voluntarily recalling two lots of Veklury® (remdesivir 100 mg for injection) to the user level. Gilead Sciences Inc. received a customer complaint, confirmed by the firm's investigation, of the presence of glass particulates.

Risk Statement: The administration of an injectable product that contains glass particulates may result in local irritation or swelling in response to the foreign material. If

the glass particulate reaches the blood vessels it can travel to various organs and block blood vessels in the heart, lungs or brain which can cause stroke and even lead to death. To date, Gilead Sciences Inc. has not received any reports of adverse events related to this recall.

Veklury is indicated for the treatment of adults and pediatric patients ≥ 12 years old and weighing ≥40 kg requiring hospitalization for COVID-19. The lyophilized form of Veklury (remdesivir 100 mg for injection) is distributed in single dose clear glass vials in powder form and reconstituted at the site of use. Veklury lots 2141001-1A and 2141002-1A were distributed nationwide in the United States, beginning October 2021. NDC, lot, expiration date and distribution dates can be found in the table below.

Product Description	NDC	Lot #	Expiration Date	Distribution date to wholesalers
Veklury® (remdesivir 100mg for injection)	61958-2901-02	2141001-1A 2141002-1A	01/2024 01/2024	10/25/21-10/26/2021 10/26/21-11/02/2021

Gilead is notifying its distributors and customers via UPS next day air mail to hospital pharmacies and is facilitating the return of any remaining vials from the affected lots. Hospitals that have Veklury which is being recalled should stop using the affected lots and return the product vials per the instructions.

Consumers with questions regarding this recall can contact Gilead Medical Information at 1-866-633-4474 Monday to Friday 6am - 4pm PST or through their website at www.askgileadmedical.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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 online, by regular mail or by fax.

- Complete and submit the report Online (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

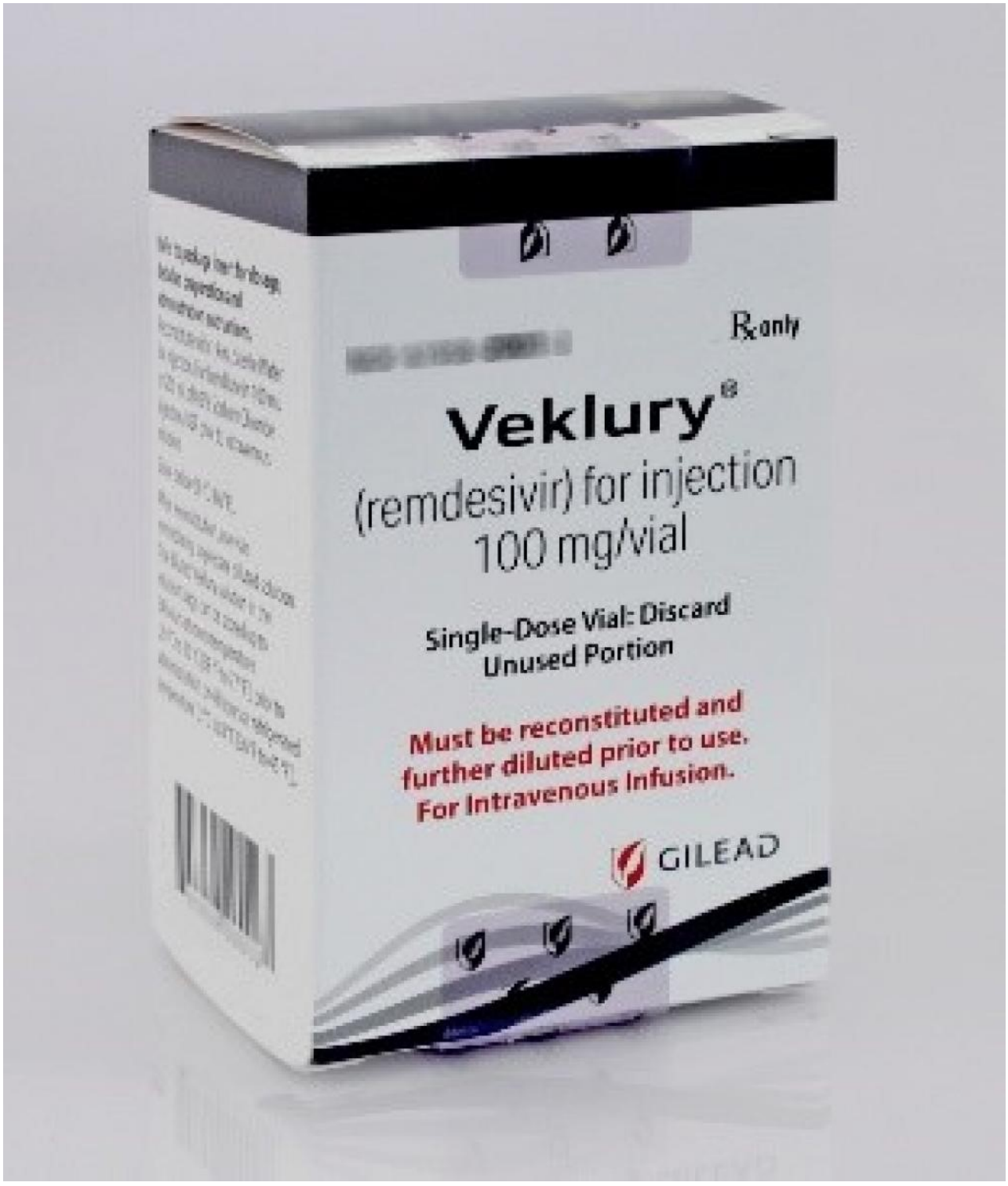
Company Contact Information

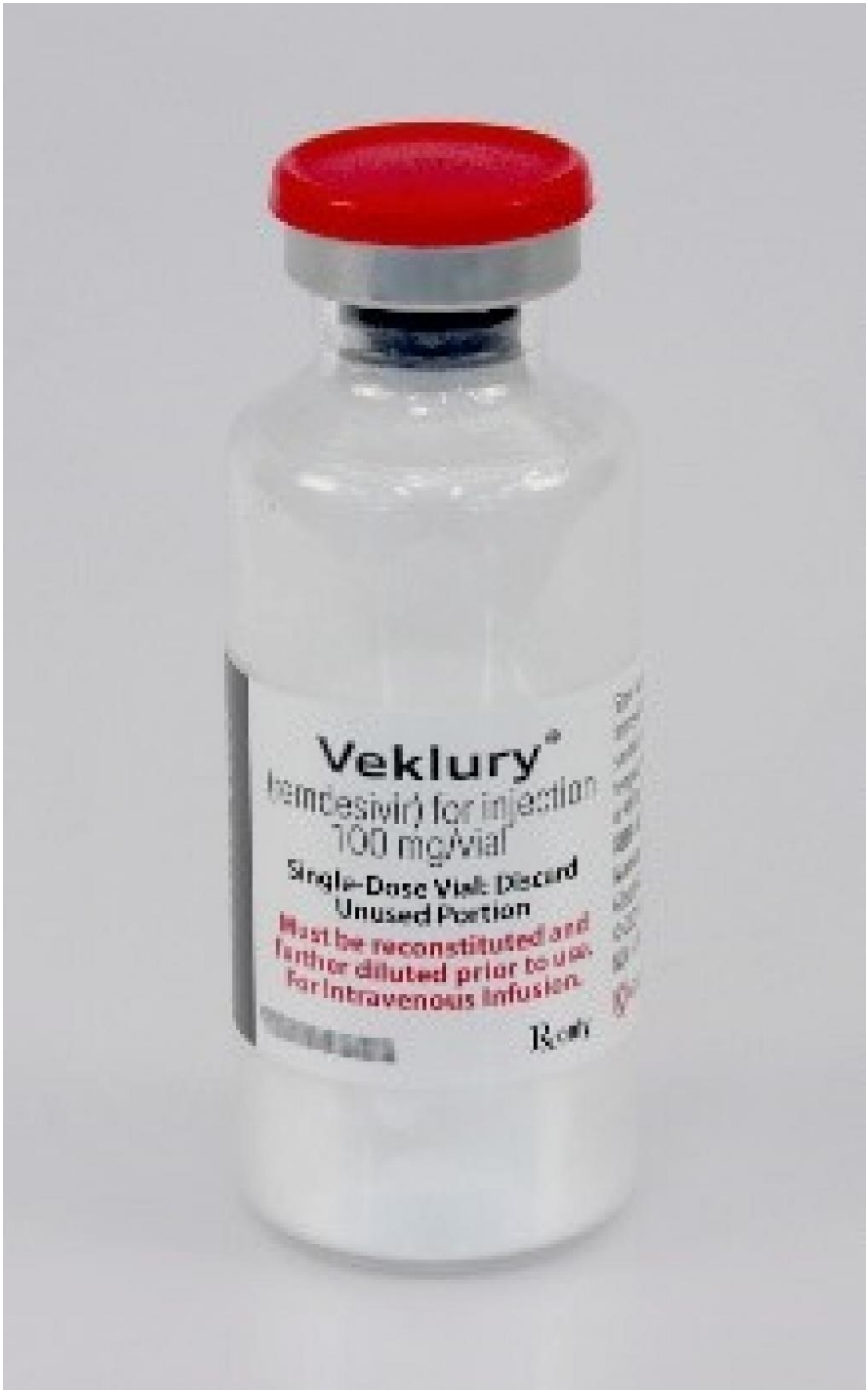
Consumers:

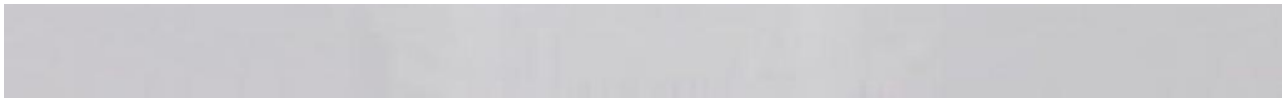
Gilead Medical Information

1-866-633-4474

Product Photos




Veklury
remdesivir) for injection
100 mg/vial
Single-Dose Vial: Discard
Unused Portion
Must be reconstituted and
further diluted prior to use.
For Intravenous infusion.



More Recalls, Market
Withdrawals, &
Safety Alerts (/safety/recalls-market-withdrawals-safety-alerts)