

Dear Health Care Provider Letter

IMPORTANT PRODUCT INFORMATION

Use of an alternate supply for active ingredient in ERBITUX® (cetuximab) vials (100 mg/50 mL and 200 mg/100 mL)

Dear Healthcare Provider:

Eli Lilly and Company (Lilly) wishes to inform you of important information about ERBITUX (cetuximab) vials manufactured using active ingredient obtained from an alternate source containing additional excipients. The US Food and Drug Administration and Lilly have determined that this temporary use of an alternate source should have no meaningful difference in safety and efficacy of ERBITUX. This temporary change will not impact the continued availability of ERBITUX for patients.

On a temporary basis, Lilly is manufacturing ERBITUX using active ingredient from an alternate supplier licensed in the European Union. These ERBITUX vials contain residual levels of excipients from the alternate supplier's buffer in addition to the phosphate buffer components used in Lilly ERBITUX.

Lilly ERBITUX vials contain 2 mg/mL of cetuximab active ingredient in phosphate buffer. The buffer balance has been modified for the alternate source of active ingredient to maintain consistent pH 7.0 to 7.4.

- For vials manufactured using the alternate source active ingredient, each 1 mL of ERBITUX drug product solution still contains 2 mg of cetuximab, with slight changes to the quantity of sodium chloride (8.48 to 8.47 mg), sodium phosphate dibasic heptahydrate (1.88 mg to 2.30 mg) and sodium phosphate monobasic monohydrate (0.41 mg to 0.20 mg).
- Residual excipients arising from alternate source buffer matrix are also present in each mL of this ERBITUX solution: 0.31 mg citric acid monohydrate, 1.1 mg glycine, and 0.015 mg polysorbate 80 (potential allergen). Rarely, polysorbates can cause severe allergic reactions.

The reason for this temporary change in the active ingredient supply for ERBITUX is to redeploy Lilly's cetuximab manufacturing capacity to be used for medicines to treat COVID-19. The prescribing information for ERBITUX is not impacted by this change, however, Section 11 (Description) of the USPI for the product using the alternate source has been revised to include the changes to the inactive ingredients.

Reporting Adverse Events

To report adverse events among patients taking ERBITUX, please call 1-800-LillyRx (1-800-545-5979).

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: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm> 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 (1-800-332-0178).

Sincerely,



Nikki Toms, MD
Vice President, Medical Affairs
Eli Lilly and Company