ERBITUX- cetuximab solution ImClone LLC

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BOXED WARNING (WHAT IS THIS?)

WARNING: INFUSION REACTIONS and CARDIOPULMONARY ARREST

Infusion Reactions: ERBITUX can cause serious and fatal infusion reactions [see Warnings and Precautions (5.1), Adverse Reactions (6)]. Immediately interrupt and permanently discontinue ERBITUX for serious infusion reactions [see Dosage and Administration (2.5)].

Cardiopulmonary Arrest: Cardiopulmonary arrest or sudden death occurred in patients with squamous cell carcinoma of the head and neck receiving ERBITUX with radiation therapy or a cetuximab product with platinum-based therapy and fluorouracil. Monitor serum electrolytes, including serum magnesium, potassium, and calcium, during and after ERBITUX administration [see Warnings and Precautions (5.2, 5.6)].

Hide

- HIGHLIGHTS OF PRESCRIBING INFORMATION
- + FULL PRESCRIBING INFORMATION: CONTENTS*
- + 1 INDICATIONS AND USAGE
- + 2 DOSAGE AND ADMINISTRATION
- + 3 DOSAGE FORMS AND STRENGTHS
- + 4 CONTRAINDICATIONS
- + 5 WARNINGS AND PRECAUTIONS
- + 6 ADVERSE REACTIONS
- **+ 8 USE IN SPECIFIC POPULATIONS**
- + 11 DESCRIPTION
- + 12 CLINICAL PHARMACOLOGY
- + 13 NONCLINICAL TOXICOLOGY
- **+ 14 CLINICAL STUDIES**
- **+ 16 HOW SUPPLIED/STORAGE AND HANDLING**
- + 17 PATIENT COUNSELING INFORMATION

View All Sections

Revised: 9/2021

Document Id: b4728a04-838a-4065-92bb-5035843ad1d4 Set id: 8bc6397e-4bd8-4d37-a007-a327e4da34d9

Version: 54

Effective Time: 20210927

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