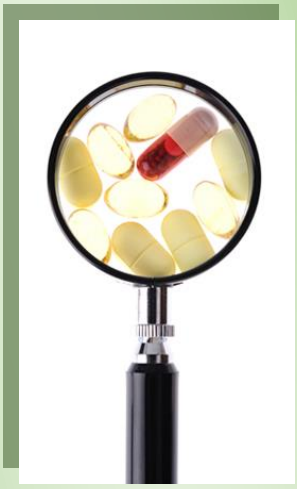
January 2020 **COM-2020-007**

DRUG SAFETY NOTIFICATION



DATE:
1/23/2020

DRUG NAME:
RITUXAN™ (RITUXIMAB)

SAFETY TOPIC:
Label Changes

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. The clinical team wants to keep you with the latest up-to-date information on drug safety.

The U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) announces label changes for drug Rituxan™ (Rituximab) regarding fetal harm effect. The following sections were reviewed and updated in the prescribing information document:

- *Warnings and Precautions - Embryo-Fetal Toxicity*
- *Use in Specific Populations*
  - *Lactation*
  - *Females and Males of Reproductive Potential*
  - *Patient Counseling Information*

Rituxan™ is a CD20-directed cytolytic antibody indicated for the treatment (alone or in combination based on individual indication) of adult patients with:

- Non-Hodgkin's Lymphoma (NHL), Chronic Lymphocytic Leukemia (CLL), Rheumatoid Arthritis (RA), Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA), and Pemphigus Vulgaris (PV)

Health care professionals should discuss the information with patients and advise females of reproductive potential to use an effective contraception method during treatment for at least 12 months after the last dose and do not breastfeed while on treatment for at least 6 months after the last dose.

PharmPix clinicians are compromised with the health and wellness of our insured. It is our priority to offer high-quality services and to promote practices for health promotion and disease prevention. If you have doubts or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137.

2 Street 1, Suite 500 Guaynabo, PR 00968 | Tel. 787.522.5252 | Fax 1.866.912.2830 | www.pharmpix.com

Best regards,

Clinical Department

Reference:

- Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER). Drug Safety-related Labeling Changes (SrLC). (2020, January 23). Retrieved from https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=1511
- **Rituxan™.** Micromedex® (2019). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https: https://www.micromedexsolutions.com/micromedex2/librarian/CS/B1CA42/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/8B6E2D/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Rituximab&fromInterSaltBase=true&false=null&false=null&=null#close
- Rituxan. Safety information. Accessed on 1/28/2020: https://www.rituxan.com/index/safety.html

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