Genentech
A Member of the Roche Group

IMPORTANT PRESCRIBING INFORMATION

October 2019

Subject: Important Prescribing Information with Use of XOFLUZA® (Baloxavir marboxil)

- **Medication Errors**

Dear Health Care Provider,

Genentech, a Member of the Roche Group, would like to inform you of important information regarding XOFLUZA.

XOFLUZA® (baloxavir marboxil) is a polymerase acidic endonuclease inhibitor that is approved by the U.S. Food and Drug Administration (FDA) for the treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours and who are otherwise healthy, or at high risk of developing influenza-related complications.

Medication errors related to prescribing and dispensing errors have led to overdosage and underdosage of XOFLUZA. In the majority of overdosage cases, no adverse events were reported. In the limited number of adverse events reported with overdosage, data was insufficient to determine specific symptoms that could be anticipated due to overdosage. Please refer to the *Adverse Reactions* section of the enclosed full prescribing information for further details on adverse events.

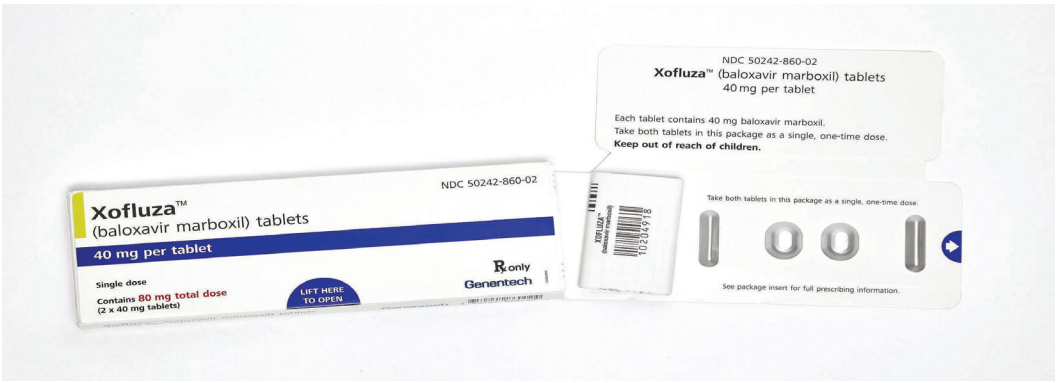
Prescriber and Pharmacist Actions

Advise patients that XOFLUZA is dosed based on weight and is available in blister cards containing two tablets to be taken together as a single dose. The dosing of XOFLUZA is described in the United States Prescribing Information (USPI) as follows:

Patient Body Weight (kg)	Recommended Single Oral Dose
40 to less than 80	Two 20 mg tablets taken at the same time for a total single dose of 40 mg (blister card contains two 20 mg tablets)
At least 80	Two 40 mg tablets taken at the same time for a total single dose of 80 mg (blister card contains two 40 mg tablets)

For patients that weigh 40 kg to less than 80 kg (or 88 lb to <176 lb), a **40 mg dose** (which consists of two 20 mg tablets) is contained in this orange package (**NDC#50242-828-02**):

For patients that weigh at least 80 kg (or ≥176 lb), an **80 mg dose** (which consists of two 40 mg tablets) is contained in this blue package (**NDC#50242-860-02**):



Reporting Adverse Events

Health Care Providers should report any medication errors and/or adverse events suspected to be associated with the use of XOFLUZA to Genentech at 1-888-835-2555.

Alternatively, this information may be reported to the FDA's MedWatch reporting system by phone (1-800-FDA-1088) or online (www.fda.gov/medwatch).

Company Contact Point

Should you have any questions about the information in this letter or the safe and effective use of XOFLUZA, please feel free to contact us at the Genentech Medical Information/Communications Department at 1-800-821-8590.

This letter is not intended as a complete description of the benefits and risks related to the use of XOFLUZA. Please refer to the enclosed full prescribing information for more information.

Sincerely,

Jamie Freedman MD, PhD
Head of U.S. Medical Affairs