Genentech
A Member of the Roche Group

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IMPORTANT
CORRECTION
OF DRUG
INFORMATION

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June 2016

Subject: Correction of Incorrect Adverse Event Reporting Telephone Number in Invirase® (saquinavir mesylate) Prescribing Information.

Dear Health Care Provider,

Genentech has recently become aware that the telephone number listed for reporting potential adverse events is incorrect in the prescribing information packaged with Invirase (saquinavir mesylate).

Correct Telephone Number

The correct telephone number for reporting potential adverse events to Genentech is 1-888-835-2555. A corrected version of the Invirase full prescribing information is attached to this letter and can also be found online at
http://www.gene.com/download/pdf/invirase_prescribing.pdf

Indication for Invirase

Invirase in combination with ritonavir and other antiretroviral agents is indicated for the treatment of HIV-1 infection in adults (over the age of 16 years).

Reporting Adverse Events

Health care providers should report potential adverse events occurring in patients taking Invirase to Genentech at 1-888-835-2555. Alternatively, this information may be reported to the FDA's MedWatch Adverse Event Reporting program online, by regular mail, by telephone or by fax.

- Online: www.fda.gov/medwatch/report.htm

- Regular Mail: use postage-paid, pre-addressed Form FDA3500 available at: http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm and mail to the address on the pre-addressed form.
- Telephone: 1-800-FDA-1088
- Fax: 1-800-FDA-0178

You may also contact the Genentech Medical Communications department at 1-800-821-8590 if you have any questions about the information contained in this letter or the safe and effective use of Invirase.

The current Invirase full prescribing information and Medication Guide can be found online at http://www.gene.com/download/pdf/invirase_prescribing.pdf.

Sincerely,

Myriam Mendila, MD
Senior Vice President, Head of U.S. Medical Affairs
Genentech, Inc.

Enclosure: Invirase Full Prescribing Information