

DR. STEPHEN OPUNI

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Dear Healthcare Professional,

**ASSOCIATION OF IBANDRONIC ACID AND ANAPHYLAXIS (ANAPHYLACTIC REACTION,
ANAPHYLACTIC SHOCK)**

The National Pharmacovigilance Centre (Food and Drugs Board) has received important safety information concerning Intravenous (IV) Ibandronic acid (Bondronat/ Bonviva) that is yet to be updated in the warnings and precautions section of the package insert from its Marketing authorization holders, F. Hoffmann-La Roche Ltd.

Cases of anaphylactic reaction/ shock, including fatal events, have been reported in patients treated with IV ibandronic acid.

Ibandronic acid is a nitrogen-containing bisphosphonate, which is indicated for the treatment of postmenopausal osteoporosis (Bonviva) and the treatment of metastatic bone disease and tumour-induced hypercalcaemia (Bandronate)

Healthcare professionals are advised to note the following recommendation when administering Intravenous (IV) ibandronic acid.

1. Appropriate medical support and monitoring measures should be readily available when ibandronic acid intravenous injection is administered.
2. If anaphylactic or other severe hypersensitivity/ allergic reaction occur, immediately discontinue the infusion / injection and initiate appropriate treatment.

Food and Drugs Board will appreciate it if prescribers closely monitor and report any suspected adverse reactions experienced by patients on Intravenous (IV) Ibandronic acid (Bondronat/ Bonviva) to the National Pharmacovigilance Centre, FDB, through the Institutional Contact Person(s) in your facilities or directly to the Food and Drugs Board through the following contact, 024 4310 297 or drugsafety@fdbghana.gov.gh. You may also download and complete Adverse Drug Reaction Form from the FDB website, www.fdbghana.gov.gh.

For further enquiries, complaints and reports of adverse reaction to any other medicinal product, contact the FDB through the following address.

Postal address: The Chief Executive
Food and Drugs Board
P. O. Box CT2783
Cantonments, Accra

Telephone: 0302 235100 / 0302 233200
Fax: 0302 229794

Yours faithfully,

DR. STEPHEN K. OPUNI
CHIEF EXECUTIVE