Bristol-Myers Squibb Company

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Dear Healthcare Provider:

Bristol-Myers Squibb Company is fully committed to assuring timely dissemination of safety information about our products to the healthcare community. We are writing to inform you of changes to the **WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, DOSING AND ADMINISTRATION**, and **PATIENT INFORMATION LEAFLET** sections of the DROXIA® (hydroxyurea capsules, USP) prescribing information.

The **WARNINGS** and **ADVERSE REACTIONS** sections have been revised to include language regarding cutaneous vasculitic toxicities, including vasculitic ulcerations and gangrene, in patients with myeloproliferative disorders during therapy with hydroxyurea, most often reported in patients with a history of, or currently receiving, interferon therapy.

The **PRECAUTIONS** and **DOSING AND ADMINISTRATION** sections have been revised to include language regarding the safe handling of DROXIA.

The following changes and additions have been made to the U.S. Package Insert for DROXIA:

1. The following information was added to the **WARNINGS** section:

Cutaneous vasculitic toxicities, including vasculitic ulcerations and gangrene, have occurred in patients with myeloproliferative disorders during therapy with hydroxyurea. These vasculitic toxicities were reported most often in patients with a history of, or currently receiving, interferon therapy. Due to potentially severe clinical outcomes for the cutaneous vasculitic ulcers reported in patients with myeloproliferative disease, hydroxyurea should be discontinued if cutaneous vasculitic ulcerations develop.

2. The Information for Patients subsection of the **PRECAUTIONS** section was revised as follows:

(See **Patient Information** at end of labeling.) Patients should be reminded that this medication must be handled with care. People who are not taking DROXIA should not be exposed to it. To decrease the risk of exposure, wear disposable gloves when handling DROXIA or bottles containing DROXIA. Anyone handling DROXIA should wash their hands before and after contact with the bottle or capsules. If the powder from the capsule is spilled, it should be wiped up immediately with a damp disposable towel and discarded in a closed container, such as a plastic bag. The medication should be kept away from children and pets. Contact your doctor for instructions on how to dispose of outdated capsules.

3. The following sentences were added to the Other subsection of the **ADVERSE REACTIONS** section:

Cutaneous vasculitic toxicities, including vasculitic ulcerations and gangrene, have occurred in patients with myeloproliferative disorders during therapy with hydroxyurea. These vasculitic toxicities were reported most often in patients with a history of, or currently receiving, interferon therapy (see **WARNINGS**).

4. The following sentences were added to the **DOSING AND ADMINISTRATION** section:

To minimize the risk of dermal exposure, always wear impervious gloves when handling bottles containing DROXIA capsules. This includes all handling activities in clinical settings, pharmacies, storerooms, and home healthcare settings, including during unpacking and inspection, transport within a facility, and dose preparation and administration.

For any questions or to report serious adverse events suspected to be associated with the use of DROXIA, call **1-800-321-1335**. By calling this number, you can speak to a representative directly or use our automated Faxback system to order document code number 2000, which is the Adverse Event Reporting Form. Alternatively this information may be reported to FDA's MedWatch Reporting System by phone at **1-800-FDA-1088**, by facsimile 1-800-FDA-0178, by mail using the Form 3500 at http://www.fda.gov/medwatch/index.html.

Please refer to the accompanying revised full prescribing information for DROXIA, including **boxed WARNING**.

Sincerely,

A. Collier Smyth, MD
Senior Vice President
Medical Affairs
Bristol-Myers Squibb Company