Bayer HealthCare

IMPORTANT DRUG WARNING

February 2006

Dear Healthcare Professional:

Bayer Pharmaceuticals Corporation (Bayer) would like to inform you that **inadvertent intravenous (IV) administration of the contents of Nimotop® (nimodipine) 30 mg oral Capsules has been associated with serious and life-threatening adverse events, including death.**

Bayer has received reports of inadvertent administration of Nimotop 30 mg oral Capsule contents through IV lines leading to serious adverse events including death.

As a result of these reports, Bayer is revising the Product Information for Nimotop, which now includes the following (see PI enclosed):

Added to the top of the U.S. PI:

DO NOT ADMINISTER NIMOTOP INTRAVENOUSLY OR BY OTHER PARENTERAL ROUTES. DEATHS AND SERIOUS, LIFE-THREATENING ADVERSE EVENTS HAVE OCCURRED WHEN THE CONTENTS OF NIMOTOP CAPSULES HAVE BEEN INJECTED PARENTERALLY (see WARNINGS and DOSAGE AND ADMINISTRATION).

Addition of a WARNINGS section to the U.S. PI:

WARNINGS
DEATH DUE TO INADVERTENT INTRAVENOUS ADMINISTRATION:

DO NOT ADMINISTER NIMOTOP INTRAVENOUSLY OR BY OTHER PARENTERAL ROUTES. DEATHS AND SERIOUS, LIFE-THREATENING ADVERSE EVENTS, INCLUDING CARDIAC ARREST, CARDIOVASCULAR COLLAPSE, HYPOTENSION, AND BRADYCARDIA HAVE OCCURRED WHEN THE CONTENTS OF NIMOTOP CAPSULES HAVE BEEN INJECTED PARENTERALLY (See DOSAGE AND ADMINISTRATION).

PRECAUTIONS and DOSAGE AND ADMINISTRATION sections have been revised to include (highlighted text added):

PRECAUTIONS
General: Blood Pressure: Nimodipine has the hemodynamic effects expected of a calcium channel blocker, although they are generally not marked. However, intravenous administration of the contents of Nimotop Capsules has resulted in serious adverse consequences including death, cardiac arrest, cardiovascular collapse, hypotension and bradycardia. In patients with subarachnoid hemorrhage given Nimotop in clinical studies, about 5% were reported to have had lowering of the blood pressure and about 1% left the study because of this (not all could be attributed to nimodipine). Nevertheless, blood pressure should be carefully monitored during treatment with Nimotop based on its known pharmacology and the known effects of calcium channel blockers. (See WARNINGS and DOSAGE AND ADMINISTRATION).

DOSAGE AND ADMINISTRATION:
DO NOT ADMINISTER NIMOTOP CAPSULES INTRAVENOUSLY OR BY OTHER PARENTERAL ROUTES (See WARNINGS). If Nimotop is inadvertently administered intravenously, clinically significant hypotension may require cardiovascular support with pressor agents. Specific treatments for calcium channel blocker overdose should also be given promptly.

PDR®
PHYSICIANS' DESK REFERENCE®
ADDENDUM

THOMSON PDR

Five Paragon Drive • Montvale, NJ 07645-1725 • 201-358-7200

Bayer HealthCare

If the capsule cannot be swallowed, e.g., at the time of surgery or if the patient is unconscious, a hole should be made in both ends of a capsule with an 18-gauge needle, and the contents of the capsule extracted into a syringe. To help minimize administration errors, it is recommended that the syringe be labeled "Not for IV Use". The contents should then be emptied into the patient's *in situ* naso-gastric tube and washed down the tube with 30 ml normal saline (0.9%).

Bayer would like to remind U.S. healthcare professionals who prescribe, prepare, dispense, and/or administer Nimotop of the importance of adherence to the current Nimotop Product Information during administration of the product to patients. We strongly recommend that staff involved in this administration process be trained to reinforce awareness of the potential for medical errors which could result in injection of the syringe contents into an IV line or by other parenteral routes.

One possible approach to prevent inadvertent intravenous administration is to have the pharmacy withdraw the capsule contents into a syringe specifically designed for NG/PEG administration (e.g., Toomey syringe) before the drug is released for patient use.

Nimotop (nimodipine) is indicated for the improvement of neurological outcome by reducing the incidence and severity of ischemic deficits in patients with subarachnoid hemorrhage from ruptured intracranial berry aneurysms regardless of their post ictus neurological condition (i.e., Hunt and Hess Grades I–V) and is safe and effective when administered as directed in the Prescribing Information.

Physicians' Desk Reference® and Bayer are pleased to enclose complete Prescribing Information for Nimotop. This revised information should be inserted in the Bayer Pharmaceuticals section of your 2006 *PDR*® on page 774. The color photo appears on page 337.

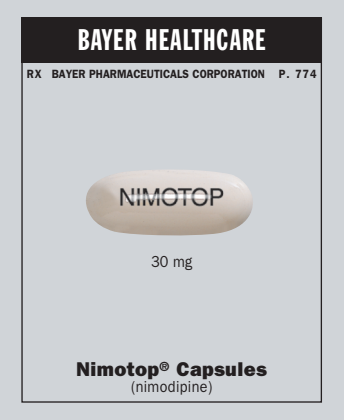
If you wish to request further information, please contact Bayer Pharmaceuticals Corporation Clinical Communications at 1-800-288-8371.

Sincerely,

Ed Tucker, MD
Vice President, Drug Safety Assurance
Bayer Pharmaceuticals Corporation

Thomas Fleming, PharmD
Director, Clinical Content
Physicians' Desk Reference

Enclosure: Nimotop Prescribing Information



Please moisten the gummed edge and affix this label to the appropriate place in the **Product Identification Guide** of your *PDR*.

PDR®
PHYSICIANS' DESK REFERENCE®
ADDENDUM

THOMSON PDR

Five Paragon Drive • Montvale, NJ 07645-1725 • 201 358•7200