



King Pharmaceuticals,® Inc.
501 Fifth Street
Bristol, TN 37620

800-336-7783
423-989-8000

Dear Healthcare Professional:

King Pharmaceuticals, Inc. would like to inform you about important labeling changes regarding **Bicillin® C-R** (penicillin G benzathine and penicillin G procaine injectable suspension) and **Bicillin® L-A** (penicillin G benzathine injectable suspension). These labeling changes highlight existing precautionary and prescribing information in an effort to provide additional assurance that these products are used and administered appropriately.

Treatment of Syphilis

Bicillin® L-A (penicillin G benzathine injectable suspension) is the only currently approved penicillin G benzathine product indicated for use in sexually transmitted infections, including syphilis. Conversely, **Bicillin® C-R** (penicillin G benzathine and penicillin G procaine injectable suspension), which consists of a combination of penicillin G benzathine and penicillin G procaine in an injectable suspension, should *not* be used for the treatment of syphilis.

CDC's 2002 Sexually Transmitted Diseases Treatment Guidelines¹ recommend penicillin G benzathine for the treatment of syphilis infection, consistent with the labeled indications for **Bicillin® LA**. However, we have recently been made aware of postmarketing reports from multiple STD clinics in the US where **Bicillin® C-R** has been inappropriately used to treat patients infected with syphilis; therefore, the US Food and Drug Administration, the Centers for Disease Control and Prevention and King Pharmaceuticals feel it necessary to remind practitioners that **Bicillin® L-A** is the only currently approved penicillin G benzathine product indicated for the treatment of syphilis and that **Bicillin® C-R** should not be administered in place of **Bicillin® L-A** for this purpose. Administration of **Bicillin® C-R** instead of **Bicillin® L-A** in the treatment of syphilis may result in inadequate treatment.

To help healthcare professionals better distinguish between the two types of **Bicillin®** and to better assure the proper use of each of these products, **Bicillin® C-R** (penicillin G benzathine and penicillin G procaine injectable suspension) cartons and syringe labels have been modified to provide greater distinction between the CR and LA products. The background colors for the C-R cartons have been changed from white to pale green (**Bicillin® CR**) and pale purple (**Bicillin® C-R 900/300**). **Bicillin® L-A** cartons will retain the white background. The reminder statement "NOT FOR THE TREATMENT OF SYPHILIS" has been added in bold, capital letters to the front panel, the back panel, and one side panel of both the **Bicillin® C-R** and **Bicillin® C-R 900/300** cartons. The statement "Not for the Treatment of Syphilis" has also been added in red text to both the **Bicillin® C-R** and **Bicillin® C-R 900/300** syringe labels.

For Deep IM Injection Only

Bicillin® C-R (penicillin G benzathine and penicillin G procaine injectable suspension) and **Bicillin® L-A** (penicillin G benzathine injectable suspension) should be administered only by deep intramuscular (IM) injection; they are not intended for intravenous (IV) administration. To more prominently emphasize this important safety information to health care professionals, the following WARNING from the current prescribing information has been relocated into a black box appearing between the product name and the DESCRIPTION section, and again at the beginning of the WARNINGS section.

WARNINGS

Warning: not for intravenous use. Do not inject intravenously or admix with other intravenous solutions. There have been reports of inadvertent intravenous administration of penicillin G benzathine which has been associated with cardiorespiratory arrest and death. Prior to administration of this drug, carefully read the WARNINGS, ADVERSE REACTIONS, and DOSAGE AND ADMINISTRATION sections of the labeling.

In addition, a new reminder “*WARNING: NOT FOR INTRAVENOUS USE*” has been added in red, bold, all capital letters to the *Bicillin*[®] *C-R* (penicillin G benzathine and penicillin G procaine injectable suspension) and *Bicillin*[®] *L-A* (penicillin G benzathine injectable suspension) cartons and syringe labels.

King Pharmaceuticals, Inc. is committed to the safety of all patients receiving *Bicillin*[®] *C-R* (penicillin G benzathine and penicillin G procaine injectable suspension) and *Bicillin*[®] *L-A* (penicillin G benzathine injectable suspension). Should you have any questions or concerns regarding these important new labeling changes, please contact the King Pharmaceuticals, Inc. Professional Information Services at 1-800-776-3637. It is important that you forward any adverse event information associated with the use of *Bicillin*[®] *C-R* (penicillin G benzathine and penicillin G procaine injectable suspension) and *Bicillin*[®] *L-A* (penicillin G benzathine injectable suspension) to King Pharmaceuticals, Inc. at 1-800-546-4905. You can also report this information directly to the FDA via the MedWatch program by phone (1-800-FDA-1088), by fax (1-800-FDA-0178) or by the internet (www.fda.gov/medwatch).

Please see accompanying Prescribing Information.

Sincerely,



Charles L. Pamplin III, M.D.
Vice-President, Medical Affairs
King Pharmaceuticals, Inc.