

Dilantin[®]

(phenytoin sodium)

100 mg Extended Oral Capsules

September 23, 2007

Dear Pharmacist:

The FDA recently approved our supplement for manufacturing changes for DILANTIN[®] (phenytoin sodium). As a result, we will discontinue manufacturing DILANTIN[®] Kapseals[®] (extended phenytoin sodium, USP) 100 mg capsules and begin manufacturing and distributing DILANTIN[®] (phenytoin sodium) 100 mg extended oral capsules. This will result in some changes in the 100 mg product that may be of interest to you and your patients. For the time being, no changes have been made to the 30 mg DILANTIN[®] Kapseal[®] or other DILANTIN[®] products.

The visible changes you and your patients may notice include:

- A new look: The new 100 mg capsules will be half orange and half white, unlike the old Kapseals which had an orange stripe down the middle (see photos below)
- A new FDA National Drug Code (NDC) number



ORIGINAL (to be discontinued)
DILANTIN[®] Kapseal[®]
(extended phenytoin sodium capsule, USP)
100 mg



NEW LOOK
DILANTIN[®] (phenytoin sodium) 100 mg
Extended Oral Capsule

Please note the new storage requirement statement. Store at 20-25° Celsius (68-77°F). Preserve in tight, light-resistant containers. Protect from moisture.

The FDA approved our supplement for DILANTIN[®] 100 mg extended oral capsules manufactured using the new manufacturing process based on two bioequivalence studies*¹ and review of our manufacturing supplement. For more information, please contact Pfizer Medical Information at 1-800-438-1985.

Please see enclosed full prescribing information for DILANTIN[®] (phenytoin sodium) 100 mg extended oral capsules.

* Two bioequivalence studies were conducted on 100 mg Dilantin Capsule drug product made using the new manufacturing process and on marketed 100 mg Dilantin Kapseals administered under fasted and fed conditions. The fasted bioequivalence study passed the protocol-specified criteria and the FDA criteria for AUC and C_{max}. The fed bioequivalence study passed the FDA criteria for AUC and C_{max} but did not pass the protocol-specified criteria for AUC.

Reference:

1. Data on file. Pfizer Inc. New York, NY.