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From: MediMedia

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To: All Tikosyn® Registered Healthcare Professionals  
From: Pfizer, Inc.  
Date: January 16, 2008  
Subject: Tikosyn Product Outage

Dear Healthcare Professional:

Pfizer is sending you this letter to update you on the Tikosyn 0.5mg and 0.25mg inventory outages.

This product outage is not the result of any efficacy or safety concern with Tikosyn. An unforeseen manufacturing issue coupled with distribution regulations for Tikosyn (this medication is only drop-shipped and there is no inventory held in trade) have resulted in the product outage. **Until the outage is resolved, we encourage you to refrain from placing new patients on Tikosyn and to contact current patients to discuss treatment options.**

Healthcare Professionals should direct product information questions (i.e. Bioequivalence data) to **Pfizer Medical Information at 1-800-438-1985.**

**In efforts to bridge this shortage we are requesting you to please substitute the 0.125mg strength capsule for the 0.5mg dosages. The bioequivalence of four 0.125mg Tikosyn capsules with one 0.5mg capsule has been confirmed in a study designed to ascertain bioequivalence.**

*During the Tikosyn inventory shortage **Pharmacists** may use the following order process with your wholesaler to support a patient who requires a Tikosyn refill and whose **Physician** has authorized a change in dosage formulation:*

**Patient requires: 0.5 mg x 60 ct (NDC 0069-5820-60)**

**Order 6 each 0.125 mg x 40 count unit dose (NDC 0069-5800-43)**

Indicate on the order "**Replacement for .5mg Tikosyn**"

Pfizer will place your order as follows:

1 ea 0.125mg x 40 unit dose \$95.49

5 ea 0.125mg x 40 unit dose No Charge

**-- OR --**

**Order 4 each 0.125 mg x 60 count bottles (NDC 0069-5800-60)**

Indicate on the order "**Replacement for .5mg Tikosyn**"

Pfizer will place your order as follows:

1 ea 0.125mg x 60 \$143.24

3 ea 0.125mg x 60 No Charge

**Bioequivalence studies of Tikosyn were only performed between the highest (0.5mg) and lowest capsule dose strengths (0.125mg). There is no bioequivalence study directly comparing Tikosyn 0.125mg and 0.250mg.**

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If a **Physician** authorizes a 0.250mg Tikosyn Patient to be switched to a 2 x 0.125mg dosage formulation the **Pharmacist** should use the following order process with your wholesaler:

**Patient requires: 0.250mg x 60 ct (NDC 0069-5810-60)**

**Order 3 each 0.125 mg x 40 unit dose (NDC 0069-5800-43)**

Indicate on the order "**Replacement for 0.250mg Tikosyn**"

Pfizer will place your order as follows:

1 ea 0.125 mg x 40 unit dose \$143.24

2 ea 0.125 mg x 40 unit dose No Charge

**-- OR --**

**Order 2 each 0.125 mg x 60 count bottles (NDC 0069-5800-60)**

Indicate on the order "**Replacement for 0.250mg Tikosyn**"

Pfizer will place your order as follows:

1 ea 0.125 mg \$143.24

1 ea 0.125 mg No Charge

We understand the seriousness of a shortage of Tikosyn and are working diligently and rapidly to have all three dosage forms available normally as soon as possible. Pfizer sincerely apologizes for the inconvenience and effect on patients this serious situation may cause and appreciate your understanding.

*Additional information, regarding the status of the Tikosyn 0.5mg and 0.250mg outage, will be communicated via fax and the web at [www.tikosyn.com](http://www.tikosyn.com) by Tuesday, January 22nd 2008.*

Sincerely,

David J. Engels

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