



Pfizer Inc.
235 E. 42nd Street
New York, NY 10017

November 2009

Subject: Tikosyn[®] (dofetilide) 250 micrograms and 500 micrograms (mcg) shortage (60 count bottles)

Dear Certified TIKOSYN[®] Healthcare Professional:

Pfizer is writing to inform you of a shortage of 60 count bottles of TIKOSYN[®] 250 mcg and 500 mcg. It is expected that the shortage of TIKOSYN[®] 250 mcg and 500 mcg will begin in early December 2009. This product shortage is a result of a manufacturing issue and not the result of any efficacy or safety issues with TIKOSYN[®]. Pfizer is working as quickly as possible to resolve the situation.

In order to minimize disruption to patient supply of this medication, Pfizer has developed the following process:

Pharmacists:

<u>Ordering 60 count TIKOSYN[®] 250 mcg</u>	<u>Ordering 60 count TIKOSYN[®] 500 mcg</u>
<p>If a patient requires 250 mcg during the product shortage AND the patient's physician has authorized a change in dosage formulation, pharmacists may use the following order process with their wholesaler for TIKOSYN[®] refills:</p> <p>Order <u>two</u> 125 mcg x 60 count bottles (NDC 0069-5800-60). Indicate on your standard order form to your wholesaler "Replacement for 250 mcg TIKOSYN[®]". All orders must be faxed to (1-800-211-3775).</p> <p>Pfizer will process your order as follows:</p> <ul style="list-style-type: none">▪ 1 each 125 mcg x 60 count at current price▪ 1 each 125 mcg x 60 count at no charge <p><i>Important Note: There is no bioequivalence study directly comparing TIKOSYN[®] 125 mcg to 250 mcg. Bioequivalence studies of TIKOSYN[®] were only performed between the highest (500 mcg) and lowest capsule dose strengths (125 mcg). Only a patient's physician can approve the use of two 125 mcg capsules in place of one 250 mcg capsule. Direct all product information questions to Pfizer Medical Information at 1-800-438-1985.</i></p>	<p>If a patient requires 500 mcg during the product shortage AND the patient's physician has authorized a change in dosage formulation, pharmacists may use the following order process with their wholesaler for TIKOSYN[®] refills:</p> <p>Order <u>four</u> 125 mcg x 60 count bottles (NDC 0069-5800-60). Indicate on your standard order form to your wholesaler "Replacement for 500 mcg TIKOSYN[®]". All orders must be faxed to (1-800-211-3775).</p> <p>Pfizer will place your order as follows:</p> <ul style="list-style-type: none">▪ 1 each 125 mcg x 60 count at current price▪ 3 each 125 mcg x 60 count at no charge <p><i>Important Note: The bioequivalence of four 125 mcg TIKOSYN[®] capsules to one 500 mcg TIKOSYN[®] capsule have been confirmed in a study designed to assess bioequivalence. Direct all product information questions to Pfizer Medical Information at 1-800-438-1985</i></p>



Physicians:

<u>TIKOSYN[®] 250 mcg</u>	<u>TIKOSYN[®] 500 mcg</u>
<p>If a patient cannot obtain TIKOSYN[®] through the pharmacy, the physician may order two 14 count bottles as follows:</p> <ul style="list-style-type: none">• Contact Pfizer Customer Service at 1-800-533-4535 extension 6127 and request two 14 count bottles of TIKOSYN[®] 250 mcg (NDC- 0069-5810-61)• Complete the Pfizer supplied request form. Sign and fax the form to the number listed (1-800-211-3775)• TIKOSYN[®] 250 mcg will be shipped within 2 days to the physician's office for distribution to the patient at no cost.	<p>If a patient cannot obtain TIKOSYN[®] through the pharmacy, the physician may order two 14 count bottles as follows:</p> <ul style="list-style-type: none">• Contact Pfizer Customer Service at 1-800-533-4535 extension 6127 and request two 14 count bottles of TIKOSYN[®] 500 mcg (NDC- 0069-5820-61)• Complete the Pfizer supplied request form. Sign and fax the form to the number listed (1-800-211-3775)• TIKOSYN[®] 500 mcg will be shipped within 2 days to the physician's office for distribution to the patient at no cost.

Pfizer is working diligently to have both dosage forms of TIKOSYN[®] available as soon as possible. If you have any product related questions, please call Pfizer Medical Information at 1-800-438-1985. Pfizer sincerely apologizes for the inconvenience to you and your patients.

Sincerely,
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Please see the enclosed full prescribing information for TIKOSYN[®].