

May 20, 2002

IMPORTANT ALERT REGARDING MEDICATION ERRORS

Dear Healthcare Professional:

AstraZeneca has received reports of medication errors involving confusion between its atypical antipsychotic **SEROQUEL**<sup>®</sup> (quetiapine fumarate), indicated for the treatment of schizophrenia, and Serzone<sup>®</sup> (nefazodone hydrochloride), a product of Bristol-Myers Squibb, indicated for the treatment of depression. These reports include instances where **SEROQUEL** was incorrectly administered to patients instead of Serzone, and visa-versa, leading to various adverse events.

The primary events noted in these reports included mental status deterioration, hallucination, paranoia, nausea, diarrhea, vomiting, muscle weakness, lethargy, dizziness and complications associated with these disorders. Three patients were hospitalized and four patients required emergency room visits. A 25 year-old female patient experienced fever and respiratory arrest after taking **SEROQUEL** for 3 days instead of Serzone, and eventually died, although a causal relationship has not been established.

According to the medication error reports, verbal and written prescriptions were incorrectly interpreted, labeled, and/or filled due to the similarity in names between **SEROQUEL** and Serzone. Furthermore, the overlapping strengths (100 mg and 200 mg), the dosage forms (tablets), the dosing interval (BID), and the fact that these two products were stocked close together in pharmacies were also critical in causing these errors.

**SEROQUEL** is supplied for oral administration as 25 mg (peach), 100 mg (yellow), 200 mg (round, white), and 300 mg (capsule-shaped, white) tablets debossed with the name "**SEROQUEL**".

Serzone tablets are available in 50, 100, 150, 200, and 250 mg hexagonal color-coded tablets, and are imprinted "BMS".

In clinical trials of **SEROQUEL**, the adverse events with an incidence of 5% or greater and twice that of placebo were dizziness, postural hypotension, dry mouth, and dyspepsia.'

In clinical trials of Serzone, the adverse events with an incidence of 5% or greater and significantly greater than placebo patients were somnolence, dry mouth, nausea, dizziness, constipation, asthenia, lightheadedness, blurred vision, confusion, and abnormal vision.

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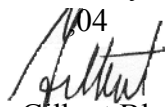
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Although both medications have short half-lives (6 hours for quetiapine, 4 hours for nefazodone and its major active metabolite), an abrupt accidental switch may result in a brief period where the medications may interact. While coadministration of these medications is not specifically contraindicated, concurrent usage has not been studied. Because quetiapine is metabolized by the cytochrome P450 3A isoenzyme system, caution is indicated when **SEROQUEL** is administered with inhibitors of this system. Serzone is an inhibitor of the cytochrome P450 3A4 isoenzyme SySteM.2

Your assistance is requested in clearly communicating oral and written prescriptions for these products to help avoid future dispensing errors. If you become aware of any dispensing errors, you should report them immediately to the appropriate manufacturer (AstraZeneca 1-800-236-9933; Bristol-Myers Squibb 1-800-321-1335); or the USP Medication Errors Reporting Program (1-800-233-7767).

Thank you for your attention to this matter.

Sincerely,



Gilbert Block, M.D., Ph.D.  
Executive Director  
CNS, Pain and Infectious Disease  
AstraZeneca Pharmaceuticals

PLEASE CONSULT COMPLETE PRESCRIBING INFORMATION FOR  
SEROQUEL ENCLOSED FOR YOUR CONVENIENCE.

1 **SEROQUEL** Prescribing Information, AstraZeneca 203348 Rev 101  
2 Serzone Prescribing Information, BMS February 2001