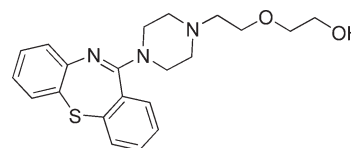


Torn from the Headlines: AstraZeneca Fined For Illegal Marketing of SEROQUEL

SEROQUEL (quetiapine fumarate, ICI 204,636) is a second generation antipsychotic from AstraZeneca based on a benzothiazepine nucleus (Figure 1) with established efficacy and a favorable side effect profile in adults with schizophrenia and bipolar disorder (1, 2). Available for over a decade, an extended-release formulation, SEROQUEL XR, was recently developed to allow once-daily oral administration (1–3). The efficacy of SEROQUEL is due to inhibition of a variety of neurotransmitters and biogenic amines (D_1 , D_2 , $5HT_{1A}$, $5HT_{2A}$, α_1 , α_2), but unlike clozapine, SEROQUEL possesses higher affinity for serotonin ($5-HT_{2A}$) receptors than dopamine (D_2) receptors and no affinity for muscarinic receptors (1–3). More recently, SEROQUEL was FDA approved as an add-on to standard antidepressant regimens for major depressive disorder (MDD). In 2009, SEROQUEL was AstraZeneca's second-best seller achieving \$4.9 billion in worldwide sales, up over 11% from 2007 figures (4).

On April 27, 2010, AstraZeneca announced that it had reached a \$520 million settlement with the United States government to resolve illegal marketing allegations for SEROQUEL (4, 5). Specifically, AstraZeneca was accused of marketing SEROQUEL for non-FDA-approved indications such as insomnia and other psychiatric disorders (other than schizophrenia and bipolar disorder). Presently, drug companies are only allowed to market medications for uses approved by the FDA; however, doctors are allowed to prescribe medications for other indications as they deem appropriate, which results in a "gray area" for patients. AstraZeneca denied the allegations but settled with the government to avoid a long, protracted court case. As a result, AstraZeneca is now facing over 25 000 product liability lawsuits related to SEROQUEL, with the majority charging that SEROQUEL causes diabetes (4, 5).



SEROQUEL™ (Quetiapine fumarate)

Figure 1. Structure of the atypical antipsychotic SEROQUEL (quetiapine fumarate, ICI 204,636).

Since its launch in 1997, SEROQUEL has been a very important medication to treat both schizophrenia and bipolar disorder. Moreover, this news comes at a bad time for an already struggling pharmaceutical industry. Hopefully, the fervor will settle, patients will continue to enjoy the benefits of SEROQUEL, and everyone will remember the standard of care for schizophrenic patients prior to the launch of SEROQUEL.

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References

1. Casey, D. E. (1996) Seroquel (quetiapine): Preclinical and clinical findings of a new antipsychotic. *Exp. Opin. Invest. Drugs* 5 (8), 939–957.
2. Goldstein, J. M. (1999) Quetiapine fumarate (Seroquel): A new atypical antipsychotic. *Drugs Today* 35 (3), 192–210.
3. Baldwin, C. M., and Scott, L. J. (2009) Quetiapine extended release. In schizophrenia. *CNS Drugs* 23 (3), 261–269.
4. For information, see www.astrazeneca.com.
5. For information, see www.seroquel.com.
6. For information, see www.news.yahoo.com/s/ap/20100427/ap_on_bi_ge/us_doj_astrazeneca.

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