

# Children in Need Less Likely to Get Samples

BY SHARON WORCESTER  
Southeast Bureau

Free drug samples not only do little to equalize medication access in the pediatric population, but they also may pose safety concerns in young patients, results of a recent study show.

The practice of providing free drug samples to children in nonurgent situations should be carefully reconsidered—and perhaps abandoned, the investigators

concluded (*Pediatrics* 2008;122:736-42).

Study author Sarah L. Cutrona of Harvard Medical School, Boston, and her colleagues said the findings show that free drug samples tend to go to children with the best health care—rather than those with the greatest financial need.

The findings were based on nationally representative longitudinal survey data from 10,295 U.S. residents under age 18 years from the Agency for Healthcare Research and Quality 2004 Medical Expendi-

ture Panel Survey, the researchers reported.

About 5% of the children in the survey received at least one free drug sample in 2004, and 10% of the children who received a prescription medication received a free drug sample that year. On multivariate analyses, routine health care access, defined for the study as three or more provider visits in 2004, was found to be associated with the receipt of free samples, but insurance status and family income was not found to play a role in determin-

ing which children received samples.

That is, poor children, defined as those from families with incomes less than 200% of the federal poverty level, were no more likely to receive free samples than those from families with incomes of 400% of the poverty level or greater (3.8% vs. 5.9%; odds ratio 0.78), and those who were uninsured for part or all of the year were no more likely to receive samples than those who were insured for the entire year, (4.5% vs. 5.1%; OR 1.05).

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### Important Safety Information for SEROQUEL, continued

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- A potentially fatal symptom complex, sometimes referred to as Neuroleptic Malignant Syndrome (NMS), has been reported in association with administration of antipsychotic drugs, including SEROQUEL. Rare cases of NMS have been reported with SEROQUEL. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include immediate discontinuation of antipsychotic drugs
- Leukopenia, neutropenia, and agranulocytosis (including fatal cases), have been reported temporally related to atypical antipsychotics, including SEROQUEL. Patients with a pre-existing low white blood cell (WBC) count or a history of drug induced leukopenia/neutropenia should have their complete blood count monitored frequently during the first few months of therapy. In these patients, SEROQUEL should be discontinued at the first sign of a decline in WBC absent other causative factors. Patients with neutropenia should be carefully monitored, and SEROQUEL should be discontinued in any patient if the absolute neutrophil count is  $< 1000/\text{mm}^3$
- Tardive dyskinesia (TD), a potentially irreversible syndrome of involuntary dyskinesic movements, may develop in patients treated with antipsychotic drugs. The risk of developing TD and the likelihood that it will become irreversible are believed to increase as the duration of treatment and total cumulative dose of antipsychotic drugs administered to the patient increase. TD may remit, partially or completely, if antipsychotic treatment is withdrawn. SEROQUEL should be prescribed in a manner that is most likely to minimize the occurrence of TD

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In addition, Hispanic and nonwhite children were much less likely to receive free samples, compared with non-Hispanic white children (2.4% and 3.5%, respectively, vs. 6.2%; OR 0.51 and 0.72, respectively). Factors indicative of health care access also were associated with free sample receipt. For example, among those who received more free samples, those who had more visits to medical or dental providers (OR of 1.77 for two vs. one visit, and OR of 3.25 for three or more vs. one visit), those who used office-based primary care vs. those with no usual site of care (OR of 1.52), and those who received more medications in 2004 were more likely to receive

free samples (OR 1.06 for incremental increase of one drug).

The high prevalence of drug sample use among pediatric patients also is of concern because the 15 most frequently distributed sample drugs in 2004 included two schedule II controlled medications (Strattera and Adderall). In addition, these two drugs, along with two others (Elidel and Advair) required a new or revised black box warning between 2004 and 2007.

The study—the first to look at free drug sample practices in the pediatric population—is an interesting and helpful study that draws attention to the widespread practice, Dr. David Fassler, clinical profes-

sor of psychiatry at the University of Vermont, Burlington, said in an interview.

“The authors raise legitimate questions about the potential safety of current practices with respect to free samples. In particular, they report that controlled substances and treatments not generally considered ‘first line’ were included in the list of medications most commonly distributed as free samples. “Of particular concern, they also note that a significant number of very young children (under 2 years of age) received samples of medications which are specifically contraindicated for this age group,” Dr. Fassler said.

However, based on the methodology

employed, the study raises more questions than it answers, he said.

“For example, did the kids actually take the medication received as a free sample? Did the families subsequently receive a prescription for ongoing treatment? Does the availability of free samples influence a physician’s overall prescription pattern? The authors have opened an interesting avenue of inquiry. I expect these and other questions will be addressed in subsequent studies,” he added.

The authors stated they had no financial relationships relevant to this study.

Dr. Fassler said he had no conflicts of interest with respect to this issue. ■



### Important Safety Information for SEROQUEL, continued

- Warnings and Precautions also include the risk of orthostatic hypotension, cataracts, seizures, hyperlipidemia, and possibility of suicide attempts. Examination of the lens by methods adequate to detect cataract formation, such as slit lamp exam or other appropriately sensitive methods, is recommended at initiation of treatment or shortly thereafter, and at 6-month intervals during chronic treatment. The possibility of a suicide attempt is inherent in schizophrenia, and close supervision of high risk patients should accompany drug therapy
- The most commonly observed adverse reactions associated with the use of SEROQUEL versus placebo in clinical trials for schizophrenia and bipolar disorder were dry mouth (9%-44% vs 3%-13%), sedation (30% vs 8%), somnolence (18%-34% vs 7%-9%), dizziness (9%-18% vs 5%-7%), constipation (8%-10% vs 3%-5%), asthenia (5%-10% vs 3%-4%), abdominal pain (4%-7% vs 1%-3%), postural hypotension (4%-7% vs 1%-2%), pharyngitis (4%-6% vs 3%), weight gain (5%-6% vs 1%-3%), lethargy (5% vs 2%), nasal congestion (5% vs 3%), SGPT increased (5% vs 1%), and dyspepsia (5%-7% vs 1%-4%)
- In long-term clinical trials of quetiapine, hyperglycemia (fasting glucose  $\geq$  126 mg/dL) was observed in 10.7% of patients receiving quetiapine (mean exposure 213 days) vs 4.6% in patients receiving placebo (mean exposure 152 days)

For bipolar disorder

References: 1. SEROQUEL Prescribing Information.  
2. Data on file, DA-SER-51, AstraZeneca Pharmaceuticals LP.  
3. Data on file, 263170, AstraZeneca Pharmaceuticals LP.

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