Use of Antipsychotic Medications ‘Off-Label’ to Treat:

Anxiety, ADHD, Depression, Insomnia, and PTSD

EVALUATING SAFETY AND EFFECTIVENESS
Newer antipsychotic medications, also sometimes referred to as “atypicals” to distinguish them from an older type of drug in the same class, are approved by the Food and Drug Administration (FDA) for treating schizophrenia. But they are also used to treat other conditions for which they have not been approved—including anxiety, attention-deficit/hyperactivity disorder (ADHD), depression (some are approved to be used along with antidepressants, but not for use by themselves), insomnia, and post-traumatic stress disorder (PTSD)—this is known as “off-label” prescribing. Off-label drug use is a concern because usually there is less evidence about both the effectiveness and the safety of medications when used for off-label conditions.

Because of the limited evidence for the eight antipsychotic medications evaluated and the complexities of treating the disorders, we have not chosen a Best Buy in this special report. Our medical advisers recommend that you discuss with your doctor first trying standard treatment options for your condition, including nondrug strategies if appropriate and medications that are FDA-approved for your condition. Carefully consider an antipsychotic drug only if those other options fail to improve your symptoms.

If you do decide to try an antipsychotic drug, carefully weigh the risks of the medication against the potential benefits, if any. Possible side effects include substantial weight gain, elevated cholesterol and triglyceride levels, uncontrollable movements and tremors that resemble Parkinson’s disease (known as extrapyramidal symptoms), and an increased risk of type 2 diabetes. In addition, these drugs have been shown to increase the risk of premature death, primarily due to strokes, in older adults with dementia.

Cost might also be an important factor to take into account. Most of these antipsychotic drugs are expensive, so if you and your doctor decide that you should start taking one, find out how much of the price your insurance plan covers and how much you will have to pay out-of-pocket.

Another important issue to consider is that it is not clear from the available studies the correct dosage a person should take for the various off-label uses. We are unable to make any recommendation about how much a person should take, so you should discuss this with your physician. In some cases, a lower dose than is typically used to treat FDA-approved indications, such as schizophrenia, might be adequate for an off-label use.

If you decide to use a newer antipsychotic medication, your doctor should monitor you for side effects. This includes assessing your weight, checking your muscles to make sure they are functioning well, and performing blood tests. If your symptoms don’t improve, you should stop taking the medication.
This report focuses on “off-label” uses of prescription medications known as “newer” antipsychotic drugs, also sometimes referred to as atypical antipsychotic drugs. This distinguishes them, from a marketing perspective, between the older antipsychotic drugs, often called “first-generation,” that were developed and widely prescribed beginning in the 1950s. Off-label means the medications are prescribed to treat conditions that have not been approved by the FDA. This is legal; doctors can prescribe any medication they think would be useful to treat a person’s particular condition. Currently, the FDA has approved all of the newer antipsychotic medications to treat schizophrenia and some are also approved to treat bipolar disorder and other conditions (See Table 1 on page 4 for a complete list of approved conditions). Those drugs are sometimes prescribed “off-label” to treat attention-deficit/hyperactivity disorder (ADHD), depression (as a stand-alone treatment), insomnia, generalized anxiety disorder, and post-traumatic stress disorder (PTSD).

To date, there is only limited research about the effectiveness and safety of those medications when used to treat the “off-label” conditions listed above, so it’s unclear whether any potential benefit outweighs the risk of side effects.

The antipsychotic drugs we evaluate in this report can cause several possible side effects, including muscle rigidity, slow movement and involuntary tremors (known as extrapyramidal symptoms, some of which can be permanent), substantial weight gain, an increased risk of type 2 diabetes, and elevated cholesterol levels. (Side effects are listed in Table 3 on page 11.) Most people who start taking an antipsychotic medication will experience at least one side effect. Of those who do, up to 30 percent of people experience a serious or intolerable adverse effect, and stop taking the medicine within days, weeks, or a few months.

Despite the safety concerns, off-label use of the newer antipsychotic drugs has increased significantly in the past decade in children and adults.

Antipsychotic drugs are commonly used off-label in long-term care settings to control agitation, aggression, hallucinations, and other behavioral symptoms in elderly patients with Alzheimer’s disease or other forms of dementia. But in 2005, the medications were found to be associated with an increased risk of death among elderly people with dementia. As a result, all antipsychotic drug labels now carry a black box warning—the strongest kind—about this risk.

The newer antipsychotic drugs are used off-label in other settings too. They are prescribed for children with various behavioral disorders, and they are sometimes prescribed to treat PTSD in military personnel.

Table 1 lists the newer antipsychotic medications evaluated in this report and their FDA-approved indications.
Clozapine (Clozaril, Fazaclo, and generic) was the first newer antipsychotic drug approved by the FDA. It was not included in our evaluation because it can cause serious side effects, including seizures and a blood disorder called agranulocytosis, which can lead to fatal infections and requires special monitoring by a doctor. The use of clozapine is generally limited to people with schizophrenia who have not responded to other antipsychotic medications. The other newer antipsychotic drugs are unlikely to cause those
problems, but they carry the risk of the side effects listed above and described in more detail starting on page 11. Of the eight antipsychotic medications evaluated in this report, olanzapine, quetiapine, and risperidone are the most commonly prescribed for off-label uses.

Due to the limited evidence and complexities of treating the off-label disorders, we have not chosen a Best Buy in this special report. Instead, we present our evaluation of the available medical research on the newer antipsychotic drugs to help you discuss with your doctor the possible benefits and risks of using one of these medications off-label and whether it is appropriate for your situation.

This report is part of a Consumer Reports project to help you find safe, effective medicines that give you the most value for your health-care dollar. To learn more about the project and other drugs we’ve evaluated for other diseases and conditions, go to www.CRBestBuyDrugs.org.

This report was published in November 2013.
What is the evidence for the off-label use of antipsychotic medications?

It's not known exactly how antipsychotic drugs work to help relieve symptoms. What is known is that they affect levels of chemicals in the brain called neurotransmitters, which play important roles in behavior, sleep, mood, attention, memory, learning, and other aspects of cognition. This might be how they reduce psychotic symptoms, such as hallucinations, delusions, disorganized thinking, and agitation in schizophrenia and bipolar disorder. But from the limited available evidence, it’s unclear how well they work for the treatment of attention-deficit/hyperactivity disorder (ADHD), generalized anxiety disorder (GAD), insomnia, major depressive disorder (MDD), and post-traumatic stress disorder (PTSD).

For each of those conditions, evidence directly comparing one newer antipsychotic medication to another is either extremely limited or nonexistent.

There are no studies involving the off-label use of three of the newest antipsychotic drugs: asenapine, iloperidone, and paliperidone. In addition, our

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<th>Condition</th>
<th>Limited evidence of effectiveness</th>
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<tr>
<td>Anxiety</td>
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<td>Depression\1</td>
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<td>Insomnia</td>
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<td>Ziprasidone</td>
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* No studies were identified that met the criteria for the Agency for Healthcare Research and Quality report that forms the basis of this report.
\1 When the medication is used alone to treat depression.
What is the evidence for the off-label use of antipsychotic medications?

analysis found almost no evidence about whether the effectiveness of antipsychotic medications for off-label conditions varies by gender, race, ethnicity, or pre-existing medical conditions of the person taking the drug.

The evidence of how well these medications work for each condition is detailed below.

**Anxiety (Generalized Anxiety Disorder)**

Generalized anxiety disorder (GAD)—an excessive, irrational dread of everyday situations—affects about 6.8 million adults in the U.S., according to the National Institute of Mental Health. Twice as many women as men suffer from the condition. People with GAD have difficulty relaxing and concentrating, startle easily, and often have trouble sleeping. GAD can also cause other symptoms, including fatigue, headaches, muscle aches, and trembling. People with severe GAD can have difficulty functioning and carrying out daily activities.

GAD is usually treated with psychotherapy and, if necessary, antidepressant medications. In some cases, an antipsychotic drug might be used alone or in addition to an antidepressant. There’s limited research that suggests quetiapine might improve symptoms, but the other antipsychotic drugs appear to be ineffective or have not been studied for treating anxiety.

The results of three studies of quetiapine showed the drug was more effective than placebo in decreasing symptoms of generalized anxiety. Another study showed quetiapine reduced the risk of relapse. Studies involving ziprasidone, olanzapine, and risperidone found those medications were ineffective for treating generalized anxiety disorder.

The four other newer antipsychotic drugs—aripiprazole, asenapine, iloperidone, and paliperidone—have not been studied for treating generalized anxiety disorder.

**Attention-Deficit/Hyperactivity Disorder (ADHD)**

Attention-deficit/hyperactivity disorder is one of the most common behavioral problems diagnosed among school-aged children in the U.S. The signs of ADHD include a persistent pattern lasting at least six months of abnormally high levels of physical activity (hyperactivity), impulsive behavior, and/or lack of ability to pay attention and focus or complete tasks. Both boys and girls with ADHD are more likely to have low self-esteem, develop emotional and social problems, and underachieve at school. ADHD can also affect adults.

If you or your child has been diagnosed with ADHD, the usual treatment options include behavioral therapy, educational interventions, and stimulant medications, such as methylphenidate (Ritalin or generic) or amphetamine (Adderall or generic).

If those strategies fail to improve ADHD symptoms, your doctor might recommend trying one of the antipsychotic medications. Our Consumer Reports medical advisers recommend caution, however. As you can see below, there is little research on antipsychotic medications in the treatment of ADHD, and there is no clear evidence they are effective.

Only two of the newer antipsychotic drugs—risperidone and aripiprazole—have been studied for treating ADHD in children. In one very small, short study, one in four children who received risperidone showed improvement...
What is the evidence for the off-label use of antipsychotic medications?

In symptoms of aggression. The children who received risperidone were more likely to experience several side effects, including abdominal pain, agitation, and increased appetite. The study lasted only four weeks, and longer-term adverse effects were not reported. In another small study, risperidone decreased aggression more than methylphenidate in children with both ADHD and mental retardation, but it was associated with weight gain.

In two studies involving aripiprazole in children with both ADHD and bipolar disorder, the medication did not reduce ADHD symptoms.

**Depression (Major Depressive Disorder)**

Depression is a common health problem in the U.S., with some 14.8 million adults suffering from the condition in any given year, according to the National Institute of Mental Health. Psychotherapy and, if necessary, antidepressant medication, such as bupropion (Wellbutrin and generics), citalopram (Celexa and generics), and fluoxetine (Prozac and generics), can often help.

Antipsychotic drugs are used as “augmentation therapy,” or add-ons to treat depression that hasn’t been helped by antidepressants or other treatments. This is known as “treatment resistant” depression. Three of the antipsychotic medications—aripiprazole, olanzapine, and quetiapine—are FDA-approved for this, but the other five are not. However, the available evidence indicates that antipsychotics aren’t very effective as augmentation therapy for treating resistant depression.

Given the possible side effects they can cause, antipsychotic drugs aren’t the best choice for this use for most people. Other options, such as increasing the dose of your standard antidepressant or switching to a different one, are at least as effective and are safer. Combining two antidepressants may also be an option. These strategies should be tried first before adding any antipsychotic drug to your antidepressant.

Some doctors may prescribe antipsychotic drugs alone to treat depression, but it’s unclear from the evidence available which of these drugs, if any, should be used by themselves for relieving depression. Only a few studies have addressed using antipsychotic medications alone for treating depression.

Three studies of olanzapine found that it was not effective when used alone for depression. The combined results of five large trials of extended-release quetiapine found it helped relieve depression symptoms better than placebo, but the studies lasted 12 weeks or less, so it’s not clear whether the beneficial effects last over the long term or whether they outweigh the potential side effects, such as weight gain and increased risk of diabetes.
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**Insomnia**

Insomnia—difficulty falling asleep or staying asleep—can lead to sleepiness and other problems during the daytime. The condition is quite common: one in three adults has insomnia occasionally, and one in 10 suffers from chronic insomnia, according to the National Heart, Lung, and Blood Institute (NHLBI).

Antipsychotic drugs have been used to treat insomnia because one of their side effects is drowsiness. However, as discussed next, there is no clear evidence they work to actually relieve insomnia. If you have persistent insomnia, instead first try improving your sleep habits, such as not watching TV or using computers in bed, sticking to a regular bedtime and wake-up time, and cutting back on caffeine and alcohol at night. Your doctor might also recommend cognitive behavioral therapy—a form of psychotherapy that can be just as helpful as, or more so, than medication. In some cases, judicious use of sleeping pills, such as zolpidem (Ambien and generic) or eszopiclone (Lunesta and generic), can often provide short-term relief.

Only two antipsychotic drugs—quetiapine and olanzapine—have been evaluated for the treatment of insomnia, and the limited results do not enable us to determine if they are effective. Quetiapine is the only newer antipsychotic medication to be evaluated in a clinical trial for the treatment of insomnia. That small trial found that it was no better than placebo. Four observational studies involving quetiapine indicated it improved insomnia symptoms, but because these types of studies are not as rigorous as clinical trials, it’s not clear how much of the benefit was attributable to the medication.

Two observational studies of olanzapine found that it might improve sleep, but again, it’s not clear how much of the benefit was due to the medication.

**Post-Traumatic Stress Disorder (PTSD)**

PTSD can develop after experiencing a traumatic event, such as military combat, sexual or physical abuse or assault, and serious accidents, such as a car wreck or natural disaster. The symptoms of PTSD can include bad memories or nightmares about the traumatic event, fear, guilt, and avoidance of situations that remind you of the traumatic event. People with PTSD can also develop anxiety, depression, drinking or drug problems, chronic pain, and problems with employment and relationships.

The standard treatments for PTSD are psychotherapy, such as cognitive behavioral therapy, and medication, including antidepressants. Although antipsychotic medications have been used off-label to treat PTSD, there’s not enough evidence overall to draw conclusions about their effectiveness or which types of PTSD symptoms they should be used to treat. The available studies indicate the medications help relieve symptoms in men who developed PTSD due to combat but not in women whose PTSD symptoms were due to non-combat incidences, such as domestic abuse.

Three newer antipsychotic drugs have been studied for treating PTSD: olanzapine, quetiapine, and risperidone. One trial indicated olanzapine is effective for reducing combat-related PTSD symptoms when added to an antidepressant. One small, eight-week study of non-
What is the evidence for the off-label use of antipsychotic medications?

Combat related PTSD also found that olanzapine by itself was helpful.

One trial of quetiapine found that when it was given with an antidepressant, the combination helped relieve PTSD symptoms (whether the PTSD was due to combat or something else was not reported).

The best evidence about risperidone comes from a study conducted by the U.S. Department of Veterans Affairs. That study, which is the largest conducted on risperidone for combat-related PTSD symptoms, found that, on average, the medication was no better than placebo at reducing PTSD severity or relieving symptoms, including depression and anxiety. People who took risperidone were more likely than those who took placebo to experience weight gain, fatigue, and drowsiness.
Newer antipsychotic drugs can cause significant side effects, some of which are serious (See Table 3). The side effects of these medications include death, weight gain, fatigue, sedation, restlessness (akathisia), muscle rigidity, and twitches or tremors (extrapyramidal symptoms, some of which can be permanent). Many people who start taking an antipsychotic drug do not take it for long, even if it reduces their symptoms, because they cannot or do not want to tolerate the side effects. So it’s important to take those into consideration when deciding whether to take one of these medications, especially if it’s for an off-label use, the benefits of which are uncertain.

Side effects associated with off-label use of these medications can include:

**Death.** Although death is a highly unlikely side effect, one large study that involved elderly people found higher rates of sudden death in those who took an antipsychotic drug. The risk was higher for those who took higher doses. The combined results of several studies found the risk of death is particularly increased for elderly people who have dementia and agitation.

**Weight gain.** Several antipsychotic drugs have been associated with weight gain, including aripiprazole, olanzapine, quetiapine, and

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<th>Table 3. Side Effects Associated with Off-Label Use of Atypical Antipsychotic Drugs</th>
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<tr>
<td><strong>Side effect</strong></td>
</tr>
<tr>
<td>Death</td>
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<td>Stroke</td>
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<td>Elevated blood pressure</td>
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| Weight gain | ■ Olanzapine poses the biggest risk  
■ Aripiprazole, quetiapine, and risperidone also pose a risk  
■ Ziprasidone not associated with this side effect |
| Diabetes | Olanzapine is the most likely to cause type 2 diabetes |
| High cholesterol | Risperidone, quetiapine, olanzapine, and ziprasidone, but not aripiprazole |
| Mental problems: confusion, dizziness, headaches, lightheadedness, seizure, tinnitus, sedation | All atypical antipsychotic drugs associated with at least some of these |
| Fatigue | All atypical antipsychotics except risperidone |
| Restlessness (akathisia) | Aripiprazole |
| Parkinson’s-like, or extrapyramidal, symptoms | Aripiprazole, quetiapine, and ziprasidone |
| Neuromuscular issues | Olanzapine and risperidone |
| Cognitive decline in the elderly | Olanzapine, risperidone, and quetiapine |
| Increased risk of serious blood clot (venous thromboembolism) | All atypical antipsychotics associated with this risk |
risperidone. The pooled results of 85 trials found strong evidence that olanzapine poses a higher risk of weight gain than any other antipsychotic. Limited evidence indicates ziprasidone is not associated with weight gain.

Diabetes and high cholesterol. Olanzapine is more likely than the other new antipsychotic drugs to cause type 2 diabetes. Risperidone, quetiapine, olanzapine, and ziprasidone appear to increase the risk of high cholesterol, but aripiprazole does not. Studies have indicated that quetiapine can also increase triglycerides, which could increase the risk of heart disease.

Mental and muscular problems. All newer antipsychotic drugs increase the risk of mental side effects, which include confusion, dizziness, headaches, lightheadedness, sedation, seizure, and tinnitus. All of them, except for risperidone, are associated with fatigue. Olanzapine, risperidone, and quetiapine were also associated with cognitive decline in the elderly. Only aripiprazole was associated with restlessness.

Aripiprazole, quetiapine, and ziprasidone are associated with uncontrollable movements and tremors that resemble Parkinson’s disease (extrapyramidal symptoms). Olanzapine and risperidone increase the risk of other neuromuscular issues when compared with placebo.

Blood clots. One study found that all newer antipsychotic drugs increase the risk of blood clots, which can lead to serious complications and death if not treated. Older people have a higher risk.

Other side effects: Quetiapine is more likely than risperidone to cause agitation, decreased salivation, neurological events, and sedation. Studies in people with schizophrenia found that risperidone is the most likely of the newer antipsychotic drugs to increase a hormone called prolactin, which can result in women missing menstrual periods, diminished sex drive, and other sexual side-effects. But it is unclear if the lower doses of risperidone typically prescribed for off-label use increases prolactin. Paliperidone is closely related to risperidone and also has been shown to elevate prolactin levels.
Choosing an antipsychotic medication for off-label uses

The lack of comparative evidence for off-label use of the newer antipsychotic drugs makes it difficult to determine the effectiveness and safety of these medications under those circumstances. So we have not chosen a Best Buy antipsychotic drug for use in anxiety, ADHD, depression, insomnia, or PTSD.

Our Consumer Reports medical advisers recommend that you discuss with your doctor first trying standard treatment options for your condition, including nondrug and lifestyle strategies, if appropriate. Consider an antipsychotic drug only if those other options fail to improve your symptoms. If you do decide to try an antipsychotic treatment, carefully weigh the risks of these drugs against any potential benefits.

In addition, the cost of the antipsychotics might be important to take into account. Most of these medications are very expensive, so before starting one, find out how much your insurance plan covers and how much your out-of-pocket costs will be.

Another important issue to be aware of is that it is not clear what dose of these medications is best for off-label uses. Our analysis found insufficient evidence about different dosages of the antipsychotic medications to draw conclusions about how much a person should take.

Often, the desired effects—for example, sedation to treat insomnia—can be achieved with a much lower dose of the medication than typically used to treat conditions for which the drug has been FDA-approved, such as schizophrenia.

If you decide to use a newer antipsychotic drug, your doctor should monitor you for side effects. This includes assessing your weight and muscle rigidity as well as blood tests. And you should stop taking the medication if it doesn’t improve your symptoms.
It’s important for you to know that the information we present here is not meant to substitute for a doctor’s judgment. But we hope it will help you and your doctor arrive at a decision about which medication and dose is best for you, if one is warranted at all, and which gives you the most value for your health-care dollar.

1. **Mention cost to your doctor.** Bear in mind that many people are reluctant to discuss the cost of medicines with their doctor, and that studies have found that doctors do not routinely take price into account when prescribing medicines. Unless you bring it up, your doctor may assume that cost is not a factor for you.

2. **Ask about older medications.** Many people (including physicians) think that newer drugs are better. While that’s a natural assumption to make, it’s not always true. Studies consistently find that many older medicines are as good as, and in some cases better than, newer medicines. Think of them as “tried and true,” particularly when it comes to their safety record. Newer drugs have not yet met the test of time, and unexpected problems can and do crop up once they hit the market. Of course, some newer prescription drugs are indeed more effective and safer. Talk with your doctor about newer vs. older medicines, including generic drugs.

3. **Consider generic drugs.** Prescription medicines go “generic” when a company’s patents on them have lapsed, usually after about 12 to 15 years. At that point, other companies can make and sell the drugs. Generics are much less expensive than newer brand-name medicines, but they are not lesser quality drugs. Indeed, most generics remain useful medicines even many years after first being marketed. That is why more than 75 percent of all prescriptions in the U.S. today are written for generics.

4. **Keep up-to-date records.** Another important issue to talk with your doctor about is keeping a record of the drugs you take. There are several reasons for this:
   - First, if you see several doctors, each may not be aware of medicines the others have prescribed.
   - Second, since people differ in their response to medications, it’s common for doctors today to prescribe several medicines before finding one that works well or best.
   - Third, many people take several prescription medications, nonprescription drugs, and dietary supplements at the same time. They can interact in ways that can either reduce the benefit you get from the drug or be dangerous.
   - Fourth, the names of prescription drugs—both generic and brand—are often hard to pronounce and remember.

For all these reasons, it’s important to keep a written list of all the drugs and supplements you take and periodically review it with your doctors.

5. **Know the facts.** Finally, always be sure that you understand the dose of the medicine being prescribed and how many pills you are expected to take each day. Your doctor should tell you this information. When you fill a prescription at a pharmacy, or if you get it by mail, check to see that the dose and the number of pills per day on the bottle match the amounts your doctor told you.
How we evaluated the atypical antipsychotic medications

Our evaluation is primarily based on an independent scientific review of the evidence on the effectiveness, safety, and adverse effects of the drugs included in this report. A team of physicians and researchers at the Southern California Evidence-Based Practice Center completed this analysis as part of a larger update on Off-Label Use of Atypical Antipsychotics, prepared for the Agency for Healthcare Research and Quality. This was a systematic review and meta-analysis comparing the effectiveness and safety of these medications. Members of the team had no financial interest in any pharmaceutical company or product.

A synopsis of that analysis, for selected conditions, along with expert opinion, forms the basis for this report. The full update (a long and technical document written for physicians) is available at www.ncbi.nlm.nih.gov/books/NBK66081/.

A consultant to Consumer Reports Best Buy Drugs is also a founder of Oregon Health & Science University’s Drug Effectiveness Review Project, or DERP, a first-of-its-kind multistate initiative to evaluate the comparative effectiveness and safety of hundreds of prescription drugs. The Oregon-based research team has no financial interest in any pharmaceutical company or product.

The Consumer Reports Best Buy Drugs methodology is described in more detail in the Methods section at www.CRBestBuyDrugs.org.
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About us

Consumer Reports is an independent and nonprofit organization whose mission since 1936 has been to provide consumers with unbiased information on goods and services and to create a fair marketplace. Its website is www.ConsumerReports.org.

Consumer Reports Best Buy Drugs is a public-education project administered by Consumers Union. These materials were made possible by the state Attorney General Consumer and Prescriber Education Grant Program, which is funded by a multistate settlement of consumer-fraud claims regarding the marketing of the prescription drug Neurontin.

The Engelberg Foundation provided a major grant to fund the creation of the project from 2004 to 2007. Additional initial funding came from the National Library of Medicine, part of the National Institutes of Health. A more detailed explanation of the project is available at www.CRBestBuyDrugs.org.

We followed a rigorous editorial process to ensure that the information in this report and on the Consumer Reports Best Buy Drugs website is accurate and describes generally accepted clinical practices. If we find an error or are alerted to one, we will correct it as quickly as possible. But Consumer Reports and its authors, editors, publishers, licensors, and suppliers cannot be responsible for medical errors or omissions, or any consequences from the use of the information on this site. Please refer to our user agreement at www.CRBestBuyDrugs.org for further information.

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References


References


