



Effective Health Care Program

Medicines for Treating Mental Health Conditions

A Review of the Research for Adults and Caregivers



Agency for Healthcare Research and Quality
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Is This Information Right for Me?

This information is for you if:

- A doctor has suggested one of these medicines (listed below) for you or someone you care for. These medicines are called “antipsychotics” because they were made to treat severe mental illnesses such as psychosis. Antipsychotics are now used for many mental health conditions and symptoms, not just psychosis.
 - Aripiprazole (Abilify®)
 - Olanzapine (Zyprexa®)
 - Quetiapine (Seroquel®)
 - Risperidone (Risperdal®)
 - Ziprasidone (Geodon®)
- A doctor has said that you or someone you care for has one of these conditions:
 - Dementia
 - Eating disorders (anorexia nervosa)
 - Generalized anxiety disorder
 - Obsessive compulsive disorder (OCD)
 - Post-traumatic stress disorder (PTSD)
 - Severe depression
 - Substance abuse

Evidence on the use of antipsychotics for some of these conditions is limited. See pages 5 and 6 to find out if there is information for your condition. Definitions of these conditions are on page 2.

This information may not be helpful to you if:

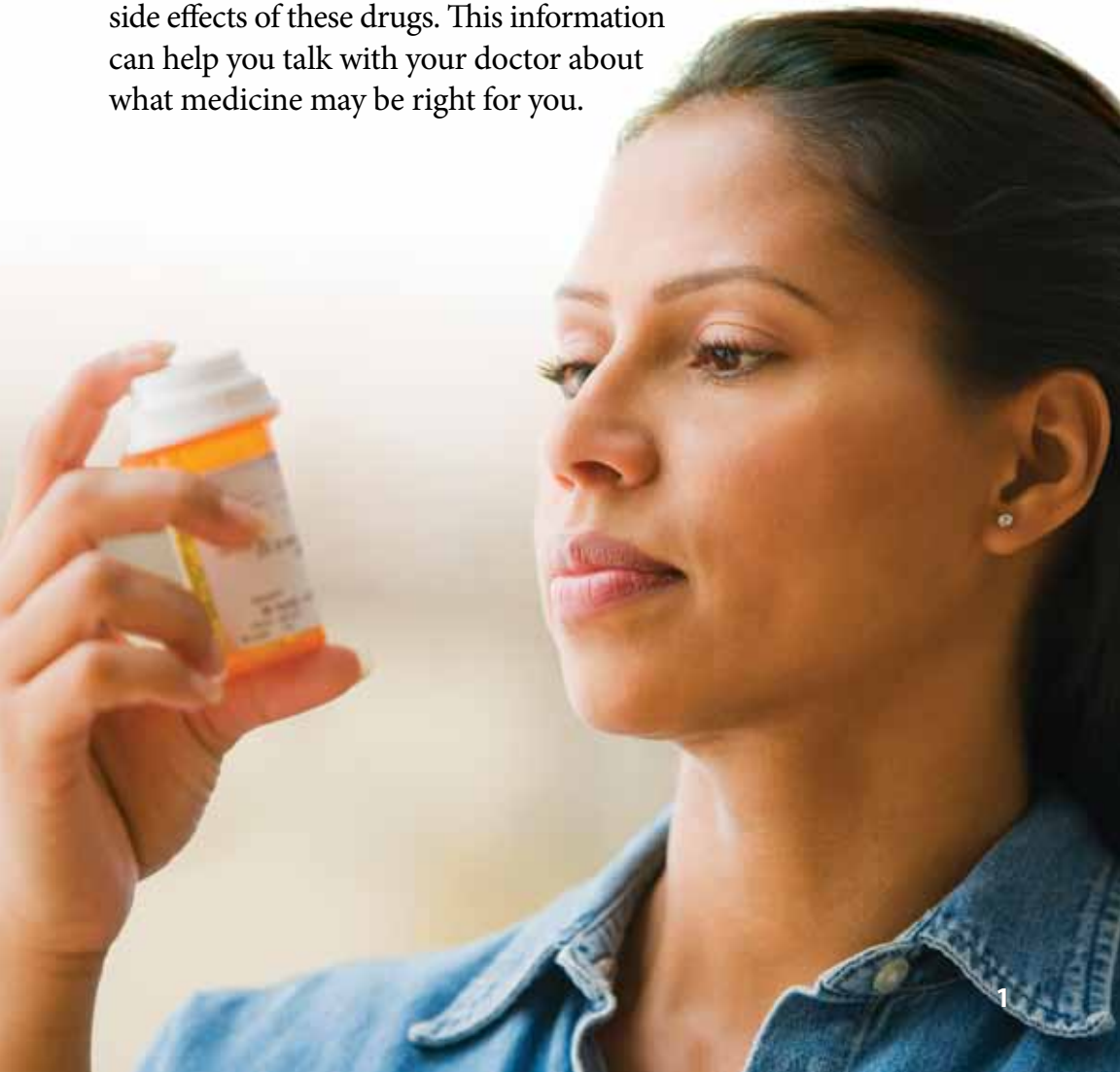
- A doctor has not suggested an antipsychotic for you or someone you care for.
- Your doctor has suggested a different antipsychotic than those listed above, such as asenapine (Saphris®), iloperidone (Fanapt®), and paliperidone (Invega®). There is not enough research available about these drugs for conditions other than psychosis or bipolar disorder.
- You are taking the antipsychotic clozapine (Clozaril®, FazaClo®). This medicine can cause a serious side effect and requires special care from your doctor.
- You are under 18. This information is from research on adults.

What will this summary tell me?

This summary will tell you about research on how well some antipsychotic medicines work for conditions other than psychosis and bipolar disorder. It will also tell you about research on the risks of side effects for these medicines.

Where does the information in this summary come from?

The information in this summary is from a report on antipsychotics taken for a variety of conditions. The report reviewed 170 studies published before May 2011 about the effectiveness of these drugs. It also reviewed 180 studies published before May 2011 about the side effects of these drugs. This information can help you talk with your doctor about what medicine may be right for you.



Understanding Antipsychotics

Why do people take antipsychotic medicines?

Antipsychotic medicines were made to help people who have psychosis, a symptom of severe mental illnesses such as schizophrenia or bipolar disorder. These medicines are now used for many other conditions (listed below). These medicines are not made to cure these conditions, but to help relieve symptoms and improve quality of life.

- **Dementia:** Problems with thinking, memory, communication, or movement. Sometimes dementia causes people to yell, fight, or see things that are not there.
- **Eating disorders:** Anorexia nervosa (not eating enough food because you think you are overweight even when you are underweight and very thin).
- **Generalized anxiety disorder:** Frequent and very strong feelings of fear and worry that go beyond the usual everyday stress that people feel.
- **Obsessive compulsive disorder (OCD):** Feeling anxious from thoughts and fears (obsessions) that lead you to repeat actions (compulsions) without a good reason. Examples include washing your hands repeatedly because you fear germs or repeatedly checking the door lock because you fear intruders.
- **Post-traumatic stress disorder (PTSD):** Anxiety, panic, or depression based on a traumatic event in your life.
- **Severe depression:** Ongoing feelings of sadness, worthlessness, and hopelessness.
- **Substance abuse:** Overusing or becoming dependent on alcohol, drugs, or other substances.

You may also be taking other medicines to treat these conditions, such as antidepressants or other anxiety medicines. Antipsychotics may be added to these other medicines, or may replace them if those medicines did not work, to help treat your condition.

What does research say about how well antipsychotics work for different conditions?

Antipsychotic medicines studied in the research for this summary include:

- Aripiprazole (Abilify®)
- Quetiapine (Seroquel®)
- Ziprasidone (Geodon®)
- Olanzapine (Zyprexa®)
- Risperidone (Risperdal®)

Antipsychotic medicines **NOT** included in this summary:

- Clozapine (Clozaril®, FazaClo®) was not included because it can cause a serious side effect and requires special care from your doctor.
- Asenapine (Saphris®), iloperidone (Fanapt®), and paliperidone (Invega®) were not included because there was not enough research available about them for conditions other than psychosis.

Not every antipsychotic medicine has been studied for each condition. For some medicines, researchers are able to say how many people saw a benefit during studies of those medicines. This information may help you understand how likely you may be to see the same benefit.



Benefits of Antipsychotics by Condition

| Condition | What benefit? | Which medicine? | How likely is the benefit? |
|---|---|---|--|
| Dementia | Improved symptoms such as aggression, delusions (believing things that are not true or logical), or hallucinations (seeing things or hearing voices that are not there) Did NOT improve problems with thinking or memory | <ul style="list-style-type: none"> All antipsychotics included in this summary, except for ziprasidone (Geodon®) There are not enough studies on ziprasidone (Geodon®) to know if it improves symptoms | Although doctors may see small improvements in tests that score symptoms, there is not enough research to know how many are likely to see the same result. |
| Generalized Anxiety Disorder | Improved symptoms by about 50 percent | <ul style="list-style-type: none"> Quetiapine (Seroquel®) | For every 8 people taking this medicine, 1 saw this benefit. |
| Severe Depression* | Improved symptoms by at least 50 percent or removed all symptoms | <ul style="list-style-type: none"> Aripiprazole (Abilify®), olanzapine (Zyprexa®), quetiapine (Seroquel®), or risperidone (Risperdal®) combined with an antidepressant Quetiapine XR (Seroquel XR®) taken by itself | <p>The research for this summary only measured the likelihood of this benefit for risperidone (Risperdal®) and quetiapine XR (Seroquel XR®):</p> <ul style="list-style-type: none"> For every 7 people taking risperidone (Risperdal®), 1 saw improved symptoms. For every 8 people taking risperidone (Risperdal®), 1 saw all symptoms removed. For every 6 people taking quetiapine XR (Seroquel XR®), 1 saw improved symptoms. For every 13 people taking quetiapine XR (Seroquel XR®), 1 saw all symptoms removed. |
| Post-traumatic Stress Disorder (PTSD; related to military combat) | Improved symptoms slightly | <ul style="list-style-type: none"> Risperidone (Risperdal®) combined with an antidepressant | Although a benefit was seen for some people, there is not enough research to know how many are likely to see the same result. |

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Benefits of Antipsychotics by Condition *(Continued)*

| Condition | What benefit? | Which medicine? | How likely is the benefit? |
|-------------------------------------|--|---|--|
| Obsessive Compulsive Disorder | Improved symptoms by at least 25 to 35 percent | <ul style="list-style-type: none"> Risperidone (Risperdal[®]) combined with an antidepressant | For every 5 people taking this medicine, 1 saw this benefit. |
| Eating Disorders (anorexia nervosa) | Did NOT help people gain weight | <ul style="list-style-type: none"> Olanzapine (Zyprexa[®]) | There was not much difference between those who took this medicine and those who did not. |
| Substance Abuse | Did NOT help people reduce the amount of alcohol or drugs they took or the amount of time they stayed drug or alcohol free | <ul style="list-style-type: none"> All antipsychotics included in this summary | There was not much difference between those who took an antipsychotic and those who did not. |

*The U.S. Food and Drug Administration (FDA) has approved the antipsychotics aripiprazole (Abilify[®]), olanzapine (Zyprexa[®]), and quetiapine (Seroquel[®]) to add to other medicines for treating severe depression. XR = extended release

What does research say about the side effects or risks of antipsychotics?

Antipsychotics have many side effects or risks. Some of these side effects and risks are serious.

Side Effects or Risks of Antipsychotics

| What side effect or risk? | Which medicine? | How likely is the side effect or risk? |
|--|---|---|
| Death in elderly* people with dementia | <ul style="list-style-type: none"> All antipsychotics included in this summary, except for ziprasidone (Geodon[®]) There are not enough studies on ziprasidone (Geodon[®]) to know if it has this side effect | For every 100 people taking one of these medicines, 1 had this side effect. |
| Stroke in the elderly* | <ul style="list-style-type: none"> Risperidone (Risperdal[®]) | For every 34 people taking this medicine, 1 had this side effect. |

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Side Effects or Risks of Antipsychotics (Continued)

| What side effect or risk? | Which medicine? | How likely is the side effect or risk? |
|---|---|---|
| Uncontrollable movements, such as tremors or tics | <p>In the elderly*:</p> <ul style="list-style-type: none"> ■ Olanzapine (Zyprexa[®]) ■ Risperidone (Risperdal[®]) <p>In adults ages 18 to 64:</p> <ul style="list-style-type: none"> ■ Aripiprazole (Abilify[®])[†] ■ Quetiapine (Seroquel[®])[†] ■ Ziprasidone (Geodon[®])[†] | <p>In the elderly*:</p> <ul style="list-style-type: none"> ■ For every 10 people taking olanzapine (Zyprexa[®]), 1 had this side effect. ■ For every 20 people taking risperidone (Risperdal[®]), 1 had this side effect. <p>In adults ages 18 to 64:</p> <ul style="list-style-type: none"> ■ For every 11 people taking aripiprazole (Abilify[®]), 1 had this side effect. ■ For every 36 people taking quetiapine (Seroquel[®]), 1 had this side effect. ■ For every 24 people taking ziprasidone (Geodon[®]), 1 had this side effect. |
| Weight gain | <ul style="list-style-type: none"> ■ All antipsychotics included in this summary, except for ziprasidone (Geodon[®])[†] ■ People taking olanzapine (Zyprexa[®]) had the greatest risk of gaining weight | <ul style="list-style-type: none"> ■ Olanzapine (Zyprexa[®]): For every 3 people taking this medicine, 1 had this side effect. ■ All other antipsychotics included in this summary, except ziprasidone (Geodon[®]): For every 25 people taking one of these medicines, 1 had this side effect. |
| Drowsiness, tiredness, and decreased alertness | <ul style="list-style-type: none"> ■ All antipsychotics included in this summary | <p>In the elderly*:</p> <ul style="list-style-type: none"> ■ For every 12 people taking an antipsychotic, 1 felt drowsy. ■ For every 19 people taking an antipsychotic, 1 felt tired. <p>In adults ages 18 to 64:</p> <ul style="list-style-type: none"> ■ For every 7 people taking an antipsychotic, 1 felt drowsy. People taking quetiapine (Seroquel[®]) were drowsy most often. ■ For every 17 people taking an antipsychotic, 1 felt tired. |
| Urinary infections and incontinence [‡] in the elderly* [†] | <ul style="list-style-type: none"> ■ Olanzapine (Zyprexa[®]) ■ Quetiapine (Seroquel[®]) ■ There are not enough studies on ziprasidone (Geodon[®]) and aripiprazole (Abilify[®]) to know if they have these side effects ■ Risperidone (Risperdal[®]) | <p>Although some people had these side effects, there is not enough research to know how many are likely to see the same result.</p> |

*Elderly = people 65 or older.

[†] A few studies found this, but there is not enough research to know for certain.

[‡] Incontinence is a condition where people have a strong urge to urinate or they leak urine when coughing, laughing, or walking.

What are other possible side effects?

Antipsychotics may cause other side effects that were not included in this research. These side effects are listed by the U.S. Food and Drug Administration (FDA).

| What side effect? | Which medicines? | | | |
|--|---|----------------------------|----------------------------|----------------------------|
| High cholesterol | ■ Aripiprazole (Abilify®) | ■ Olanzapine (Zyprexa®) | ■ Quetiapine (Seroquel®) | |
| Swelling in the ankles and calves | ■ Olanzapine (Zyprexa®) | ■ Risperidone (Risperdal®) | | |
| Low blood pressure | All antipsychotics included in this summary | | | |
| Dizziness or light-headedness | All antipsychotics included in this summary | | | |
| Headaches | All antipsychotics included in this summary | | | |
| Constipation | ■ Aripiprazole (Abilify®) | ■ Olanzapine (Zyprexa®) | ■ Quetiapine (Seroquel®) | ■ Risperidone (Risperdal®) |
| Dry mouth | ■ Olanzapine (Zyprexa®) | ■ Quetiapine (Seroquel®) | ■ Risperidone (Risperdal®) | |
| An increase in the level of a certain hormone in your body called prolactin* | ■ Olanzapine (Zyprexa®) | ■ Quetiapine (Seroquel®) | ■ Risperidone (Risperdal®) | ■ Ziprasidone (Geodon®) |

*An increased level of prolactin can cause problems with sexual function and enlarged breasts in both men and women.



What should I think about when deciding?

There are several things to consider when deciding if an antipsychotic medicine is right for you or someone you care for. Only you and your doctor can decide whether any medicine's ability to help is worth the risk of a serious side effect. Each person responds differently to different antipsychotic medicines. Your doctor may try several medicines before finding the right one.

You and your doctor should discuss:

- How well medicines other than antipsychotics are working or might work to improve your symptoms.
- The risk for a serious side effect based on your medical history and how long the side effect might last.
- The trade-offs between the specific benefits and side effects of each medicine for you or someone you care for.
- How likely the medicines will cause weight gain or will require changes to your lifestyle.
- Ways your doctor can help you notice side effects so they can be treated or so the medicine you are taking can be changed.
- The cost of each medicine.
- Other medicines and supplements you are taking and how they may affect your treatment.



What are the costs of the medicines?

The wholesale prices of prescription antipsychotics are listed on the next page. Wholesale prices are the prices paid by pharmacies. These prices are given here so you can compare the costs of different medicines.

The cost to you for each medicine depends on your health insurance, the dose (amount) needed, and whether the medicine comes in generic form.

Wholesale Prices of Prescription Antipsychotics

| Drug Name | Daily Dose | Form | Price per Month for Generic* | Brand Name | Price per Month for Brand Name* |
|--------------|------------|---------|------------------------------|------------|---------------------------------|
| Aripiprazole | 2 mg | Tablet | N/A | Abilify® | \$657 |
| | 5 mg | | N/A | | \$654 |
| | 10 mg | | N/A | | \$657 |
| | 15 mg | | N/A | | \$657 |
| | 20 mg | | N/A | | \$928 |
| | 30 mg | | N/A | | \$928 |
| Olanzapine | 2.5 mg | Tablet | \$336 | Zyprexa® | \$373 |
| | 5 mg | | \$423 | | \$441 |
| | 7.5 mg | | \$482 | | \$536 |
| | 10 mg | | \$622 | | \$664 |
| | 15 mg | | \$918 | | \$996 |
| | 20 mg | | \$1,213 | | \$1,328 |
| Quetiapine | 25 mg | Tablet | N/A | Seroquel® | \$116 |
| | 50 mg | | N/A | | \$232 |
| | 100 mg | | N/A | | \$381 |
| | 200 mg | | N/A | | \$398 |
| | 400 mg | | N/A | | \$750 |
| | 600 mg | | N/A | | \$983 |
| | 800 mg | | N/A | | \$1,156 |
| Risperidone | 0.25 mg | Tablet | \$117 | Risperdal® | \$166 |
| | 0.5 mg | | \$128 | | \$182 |
| | 1 mg | | \$136 | | \$194 |
| | 2 mg | | \$228 | | \$323 |
| | 3 mg | | \$267 | | \$380 |
| | 4 mg | | \$360 | | \$510 |
| | 6 mg | | \$534 | | \$759 |
| Ziprasidone | 40 mg | Capsule | N/A | Geodon® | \$548 |
| | 60 mg | | N/A | | \$332 |
| | 80 mg | | N/A | | \$457 |
| | 160 mg | | N/A | | \$665 |

* Prices are the average wholesale prices from RED BOOK Online®. Generic prices are the middle value in the range of prices listed from different manufacturers. The actual prices of the medicines may be higher or lower than the prices listed here, depending on the manufacturer used by your pharmacy.

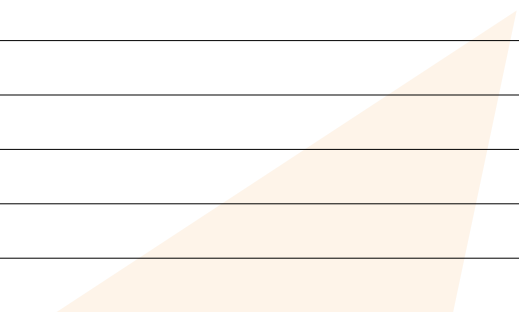
N/A = not available

Ask your doctor

- What are your reasons for wanting me or someone I care for to take an antipsychotic or add one to treatment?
- What other ways can we treat the condition without antipsychotics?
- How long will it take for the medicine to start working?
- What side effects should I watch for, and when should I call you about them?
- How will we monitor my weight, cholesterol, and risk of diabetes?
- Will an antipsychotic interfere with other medicines I am taking?

Other questions:

Write the answers here:



Source

The information in this summary comes from the report *Off-Label Use of Atypical Antipsychotics: An Update*, September 2011.

The report was produced by the Southern California Evidence-based Practice Center through funding by the Agency for Healthcare Research and Quality (AHRQ).

For a copy of the report or for more information about AHRQ and the Effective Health Care Program, go to www.effectivehealthcare.ahrq.gov/offlabelantipsych.cfm. Additional information came from the MedlinePlus® Web site, a service of the National Library of Medicine and the National Institutes of Health. This site is available at www.nlm.nih.gov/medlineplus.

This summary was prepared by the John M. Eisenberg Center for Clinical Decisions and Communications Science at Baylor College of Medicine, Houston, TX. Patients and caregivers of patients who take off-label antipsychotics reviewed this summary.

