

Atypical Antipsychotics: U.S. Food and Drug Administration-Approved Indications and Dosages for Use in Adults

The therapeutic dosing recommendations for atypical antipsychotics are based on U.S. Food and Drug Administration (FDA)-approved product labeling. Nevertheless, the dosing regimen is adjusted according to a patient's individual response to pharmacotherapy. The FDA-approved adult indications and dosages for atypical antipsychotics are provided in this table. All doses are for oral administration; the injectable atypical antipsychotics are not included in this document. Information on the generic availability of the atypical antipsychotics can be found by searching the Electronic Orange Book at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm> on the FDA website.



Medication	Indication	Dosing Information	Other Information	Generic Availability
aripiprazole[1]	bipolar I disorder, monotherapy	Initial dose: 15 mg once a day; Recommended target dose: 15 mg once a day; Maximum dose: 30 mg once a day	Dose may be increased based on clinical response. Maintain at the dose needed to stabilize the patient during the acute phase.	No
aripiprazole	bipolar I disorder, adjunct therapy	Initial dose: 10 mg to 15 mg once a day; Recommended target dose: 15 mg once a day; Maximum dose: 30 mg once a day	Prescribed in conjunction with lithium or valproate. Dose may be increased based on clinical response.	No
aripiprazole	major depressive disorder (MDD), adjunct therapy	Initial dose: 2 mg to 5 mg per day; Effective dose range: 2 mg to 15 mg per day; Maximum dose: 15 mg per day	Prescribed in conjunction with antidepressants. Dose adjustments of up to 5 mg per day may be made at intervals of no less than 1 week.	No
aripiprazole	schizophrenia	Initial dose: 10 mg or 15 mg once a day; Recommended target dose: 10 mg or 15 mg once a day; Maximum dose: 30 mg once a day	Dose increases should generally not be made before 2 weeks.	No
asenapine*[2]	bipolar I disorder, monotherapy	Initial dose: 10 mg twice a day; Recommended dose range: 5 mg to 10 mg twice a day; Maximum dose: 10 mg twice a day	May reduce to 5 mg twice a day if tolerability issues present.	No
asenapine*	bipolar I disorder, adjunct therapy	Initial dose: 5 mg twice a day; Recommended dose range: 5 mg to 10 mg twice a day; Maximum dose: 10 mg twice a day	Prescribed in conjunction with lithium or valproate.	No
asenapine*	schizophrenia, acute treatment	Initial dose: 5 mg twice a day; Recommended dose: 5 mg twice a day; Maximum dose: 10 mg twice a day	Safety of more than 10 mg twice a day has not been evaluated.	No
asenapine*	schizophrenia, maintenance therapy	Initial dose: 5 mg twice a day; Recommended dose: 10 mg twice a day; Maximum dose: 10 mg twice a day	Increase to recommended dose after 1 week if tolerated.	No

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Medication	Indication	Dosing Information	Other Information	Generic Availability
clozapine†[3, 4]	schizophrenia, treatment-resistant; schizophrenia or schizoaffective disorder, reducing the risk of recurrent suicidal behavior in patients with	Initial dose: 12.5 mg once or twice a day; Target dose range: 300 mg to 450 mg per day; Maximum dose: 900 mg per day	Increase by 25 mg to 50 mg per day up to the target dose by the end of 2 weeks; may further increase dose once or twice weekly by 100 mg per day; total daily dose may be divided 3 times per day.	Yes‡
iloperidone[5]	schizophrenia	Initial dose: 1 mg twice a day; Target dose range: 6 mg to 12 mg twice a day; Maximum dose: 12 mg twice a day	Dose may be increased to 2 mg twice a day on Day 2, then by 2 mg per dose per day.	No
lurasidone[6]	schizophrenia	Initial dose: 40 mg once a day; Effective dose range: 40 mg to 120 mg once a day; Maximum dose: 80 mg once a day	Titration not necessary; no increased benefit at 120 mg once a day.	No
olanzapine[7]	bipolar I disorder, monotherapy	Initial dose: 10 mg to 15 mg once a day; Effective dose range: 5 mg to 20 mg once a day; Maximum dose: 20 mg once a day	May adjust dose by 5 mg per day at intervals of no less than 24 hours.	Yes
olanzapine	bipolar I disorder, adjunct therapy	Initial dose: 10 mg once a day; Recommended dose range: 5 mg to 20 mg once a day; Maximum dose: 20 mg once a day	Adjunct to lithium or valproate.	Yes
olanzapine	bipolar I disorder, depressive episodes associated with	Initial dose: 5 mg once a day; Effective dose range: 5 mg to 12.5 mg once a day; Maximum dose: 12.5 mg once a day	In combination with 20 mg fluoxetine initially; efficacy of fluoxetine in combination is 20 mg to 50 mg.	Yes
olanzapine	depression, treatment-resistant	Initial dose: 5 mg once a day; Effective dose range: 5 mg to 20 mg once a day; Maximum dose: 20 mg once a day	In combination with 20 mg fluoxetine initially; efficacy of fluoxetine in combination is 20 mg to 50 mg.	Yes

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Medication	Indication	Dosing Information	Other Information	Generic Availability
olanzapine	schizophrenia	Initial dose: 5 mg to 10 mg once a day; Target dose: 10 mg once a day; Maximum dose: 20 mg once a day	Target dose may be achieved within several days; further dose adjustments of 5 mg once a day may be made in intervals of at least 1 week. Doses above 10 mg per day are no more effective than 10 mg per day.	Yes
paliperidone‡[8]	schizophrenia	Initial dose: 6 mg once a day; Recommended dose range: 3 mg to 12 mg once a day; Maximum dose: 12 mg once a day	No initial dose titration necessary; dose adjustments of 3 mg per day at intervals of more than 5 days may be made if necessary.	No
paliperidone‡	schizoaffective disorder	Initial dose: 6 mg once a day; Recommended dose range: 3 mg to 12 mg once a day; Maximum dose: 12 mg once a day	No initial dose titration necessary; dose adjustments of 3 mg per day at intervals of more than 4 days may be made if necessary.	No
quetiapine[9]	bipolar I disorder, acute treatment of manic episodes	Initial dose: 50 mg twice a day; Recommended dose range: 400 mg to 800 mg per day; Maximum dose: 800 mg per day	May increase by 100 mg per day up to 400 mg per day by Day 4; further dose adjustments of 200 mg per day may be made. Monotherapy or as adjunct with lithium or divalproex. Take in 2 divided doses.	Yes
quetiapine	bipolar I disorder, acute treatment of depressive episodes	Day 1: 50 mg once; Day 2: 100 mg once; Day 3: 200 mg once; Recommended dose: 300 mg once a day; Maximum dose: 600 mg per day	May increase to recommended dose on Day 4. If further dose increases are necessary, may increase to 400 mg once a day on Day 5 and 600 mg once a day on Day 8. No additional benefit was seen at 600 mg than at 300 mg once a day. Take at bedtime.	Yes
quetiapine	bipolar I disorder, maintenance therapy	Recommended dose range: 400 mg to 800 mg per day; Maximum dose: 800 mg per day	Patients generally continue on the same dose that they were stabilized on during the stabilization phase. Efficacy was demonstrated as adjunct therapy to lithium or divalproex; take in 2 divided doses.	Yes
quetiapine	schizophrenia	Initial dose: 25 mg twice a day; Effective dose range: 150 mg to 750 mg per day; Maximum dose: 800 mg per day	May increase by 25 mg to 50 mg per day up to 300 mg to 400 mg per day by Day 4. Further dose adjustments of 25 mg to 50 mg per day may be made no less than every 2 days. Take in 2 or 3 divided doses.	Yes
quetiapine XR‡[10]	bipolar mania	Day 1: 300 mg once; Day 2: 600 mg once; Recommended dose range: 400 mg to 800 mg once a day; Maximum dose: 800 mg once a day	Monotherapy or as adjunct with lithium or valproate; may adjust to recommended dose range on Day 3. Take in the evening.	No
quetiapine XR‡	bipolar disorder, depressive episodes associated with	Day 1: 50 mg once; Day 2: 100 mg once; Day 3: 200 mg once; Recommended dose: 300 mg once a day; Maximum dose: 300 mg once a day	May increase to recommended dose on Day 4. Take in the evening.	No

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Medication	Indication	Dosing Information	Other Information	Generic Availability
quetiapine XR‡	bipolar I disorder, maintenance treatment	Recommended dose range: 400 mg to 800 mg once a day; Maximum dose: 800 mg once a day	Patients generally continue on the same dose that they were stabilized on during the stabilization phase. Efficacy was demonstrated as adjunct therapy to lithium or divalproex. Take in the evening.	No
quetiapine XR‡	MDD, adjunct therapy	Initial dose: 50 mg once a day; Effective dose range: 150 mg to 300 mg once a day; Maximum dose: 300 mg once a day	May increase to 150 mg on Day 3. As adjunct with antidepressants. Take in the evening.	No
quetiapine XR‡	schizophrenia	Initial dose: 300 mg once a day; Recommended dose range: 400 mg to 800 mg once a day; Maximum dose: 800 mg once a day	May increase by up to 300 mg once per day in 1 day intervals. Take in the evening.	No
risperidone§[11]	bipolar mania	Initial dose: 2 mg to 3 mg once a day; Recommended target dose: 1 mg to 6 mg once a day; Effective dose range: 1 mg to 6 mg once a day; Maximum dose: 6 mg once a day	May increase by 1 mg once a day at intervals no less than 24 hours.	Yes
risperidone§	schizophrenia	Initial dose: 2 mg per day; Recommended target dose: 4 mg to 8 mg per day; Effective dose range: 4 mg to 16 mg per day; Maximum dose: 16 mg per day	May increase by 1 mg to 2 mg per day at intervals no less than 24 hours. Doses above 3 mg twice a day are no more effective than lower doses for twice daily dosing. Doses of 8 mg once a day were generally more effective than 4 mg once a day. Dose may be given once a day or in 2 divided doses.	Yes
ziprasidone[12]	bipolar I disorder	Initial dose: 40 mg twice a day; Effective dose range: 40 mg to 80 mg twice a day; Maximum dose: 80 mg twice a day	May increase to 60 mg or 80 mg twice a day on Day 2. May add lithium or valproate as adjunct therapy. Take with food.	Yes
ziprasidone	schizophrenia	Initial dose: 20 mg twice a day; Effective dose range: 20 mg to 80 mg twice a day; Maximum dose: 80 mg twice a day	May adjust dose at intervals of no less than every 2 days. Patients should be observed for several weeks before increasing dose to ensure lowest effective dose. Take with food.	Yes

XR = extended-release

* Dissolve completely under the tongue; tablets should not be crushed, chewed, or swallowed; do not eat or drink within 10 minutes of taking medication.

† Because of the risk of agranulocytosis, the FDA requires patients to have their white blood cell count and absolute neutrophil count monitored weekly before receiving each new supply of the medication. The FDA also requires each patient and prescriber to register with the respective manufacturer's clozapine registry.

‡ Tablets or capsules should not be chewed, divided, or crushed.

§ Risperdal® (risperidone) prescribing information section 2.1 (page 4) states: "Efficacy has been demonstrated in a range of 4 to 16 mg/day. ... However, doses above 6 mg/day for twice daily dosing were not demonstrated to be more efficacious than lower doses, were associated with more extrapyramidal symptoms and other adverse effects, and are generally not recommended. In a single study supporting once-daily dosing, the efficacy results were generally stronger for 8 mg than for 4 mg. The safety of doses above 16 mg/day has not been evaluated in clinical trials."

|| Geodon® (ziprasidone) prescribing information section 2.1 (page 3) states: “Efficacy in schizophrenia was demonstrated in a dose range of 20 mg to 100 mg twice daily in short-term, placebo-controlled clinical trials. There were trends toward dose response within the range of 20 mg to 80 mg twice daily, but results were not consistent. An increase to a dose greater than 80 mg twice daily is not generally recommended. The safety of doses above 100 mg twice daily has not been systematically evaluated in clinical trials.

References

- 1 Abilify® (aripiprazole) prescribing information. (2011, February). Retrieved April 12, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021436s032,021866s019,021713s024,021729s017lbl.pdf
- 2 Saphris® (asenapine) prescribing information. (2013, March). Retrieved June 12, 2013, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022117s012lbl.pdf
- 3 Clozaril® (clozapine) prescribing information. (2013, March). Retrieved June 12, 2013, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/019758s067s068s070lbl.pdf
- 4 FazaClo® (clozapine) prescribing information. (2011, November). Retrieved March 30, 2012, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021590s024lbl.pdf
- 5 Fanapt® (iloperidone) prescribing information. (2011, March). Retrieved April 14, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022192s004lbl.pdf
- 6 Latuda® (lurasidone) prescribing information (2010, October). Retrieved May 27, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/200603s001lbl.pdf
- 7 Zyprexa® (olanzapine) prescribing information. (2010). Retrieved April 12, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020592s057,021086s036,021253s045lbl.pdf
- 8 Invega® (paliperidone) prescribing information. (2011, April). Retrieved April 14, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021999s020s024lbl.pdf
- 9 Seroquel® (quetiapine) prescribing information. (2011, November). Retrieved February 3, 2012, from <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=0584dda8-bc3c-48fe-1a90-79608f78e8a0>
- 10 Seroquel XR® (quetiapine extended-release) prescribing information. (2011, November). Retrieved February 3, 2012, from <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=473a3ac4-67f4-4782-baa9-7f9bdd8761f4>
- 11 Risperdal® (risperidone) prescribing information. (2010, December). Retrieved April 12, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020272s063,020588s051,021346s040,021444s039lbl.pdf
- 12 Geodon® (ziprasidone) prescribing information. (2012, February). Retrieved June 12, 2013, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020825s046,020919s030,021483s009lbl.pdf

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