

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 indications and dosages for the use of atypical antipsychotics in adults are provided in this table. All doses are for oral administration; dosing information for injectable atypical antipsychotics is not discussed in this document. Information on the generic availability of atypical antipsychotics can be found by searching the Electronic Orange Book at <https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm> on the FDA website.



| Medication | Indication | Dosing Information | Other Information | Generic Availability |
|--------------------|--|--|---|----------------------|
| aripiprazole[1, 2] | bipolar I disorder, (manic or mixed episodes); 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. | Yes |
| 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. | Yes |
| 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. | Yes |
| aripiprazole | 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 |

| Medication | Indication | Dosing Information | Other Information | Generic Availability |
|------------------|---|---|---|----------------------|
| asenapine*[3] | 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 |
| brexpiprazole[4] | MDD, adjunctive therapy with antidepressant | Initial dose: 0.5 mg once a day or 1 mg once a day; Target dose range: 2 mg once a day; Maximum dose: 3 mg per day | Titrate to 1 mg once a day, then up to 2 mg once a day. Increase dosage at weekly intervals. Choice of adjunctive antidepressant did not impact efficacy. | No |
| brexpiprazole | schizophrenia | Days 1–4: 1 mg once a day; Days 5–7: titrate to 2 mg once a day; Day 8: titrate to 4 mg based on response and tolerability; Maximum dose: 4 mg per day | Periodically reassess to determine efficacy of dosage and continued need for treatment. | No |

| Medication | Indication | Dosing Information | Other Information | Generic Availability |
|--------------------------------|--|--|---|----------------------|
| Cariprazine[5] | bipolar I disorder, manic or mixed episodes | Day 1: 1.5 mg; Day 2: 3 mg; Recommended dose: 3 mg to 6 mg once a day; Maximum dose: 6 mg per day | Dose adjustments may be made in 1.5 mg or 3 mg increments based on clinical response and tolerability. | No |
| cariprazine | schizophrenia | Day 1: 1.5 mg; Day 2: 3 mg; Recommended dose: 1.5 mg to 6 mg once a day; Maximum dose: 6 mg per day | Dose adjustments may be made in 1.5 mg or 3 mg increments based on clinical response and tolerability. | No |
| clozapine†‡[6, 7] | 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 |
| clozapine oral suspension†§[8] | 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 in divided doses by the end of 2 weeks; Maximum dose: 900 mg per day | Use cautious titration and divided dosing schedule; increase by 25 mg to 50 mg per day if well tolerated; once target dose is reached, may increase in increments of 100 mg or less once or twice weekly. | No |
| iloperidone[9] | 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 |

| Medication | Indication | Dosing Information | Other Information | Generic Availability |
|--------------------|---|--|--|----------------------|
| lurasidone [10] | bipolar I disorder (depressive episodes), monotherapy or adjunctive therapy | Initial dose: 20 mg once a day; Target dose range: 20 to 120 mg once a day; Maximum dose: 120 mg per day | Titration not necessary. Doses are the same for monotherapy or adjunctive therapy with lithium or valproate. Doses from 80 mg to 120 mg per day did not provide additional efficacy. | No |
| lurasidone | schizophrenia | Initial dose: 40 mg once a day; Effective dose range: 40 mg to 160 mg once a day; Maximum dose: 160 mg per day | Titration not necessary. | No |
| olanzapine[11] | bipolar I disorder (manic or mixed episodes); 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 (manic or mixed episodes); 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); adjunct therapy | 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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|-------------------|---|---|---|----------------------|
| 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‡[12] | 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. | Yes |
| paliperidone‡ | schizoaffective disorder; monotherapy or adjunctive therapy | 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. | Yes |
| quetiapine[13] | bipolar I disorder (manic episodes), acute treatment | 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 (depressive episodes), acute treatment | 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 at bedtime. | Yes |

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|---------------------------------|---|---|---|----------------------|
| 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: 750 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 [‡] [14] | 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) | 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 |
| 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 |

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|------------------|----------------------|--|---|----------------------|
| 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 a day in 1 day intervals. Take in the evening. | No |
| risperidone#[15] | 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. Patients experiencing persistent somnolence may benefit from administering half the daily dose twice daily. | 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 |

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|-----------------|---|---|--|----------------------|
| ziprasidone[16] | bipolar I disorder (mixed or manic episodes) | 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 for maintenance. 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 |

MDD = major depressive disorder 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.
- § Administer orally using syringe provided. Versacloz[™] prescribing information, section 2.3 states: “After shaking the bottle for 10 seconds prior to each use, the syringe adaptor is pressed on top of the bottle. The oral syringe (1 mL or 9 mL) is filled with air, and inserted into the adaptor. The air is dispelled into the bottle and then the bottle is turned upside down. The prescribed amount of the suspension is drawn from the bottle and dispensed directly to the mouth.”
- || Latuda® should be taken with food (at least 350 calories).
- # Risperdal® (risperidone) prescribing information section 2.1 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 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.”

To see the electronic version of this dosing table and the other products included in the “Atypical Antipsychotics” Toolkit, visit the Medicaid Program Integrity Education page at <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Pharmacy-Education-Materials/pharmacy-ed-materials.html> on the Centers for Medicare & Medicaid Services (CMS) website.

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References

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