

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

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 pediatric patients are provided in this table. Information on the generic availability of the 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	Age or Weight	Dosing Information	Other Information	Generic Availability
aripiprazole[1, 2]	schizophrenia	13 to 17 years old	Initial dose: 2 mg once a day; Recommended target dose: 10 mg once a day; Maximum dose: 30 mg once a day	May increase to 5 mg once a day after 2 days, then may increase to 10 mg once a day after 2 additional days. Further dose increases may be made in 5 mg per day increments. A dose of 30 mg once a day was no more effective than 10 mg once a day.	Yes
aripiprazole	bipolar I disorder (manic or mixed episodes)	10 to 17 years old	Initial dose: 2 mg once a day; Recommended target dose: 10 mg once a day; Maximum dose: 30 mg once a day	May increase to 5 mg once a day after 2 days, then may increase to 10 mg once a day after 2 additional days. Further dose increases, if needed, may be made in 5 mg increments. May be used as monotherapy or as adjunct to lithium or valproate.	Yes
aripiprazole	irritability associated with autistic disorder	6 to 17 years old	Initial dose: 2 mg per day; Recommended dose range: 5 mg to 10 mg per day; Effective dose range: 5 mg to 15 mg per day; Maximum dose: 15 mg per day	May increase to 5 mg once a day then may increase by up to 5 mg per day at intervals of 1 week.	Yes

Medication	Indication	Age or Weight	Dosing Information	Other Information	Generic Availability
aripiprazole	Tourette's disorder	6 to 18 years old and less than 50 kg	Initial dose: 2 mg per day Target dose: 5 mg per day after 2 days Maximum dose: 10 mg per day	Dosage adjustments should occur gradually at intervals of no less than 1 week.	Yes
aripiprazole	Tourette's disorder	6 to 18 years old and 50 kg or more	Initial dose: 2 mg per day for 2 days, then increase to 5 mg per day for 5 days Target dose: 10 mg per day on day 8 Maximum dose: 20 mg per day	Dosage adjustments should occur gradually in increments of 5 mg per day at intervals of no less than 1 week.	Yes
asenapine*[3]	bipolar I disorder (manic or mixed episodes)	10 to 17 years old	Days 1–3: 2.5 mg twice a day; Days 4–6: 5 mg twice a day; Day 7 and following: 10 mg twice a day; Recommended dose: 2.5 mg twice a day to 10 mg twice a day; Maximum dose: 10 mg twice a day	Patients may be more sensitive to dystonia if the recommended escalation schedule is not followed. Initial dosing may be adjusted based on clinical response and tolerability.	No
olanzapine[4]	schizophrenia or bipolar I disorder (manic or mixed episodes)	13 to 17 years old	Initial dose: 2.5 mg or 5 mg once a day; Target dose: 10 mg once a day; Effective dose range: 2.5 mg to 20 mg once a day; Maximum dose: 20 mg once a day	May adjust dose by 2.5 mg or 5 mg once a day.	Yes

Medication	Indication	Age or Weight	Dosing Information	Other Information	Generic Availability
olanzapine	bipolar I disorder (depressive episodes); adjunct therapy	10 to 17 years old	Initial dose: 2.5 mg once a day in evening; Maximum dose: 12 mg once a day	In combination with 20 mg fluoxetine initially; make dosage adjustments according to efficacy and tolerability. Safety of coadministration of more than 50 mg fluoxetine not established.	Yes
paliperidone[5]	schizophrenia	12 to 17 years old and less than 51 kg	Initial dose: 3 mg once a day; Target dose: 3 mg to 6 mg once a day; Maximum dose: 6 mg once a day	May increase dose by 3 mg once a day at intervals of more than 5 days. There is no clear enhancement to efficacy at doses of 6 mg once a day.	No
paliperidone	schizophrenia	12 to 17 years old and 51 kg or more	Initial dose: 3 mg once a day; Target dose: 3 mg to 12 mg once a day; Maximum dose: 12 mg once a day	May increase dose by 3 mg once a day at intervals of more than 5 days. There is no clear enhancement to efficacy at doses of 12 mg once a day.	No
quetiapine[6]	schizophrenia	13 to 17 years old	Day 1: 25 mg twice a day; Day 2: 50 mg twice a day; Day 3: 100 mg twice a day; Recommended dose: 400 mg to 800 mg per day; Maximum dose: 800 mg per day	On Days 4 and 5, increase dose by 50 mg twice a day. After Day 5, may adjust dose based on patient response and tolerability in increments of no more than 100 mg per day. Total daily dose should be divided into 2 or 3 doses. No additional benefit was seen with 800 mg per day.	Yes

Medication	Indication	Age or Weight	Dosing Information	Other Information	Generic Availability
quetiapine	bipolar mania	10 to 17 years old	Day 1: 25 mg twice a day; Day 2: 50 mg twice a day; Day 3: 100 mg twice a day; Recommended dose: 400 mg to 600 mg per day; Maximum dose: 600 mg per day	On Days 4 and 5, increase dose by 50 mg twice a day. After Day 5, may adjust dose based on patient response and tolerability in increments of no more than 100 mg per day. Total daily dose should be divided into 2 or 3 doses. No additional benefit was seen with 600 mg per day.	Yes
quetiapine XR†[7]	bipolar I disorder, manic, acute monotherapy	10 to 17 years old	Day 1: 50 mg once a day; Day 2: 100 mg once a day; Day 3: 200 mg once a day; Recommended dose range: 400 mg to 600 mg once a day; Maximum dose: 600 mg once a day	Days 4 and 5, increase by 100 mg per day once a day.	No
quetiapine XR†	schizophrenia	13 to 17 years old	Day 1: 50 mg once a day; Day 2: 100 mg once a day; Day 3: 200 mg once a day; Recommended dose range: 400 mg to 800 mg once a day; Maximum dose: 800 mg once a day	Days 4 and 5, increase by 100 mg per day once a day.	No
risperidone[8]	schizophrenia	13 to 17 years old	Initial dose: 0.5 mg once a day; Recommended target dose: 3 mg per day; Maximum dose: 6 mg per day	May increase dose by 0.5 mg or 1 mg per day at intervals not less than 24 hours. No additional benefit was seen with doses above 3 mg per day.	Yes

Medication	Indication	Age or Weight	Dosing Information	Other Information	Generic Availability
risperidone	bipolar mania	10 to 17 years old	Initial dose: 0.5 mg once a day; Recommended target dose: 2.5 mg per day; Maximum dose: 6 mg per day	May increase dose by 0.5 mg or 1 mg per day at intervals not less than 24 hours. No additional benefit was seen with doses above 2.5 mg per day. ^{†‡}	Yes
risperidone	irritability associated with autistic disorder	5 to 17 years old and less than 20 kg	Initial dose: 0.25 mg once a day; Recommended target dose: 0.5 mg per day; Effective dose range: 0.5 mg to 3 mg per day	May increase to 0.5 mg per day after at least 4 days, then by 0.25 mg per day at intervals equal to or longer than 2 weeks.	Yes
risperidone	irritability associated with autistic disorder	5 to 17 years old and 20 kg or more	Initial dose: 0.5 mg once a day; Recommended target dose: 1 mg per day; Effective dose range: 0.5 mg to 3 mg per day	May increase to 1 mg per day after at least 4 days, then by 0.5 mg per day at intervals equal to or longer than 2 weeks.	Yes

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

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

‡ Risperdal® (risperidone) prescribing information section 2.2 states: “While it is generally agreed that pharmacological treatment beyond an acute response in mania is desirable, both for maintenance of the initial response and for prevention of new manic episodes, there are no systematically obtained data to support the use of RISPERDAL® in such longer-term treatment (i.e., beyond 3 weeks).”

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

- 1 Abilify® (aripiprazole) prescribing information. (2014, December 12). Retrieved August 7, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021436s038,021713s030,021729s022,021866s023lbl.pdf
- 2 Aripiprazole prescribing information. (2015, April 28). Retrieved August 13, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/202101s000lbl.pdf
- 3 Saphris® (asenapine) prescribing information. (2015, March 12). Retrieved August 7, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022117s017s018s019lbl.pdf
- 4 Zyprexa® (olanzapine) prescribing information. (2015, July 23). Retrieved August 7, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/020592s064,021086s042,021253s049lbl.pdf
- 5 Invega® (paliperidone) prescribing information. (2014, April 29). Retrieved August 10, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021999s029lbl.pdf
- 6 Seroquel® (quetiapine) prescribing information. (2013, October 29). Retrieved August 10, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020639s061lbl.pdf
- 7 Seroquel XR® (quetiapine extended-release) prescribing information. (2013, October 29). Retrieved August 10, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022047s034lbl.pdf
- 8 Risperdal® (risperidone) prescribing information. (2014, April 28). Retrieved August 11, 2015, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/020272s073,020588s062,021444s048lbl.pdf

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