

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 <http://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] | 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. | No |
| 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 per day increments. May be used as monotherapy or as adjunct to lithium or valproate. | No |
| 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. | No |
| olanzapine[2] | 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 |
| paliperidone[3] | 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 equal to or greater than 51 kg | 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 |

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

| Medication | Indication | Age or Weight | Dosing Information | Other Information | Generic Availability |
|----------------|--|--|--|--|----------------------|
| quetiapine[4] | 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 |
| 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 |
| risperidone[5] | 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 |
| 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 equal to or greater than 20 kg | 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 |

* Risperdal® (risperidone) prescribing information section 2.2 (page 5) 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).”

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 Zyprexa® (olanzapine) prescribing information. (2010). Retrieved April 12, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020592s057,021086s036,021253s045lbl.pdf
- 3 Invega® (paliperidone) prescribing information. (2011, April). Retrieved April 14, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021999s020s024lbl.pdf
- 4 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>
- 5 Risperdal® (risperidone) prescribing information. (2012, August). Retrieved August 27, 2012, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020272s065,020588s053,021444s041lbl.pdf

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