

## Antidepressant Medications: U.S. Food and Drug Administration-Approved Indications and Dosages for Use in Pediatric Patients

The therapeutic dosing recommendations for antidepressant medications 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 antidepressant medications in pediatric patients are provided in this table. All of the antidepressant medications listed are for oral administration unless otherwise stated. Information on the generic availability of the antidepressant medications 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	Initial Dose	Maximum Dose	Other Information	Generic Availability
clomipramine[1]	OCD	10 to 17 years old	25 mg once a day	3 mg per kg or 200 mg per day, whichever is lower	Dose may be increased gradually over the first 2 weeks to 3 mg per kg or 100 mg per day, whichever is lower. Further dose increases should occur gradually over several weeks. During initial titration, give in divided doses with meals. After initial titration, dose may be given once a day at bedtime.	Yes
duloxetine[2]	GAD	7 to 17 years old	30 mg once a day for 2 weeks	120 mg once a day	Recommended dose range is 30 to 60 mg once a day. Dose increases should be in increments of 30 mg. There is no evidence that doses above 60 mg once a day provide any additional benefit.	Yes
escitalopram[3]	MDD	12 to 17 years old	10 mg once a day	20 mg once a day	Dose may be increased to 20 mg once a day after 3 weeks.	Yes
fluoxetine (Prozac®)[4]	MDD	8 to 18 years old	10 mg or 20 mg once a day	20 mg once a day	Lower weight children should be started on 10 mg once a day.	Yes

Medication	Indication	Age	Initial Dose	Maximum Dose	Other Information	Generic Availability
fluoxetine (Prozac®)	OCD	7 to 17 years old	10 mg once a day	60 mg per day	After 2 weeks, the dose may be increased to 20 mg once a day. Additional dose increases may be considered after several more weeks if insufficient clinical improvement is observed. Doses above 20 mg per day may be given once a day or in 2 divided doses.	Yes
fluvoxamine*[5]	OCD	8 to 11 years old	25 mg once a day	200 mg per day	Dose may be increased by 25 mg every 4 to 7 days. Doses over 50 mg per day should be given in 2 divided doses.	Yes
fluvoxamine*	OCD	12 to 17 years old	25 mg once a day	300 mg per day	Dose may be increased by 25 mg every 4 to 7 days. Doses over 50 mg per day should be given in 2 divided doses.	Yes
imipramine[6]	childhood enuresis	6 to 11 years old	25 mg once a day, 1 hour before bedtime	2.5 mg per kg up to 50 mg once a day	Dose may be increased after 1 week. Evidence suggests that in early-night bedwetters, the medication is more effective given earlier and in divided amounts.	Yes
imipramine	childhood enuresis	12 years old and older	25 mg once a day, 1 hour before bedtime	2.5 mg per kg up to 75 mg once a day	Dose may be increased after 1 week. Evidence suggests that in early-night bedwetters, the medication is more effective given earlier and in divided amounts.	Yes
sertraline[7]	OCD	6 to 12 years old	25 mg once a day	200 mg once a day	Dose changes should not occur at intervals of less than 1 week.	Yes
sertraline	OCD	13 to 17 years old	50 mg once a day	200 mg once a day	Dose changes should not occur at intervals of less than 1 week.	Yes

MDD = major depressive disorder    OCD = obsessive-compulsive disorder

\* Luvox CR® (fluvoxamine extended-release) is approved for use in children and adolescents 8 to 17 years old; however, the lowest available dose may not be appropriate for pediatric patients naive to fluvoxamine. Further dosing recommendations are not provided in the Luvox CR® prescribing information.[8]

To see the electronic version of this dosing table and the other products included in the “Antidepressants” 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 Anafranil® (clomipramine) prescribing information. (2014, July 28). Retrieved August 3, 2015, from [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/019906s039lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/019906s039lbl.pdf)
- 2 Cymbalta® (duloxetine) prescribing information. (2015, June 18). Retrieved August 3, 2015, from [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/021427s046lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021427s046lbl.pdf)
- 3 Lexapro® (escitalopram) prescribing information. (2014, October 31). Retrieved August 4, 2015, from [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/021323s044,021365s032lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021323s044,021365s032lbl.pdf)
- 4 Prozac® (fluoxetine) prescribing information. (2014, October 10). Retrieved August 4, 2015, from [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/018936s102lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/018936s102lbl.pdf)
- 5 Luvox® (fluvoxamine) prescribing information. (2014, October 23). Retrieved August 4, 2015, from [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/021519Orig1s008lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021519Orig1s008lbl.pdf)
- 6 Tofranil® (imipramine) prescribing information. (2014, July 17). Retrieved August 4, 2015, from [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/087846s028,087844s027,087845s027lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/087846s028,087844s027,087845s027lbl.pdf)
- 7 Zoloft® (sertraline) prescribing information. (2014, September 12). Retrieved August 5, 2015, from [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2013/019839s079,020990s038lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/019839s079,020990s038lbl.pdf)
- 8 Luvox CR® (fluvoxamine extended-release) prescribing information. (2014, July 18). Retrieved August 4, 2015, from [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/022033s010lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022033s010lbl.pdf)

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