

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

The therapeutic dosing recommendations for anticonvulsant 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 pediatric indications and dosages for the anticonvulsant medications are provided in this table. Lennox-Gastaut syndrome (LGS) affects approximately 4 percent of pediatric patients diagnosed with childhood epilepsy.[1] Since this is a rare condition and treatment is highly individualized, the FDA-approved anticonvulsant medications for the treatment of LGS are not included in this document. All of the medications listed are for oral administration. Information on the generic availability of the anticonvulsant medications 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	Initial Dose	Maximum Dose	Other Information	Generic Availability
carbamazepine[2]	epilepsy	Younger than 6 years old	10 mg per kg to 20 mg per kg per day	35 mg per kg per day	May increase dose at weekly intervals to achieve optimal clinical response. Give tablets in 2 or 3 divided doses; give suspension in 4 divided doses.	Yes
carbamazepine	epilepsy	6 to 12 years old	100 mg twice a day (tablets) <b>or</b> 50 mg 4 times a day (suspension)	1000 mg per day	May increase dose at weekly intervals by up to 100 mg per day. Give in 3 or 4 divided doses.	Yes
carbamazepine	epilepsy	Older than 12 years old	200 mg twice a day (tablets) <b>or</b> 100 mg 4 times a day (suspension)	<b>12 to 15 years old:</b> 1000 mg per day; <b>Older than 15 years old:</b> 1200 mg per day	May increase dose at weekly intervals by up to 200 mg per day. Give in 3 or 4 divided doses.	Yes
carbamazepine XR*[3]	epilepsy	6 to 12 years old	100 mg twice a day	1000 mg per day	May increase dose at weekly intervals by up to 100 mg per day. Give in 2 divided doses.	Yes
carbamazepine XR*	epilepsy	Older than 12 years old	200 mg twice a day	<b>12 to 15 years old:</b> 1000 mg per day; <b>Older than 15 years old:</b> 1200 mg per day	May increase dose at weekly intervals by 200 mg per day. Give in 2 divided doses.	Yes
ethosuximide[4]	absence (petit mal) seizures	3 to 6 years old	250 mg per day	1500 mg per day	May increase dose by 250 mg every 4 to 7 days. The optimal dose for most patients is 20 mg per kg per day.	Yes
ethosuximide	absence (petit mal) seizures	6 years old and older	500 mg per day	1500 mg per day	May increase dose by 250 mg every 4 to 7 days. The optimal dose for most patients is 20 mg per kg per day.	Yes
ethotoin[5]	complex partial seizures <b>or</b> tonic-clonic (grand mal) seizures	1 year old and older	Should not exceed 750 mg per day	3000 mg per day	May increase dose gradually over several days. The usual maintenance dose is 500 mg to 1000 mg per day. Doses above 2000 mg per day are rarely necessary. Give in 4 to 6 divided doses.	No
gabapentin[6]	partial seizures, adjunct therapy	3 to 12 years old	10 mg per kg to 15 mg per kg per day	50 mg per kg per day	The maximum time between doses should not exceed 12 hours. Give in 3 divided doses.	Yes

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Medication	Indication	Age	Initial Dose	Maximum Dose	Other Information	Generic Availability
gabapentin	partial seizures, adjunct therapy	Older than 12 years old	300 mg 3 times a day	600 mg 3 times a day	The maximum time between doses should not exceed 12 hours.	Yes
lacosamide[7]	partial seizures, adjunct therapy	17 years old and older	50 mg twice a day	200 mg twice a day	May increase dose by 50 mg twice a day at weekly intervals.	No
lamotrigine†‡[8]	epilepsy	2 to 12 years old	0.3 mg per kg per day rounded down to nearest whole tablet	300 mg per day	May increase dose to 0.6 mg per kg per day weeks 3 and 4, then may increase by 0.6 mg per kg per day rounded down to the nearest whole tablet starting with week 5. Usual maintenance dose: 4.5 mg per kg to 7.5 mg per kg per day. Give in 2 divided doses.	Yes§
lamotrigine†‡	epilepsy	12 years old and older	25 mg once a day	375 mg per day	May increase dose to 50 mg per day weeks 3 and 4, then by 50 mg per day every 1 to 2 weeks. Give in 2 divided doses.	Yes§
lamotrigine XR*‡   [9]	partial seizures, adjunct therapy	13 years old and older	25 mg once a day	400 mg once a day	May increase dose to 50 mg once a day weeks 3 and 4, then by 50 mg once a day at weekly intervals for 3 weeks, then by no more than 100 mg once a day at weekly intervals.	No
lamotrigine XR*‡	tonic-clonic (grand mal) seizures, adjunct therapy	13 years old and older	25 mg once a day	400 mg once a day	May increase dose to 50 mg once a day weeks 3 and 4, then by 50 mg once a day at weekly intervals for 3 weeks, then by 100 mg once a day at weekly intervals.	No
levetiracetam[10]	myoclonic seizures, adjunct therapy	12 years old and older	500 mg twice a day	3000 mg per day	May increase dose by 1000 mg per day every 2 weeks.	Yes
levetiracetam	partial seizures, adjunct therapy	1 month old to younger than 6 months old	7 mg per kg twice a day	21 mg per kg twice a day	May increase dose by 7 mg per kg twice a day every 2 weeks.	Yes
levetiracetam	partial seizures, adjunct therapy	6 months old to younger than 4 years old	10 mg per kg twice a day	25 mg per kg twice a day	May increase dose by 10 mg per kg twice a day every 2 weeks.	Yes
levetiracetam	partial seizures, adjunct therapy	4 years old to younger than 16 years old	10 mg per kg twice a day	30 mg per kg twice a day up to 1500 mg twice a day	May increase dose by 10 mg per kg twice a day every 2 weeks.	Yes
levetiracetam	partial seizures, adjunct therapy	4 years old to younger than 16 years old and weighing 20 kg to 40 kg	250 mg twice a day	750 mg twice a day	May increase dose by 250 mg twice a day every 2 weeks.	Yes
levetiracetam	partial seizures, adjunct therapy	4 years old to younger than 16 years old and weighing more than 40 kg	500 mg twice a day	1500 mg twice a day	May increase dose by 500 mg twice a day every 2 weeks.	Yes

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Medication	Indication	Age	Initial Dose	Maximum Dose	Other Information	Generic Availability
levetiracetam	partial seizures, adjunct therapy	16 years old and older	500 mg twice a day	1500 mg twice a day	May increase dose by 500 mg twice a day every 2 weeks.	Yes
levetiracetam	tonic-clonic (grand mal) seizures, adjunct therapy	6 years old to younger than 16 years old	10 mg per kg twice a day	30 mg per kg twice a day	May increase dose by 10 mg per kg twice a day every 2 weeks.	Yes
levetiracetam	tonic-clonic (grand mal) seizures, adjunct therapy	16 years old and older	500 mg twice a day	1500 mg twice a day	May increase dose by 500 mg twice a day every 2 weeks.	Yes
levetiracetam XR*[11]	partial seizures, adjunct therapy	16 years old and older	1000 mg once a day	3000 mg once a day	May increase dose by 1000 mg per day every 2 weeks.	Yes
methsuximide[12]	absence (petit mal) seizures	No age specified	300 mg per day	1200 mg per day	May increase dose by 300 mg at weekly intervals.	No
oxcarbazepine#[13]	partial seizures, monotherapy	4 to 16 years old	4 mg per kg to 5 mg per kg twice a day	<b>By patient's weight:</b> <b>Up to 20 kg:</b> 900 mg per day; <b>20.1 kg to 30 kg:</b> 1200 mg per day; <b>30.1 kg to 45 kg:</b> 1500 mg per day; <b>45.1 kg to 55 kg:</b> 1800 mg per day; <b>More than 55 kg:</b> 2100 mg per day	May increase dose by 5 mg per kg per day every 3 days. Give in 2 divided doses.	Yes
oxcarbazepine	partial seizures, adjunct therapy	2 years old to younger than 4 years old	4 mg per kg to 5 mg per kg twice a day up to 600 mg per day	30 mg per kg twice a day	Patients less than 20 kg may start at 16 to 20 mg per kg per day. Titrate the dose over 2 to 4 weeks. Give in 2 divided doses.	Yes
oxcarbazepine	partial seizures, adjunct therapy	4 to 16 years old	4 mg per kg to 5 mg per kg twice a day up to 300 mg twice a day	<b>By patient's weight:</b> <b>20 kg to 29 kg:</b> 900 mg per day; <b>29.1 kg to 39 kg:</b> 1200 mg per day; <b>More than 39 kg:</b> 1800 mg per day	Titrate the dose over 2 to 4 weeks. Give in 2 divided doses.	Yes
peramppanel**[14]	partial seizures, adjunct therapy	12 years old and older	2 mg once a day at bedtime	12 mg once a day at bedtime	May increase dose by 2 mg per day no more frequently than once a week.	No
phenytoin[15]	complex partial seizures; seizures during or after neurosurgery; tonic-clonic (grand mal) seizures	No age specified	5 mg per kg per day	300 mg per day	A period of 7 to 10 days may be required to reach steady-state blood levels. Give in 2 or 3 divided doses.	Yes‡

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Medication	Indication	Age	Initial Dose	Maximum Dose	Other Information	Generic Availability
tiagabine††[16]	partial seizures, adjunct therapy	12 to 18 years old	4 mg once a day	32 mg per day	May increase dose by 4 mg per day at the beginning of week 2 then by 4 mg to 8 mg per day at weekly intervals. Give in 2 to 4 divided doses.	Yes‡‡
topiramate[17]	epilepsy, monotherapy	2 years old to younger than 10 years old	25 mg once a day at night	<b>By patient's weight:</b> <b>Up to 11 kg:</b> 125 mg twice a day; <b>12 kg to 22 kg:</b> 150 mg twice a day; <b>23 kg to 38 kg:</b> 175 mg twice a day; <b>More than 38 kg:</b> 200 mg twice a day	May increase dose to 25 mg twice a day after 1 week then by 25 mg to 50 mg per day at weekly intervals. Titration to the minimum maintenance dose should be attempted over 5 to 7 weeks.	Yes
topiramate	epilepsy, monotherapy	10 years old and older	25 mg twice a day	200 mg twice a day	May increase dose by 25 mg twice a day at weekly intervals up to 100 mg twice a day, then may increase by 50 mg twice a day at weekly intervals.	Yes
topiramate	epilepsy, adjunct therapy	2 to 16 years old	1 mg per kg to 3 mg per kg up to 25 mg once a day at night for 1 week	4.5 mg per kg twice a day	May increase dose by 1 mg per kg to 3 mg per kg per day at weekly intervals. Give in 2 divided doses after the first week.	Yes
topiramate	epilepsy, adjunct therapy	17 years old and older	25 mg to 50 mg per day	200 mg twice a day	May increase dose by 25 mg to 50 mg per day at weekly intervals.	Yes
valproic acid and divalproex§§[18, 19, 20]	complex partial seizures, monotherapy	10 years old and older	10 mg per kg to 15 mg per kg per day	60 mg per kg per day	May increase dose by 5 mg per kg to 10 mg per kg per day at weekly intervals until optimal response.	Yes§
valproic acid and divalproex§§	complex partial seizures, adjunct therapy	10 years old and older	10 mg per kg to 15 mg per kg per day	60 mg per kg per day	May increase dose by 5 mg per kg to 10 mg per kg per day at weekly intervals until optimal response; if the total daily dose is more than 250 mg, give in divided doses.	Yes§
valproic acid and divalproex§§	absence (petit mal) seizures	10 years old and older	15 mg per kg per day	60 mg per kg per day	May increase dose by 5 mg per kg to 10 mg per kg per day at weekly intervals until optimal response; if the total daily dose is more than 250 mg, give in divided doses.	Yes§
divalproex ER[21]	complex partial seizures	10 years old and older	10 mg per kg to 15 mg per kg once a day	60 mg per kg once a day	May increase dose by 5 mg per kg to 10 mg per kg per day at weekly intervals until optimal response.	Yes
divalproex ER	absence (petit mal) seizures	10 years old and older	15 mg per kg once a day	60 mg per kg once a day	May increase dose by 5 mg per kg to 10 mg per kg per day at weekly intervals until optimal response.	Yes
zonisamide*[22]	partial seizures, adjunct therapy	16 years old and older	100 mg per day	400 mg per day	May increase dose by 100 mg per day every 2 weeks. Give once a day or in 2 divided doses.	Yes

XR or ER = extended-release

- \* Tablets or capsules must be swallowed whole. Do not chew, crush, or divide.
- † Lamotrigine is only approved as monotherapy in patients 16 years old and older.
- ‡ Dose adjustments are necessary in patients taking valproic acid, carbamazepine, phenytoin, phenobarbital, or primidone. Consult the prescribing information for dosing recommendations in these patients and for recommendations on converting to lamotrigine monotherapy.
- § Some dosage forms may not be available in a generic formulation.
- || Lamotrigine XR is also approved for conversion to monotherapy for the treatment of partial seizures in patients 13 years old and older.
- # Consult prescribing information for conversion to oxcarbazepine monotherapy from another anticonvulsant.
- \*\* Dosing is for patients who are not taking an enzyme-inducing antiepileptic medication (e.g., carbamazepine, oxcarbazepine, and phenytoin). The recommended starting dose of perampanel in patients taking an enzyme-inducing antiepileptic medication is 4 mg once a day at bedtime.
- †† Dosing is for patients already taking an enzyme-inducing antiepileptic medication (e.g., carbamazepine, phenytoin, primidone, and phenobarbital). Patients not taking an enzyme-inducing antiepileptic medication require a lower dose of tiagabine and may also require a slower titration schedule.
- ‡‡ Some strengths of medication are not available in a generic formulation.
- §§ Stavzor® capsules must be swallowed whole.

## References

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