

How to calculate the appropriate individualized dose:

The following table provides acceptable weight ranges for each dose and age category, such that patients will receive the maximum beneficial effect – between 90% and 180% of the calculated recommended dose.

The safety of this strategy has been established in clinical trials¹.

DIASTAT[®] AcuDial[™] (diazepam rectal gel) Dosing Recommendations (by age and weight)

| Recommended Dose by Age 2 to 5 yrs. /0.5 mg/kg (1.1mg/lb) | | Recommended Dose by Age 6 to 11 yrs. /0.3 mg/kg (.66mg/lb) | | Recommended Dose by Age 12+ yrs. /0.2 mg/kg (.44mg/lb) | |
|--|-----------|---|-----------|---|-----------|
| Weight | Dose (mg) | Weight | Dose (mg) | Weight | Dose (mg) |
| 6 to 10 kg (3 to 22 lbs) | 5 | 10 to 16 kg (22 to 35 lbs) | 5 | 14 to 25 kg (31 to 55 lbs) | 5 |
| 11 to 15 kg (23 to 33 lbs) | 7.5 | 17 to 25 kg (36 to 55 lbs) | 7.5 | 26 to 37 kg (56 to 81 lbs) | 7.5 |
| 16 to 20 kg (34 to 44 lbs) | 10 | 26 to 33 kg (56 to 73 lbs) | 10 | 38 to 50 kg (82 to 110 lbs) | 10 |
| 21 to 25 kg (45 to 55 lbs) | 12.5 | 34 to 41 kg (74 to 90 lbs) | 12.5 | 51 to 62 kg (111 to 136 lbs) | 12.5 |
| 26 to 30 kg (56 to 66 lbs) | 15 | 42 to 50 kg (91 to 110 lbs) | 15 | 63 to 75 kg (137 to 165 lbs) | 15 |
| 31 to 35 kg (67 to 77 lbs) | 17.5 | 51 to 58 kg (111 to 128 lbs) | 17.5 | 76 to 87 kg (166 to 191 lbs) | 17.5 |
| 36 to 44 kg (78 to 97 lbs) | 20 | 59 to 74 kg (129 to 163 lbs) | 20 | 88 to 111 kg (192 to 244 lbs) | 20 |

Reference: 1 DIASTAT AcuDial Full Prescribing Information, Valeant Pharmaceuticals North America.



Important Safety Information

DIASTAT[®] AcuDial[™] (diazepam rectal gel) is a gel formulation of diazepam intended for rectal administration in the management of selected, refractory patients with epilepsy, on stable regimens of AEDs, who require intermittent use of diazepam to control bouts of increased seizure activity, for patients 2 years and older.

In clinical trials with DIASTAT, the most frequent adverse event was somnolence (23%). Less frequent adverse events reported were dizziness, headache, pain, vasodilatation, diarrhea, ataxia, incoordination, asthma, rash, abdominal pain, nervousness, and rhinitis (1%–5%).

Please see accompanying full Prescribing Information or visit

www.diastatacudial.com.

