How to prepare and administer AGILUS®

(dantrolene sodium hemiheptahydrate)

For the treatment of malignant hyperthermia

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Norgine Pharmaceuticals Ltd on:
Tel: +44 (0)1895 826 606 Email: medinfo@norgine.com

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AGILUS™
DANTROLENE SODIUM HEMIHEPTAHYDRATE

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In combination with adequate support measures, AGILUS® is indicated for the treatment of malignant hyperthermia in adults and children of all ages.[1]

Job code: UK-EC-AGI-2500012 **Date of preparation:** September 2025

Preparation and administration summary[1]

How to prepare AGILUS®

- Each vial should be reconstituted by adding 20 mL water for injections and shaking for approximately 1 minute, before inspecting for particulates. Further shaking may be necessary.
- Reconstituted AGILUS® does not need to be filtered prior to administration.

How to administer AGILUS®

1. A reconstituted vial of AGILUS® contains 120 mg of dantrolene, with a final volume of 22.6 mL.
2. Reconstituted AGILUS® must not be mixed with other solutions or given via the same venous access.
3. The therapy is given rapidly by intravenous injection at a dose of 2.5 mg/kg body weight for adult and paediatric patients.

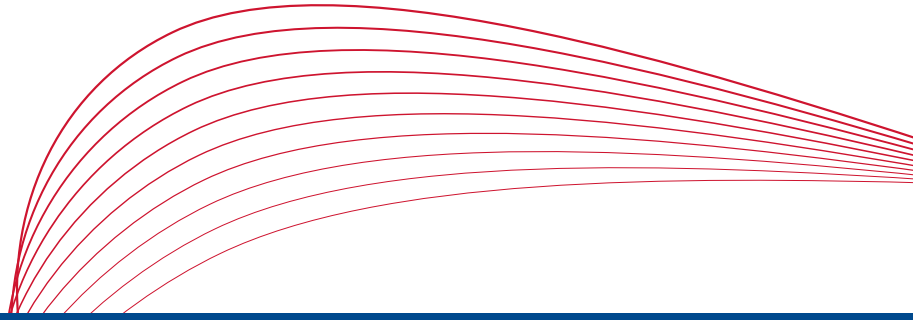
How to dose AGILUS®

In addition to treating the patient with AGILUS®, other supportive measures must be continued.

AGILUS® should be administered rapidly by intravenous injection at a dose of 2.5 mg/kg body weight for adult and paediatric patients.

For all body weights ≥120 kg, the maximum amount given as a single bolus for each individual dose (whether an initial or repeat dose) should not exceed 300 mg.

Further bolus doses of 2.5 mg/kg should be repeated every 10 minutes when the main clinical symptoms of malignant hyperthermia (MH) are still present.



Suggested dose of AGILUS®[1]

Dosing examples by body weight to achieve a dose of 2.5 mg/kg for both adults and children

For all body weights ≥120 kg, the maximum amount given as a single bolus for each individual dose (whether an initial or repeat dose) should not exceed 300 mg.

Number of vials to be prepared	Body weight range	Example dosing recommendation	
		Body weight	Dose to be administered
1	Up to 48 kg	3 kg	7.5 mg
		6 kg	15 mg
		12 kg	30 mg
		24 kg	60 mg
		48 kg	120 mg
2	From 49 kg to 96 kg	72 kg	180 mg
		96 kg	240 mg
3	From 97 kg	120 kg	300 mg
		144 kg	300 mg

Please refer to the Summary of Product Characteristics for full dosing details.

Continued monitoring of the patient is necessary, as the clinical features of MH may recur within the first 24 hours.

If this occurs, AGILUS® should be re-administered at a dose of 2.5 mg/kg every 10 minutes until the signs of MH stop.

If a cumulative dose of 10 mg/kg or above is needed, the diagnosis of MH should be re-examined.

Prescribing Information

Click or scan to view Prescribing Information

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Please refer to the Summary of Product Characteristics for full details on preparation and administration.

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Reference: 1. AGILUS®. Summary of Product Characteristics.

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AGILUS™