

AGAMREE (vamorolone) 40mg/ml oral suspension

Patient Alert Card

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions

This patient is on long term treatment with AGAMREE (vamorolone), a dissociative corticosteroid for the chronic treatment of Duchenne Muscular Dystrophy, and therefore is physically dependent on daily steroid therapy as a critical medicine.

If this patient is unwell (excess fatigue, unexpected weakness, vomiting, diarrhea, dizziness or confusion), acute adrenal insufficiency or crisis must be taken into consideration.

Reporting of Side effects

If you get any side effects talk to your doctor or pharmacist. You can also report side effects directly (see details below)

Malta

ADR Reporting Website : <https://medicinesauthority.gov.mt/adrportal?l=1>

RMM Link : <https://medicinesauthority.gov.mt/rmm>

Market Authorisation Holder:

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Malta Distribution

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