

Specialty Quantity Limit Program Miplyffa (arimoclomol)

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over the counter (OTC) products are not included unless otherwise stated.

I	Brand Name	Generic Name
	Miplyffa	arimoclomol

Program Description

The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. If the member's plan allows a quantity limit exception review for the requested medication, coverage of an additional quantity may be provided up to the exception limit with prior authorization.

FDA-recommended Dosing

The recommended Miplyffa oral dosage, in combination with miglustat, for patients with actual body weight of:

- 8 kg to 15 kg, is 47 mg three times a day
- > 15 kg to 30 kg, is 62 mg three times a day
- > 30 kg to 55 kg, is 93 mg three times a day
- > 55 kg, is 124 mg three times a day

Covered Quantities

The limit may apply to the generic equivalent medications.

Medication	Standard Limit
Miplyffa (arimoclomol) 47 mg capsules	90 capsules per 30 days
Miplyffa (arimoclomol) 62 mg capsules	90 capsules per 30 days

Specialty Quantity Limit Miplyffa 6674-H P2024.docx

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Reference number(s) 6674-H

Medication	Standard Limit
Miplyffa (arimoclomol) 93 mg capsules	90 capsules per 30 days
Miplyffa (arimoclomol) 124 mg capsules	90 capsules per 30 days

References

1. Miplyffa [package insert]. Celebration, FL: Zevra Therapeutics, Inc.; September 2024.