

DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Antiemetics – Doxylamine and Pyridoxine Combination Products Drug Quantity Management Policy – Per Days

- Bonjesta® (doxylamine succinate and pyridoxine hydrochloride tablets – Duchesnay USA)
- Diclegis® (doxylamine succinate and pyridoxine hydrochloride delayed-release tablets – Duchesnay USA, generic)

REVIEW DATE: 04/19/2022

OVERVIEW

Bonjesta and Diclegis are fixed dose combination drug products of doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, a Vitamin B6 analog.^{1,2} Diclegis and Bonjesta are indicated for the treatment of **nausea and vomiting of pregnancy** in women who do not respond to conservative management.

Dosing

On Day 1, the dose of Bonjesta is one tablet at bedtime.¹ If this dose adequately controls symptoms on Day 2, the patient continues to take one tablet at bedtime. However, if symptoms persist on Day 2, the dose is increased to two tablets daily (one tablet in the morning and one tablet at bedtime). The maximum recommended dose is two tablets per day.

On Day 1, the dose of Diclegis is two tablets at bedtime.² If this dose adequately controls symptoms on Day 2, the patient continues to take two tablets at bedtime. However, if symptoms persist into the afternoon of Day 2, the dose is increased to three tablets daily on Day 3 (one tablet in the morning and two tablets at bedtime). If three tablets adequately control symptoms on Day 4, the dose is continued. If symptoms persist, the dose on Day 4 is four tablets daily (one tablet in the morning, one tablet mid-afternoon, and two tablets at bedtime). The maximum recommended dose is four tablets per day.

For both Bonjesta and Diclegis, the tablets must be swallowed whole.^{1,2} Tablets should not be crushed, chewed or split.

Availability

Bonjesta is available as tablets containing 20 mg of doxylamine succinate and 20 mg of pyridoxine hydrochloride in bottles of 60 tablets.¹ Diclegis (generic) is available as delayed-release tablets containing 10 mg of doxylamine succinate and 10 mg of pyridoxine hydrochloride in bottles of 100 tablets.²

POLICY STATEMENT

This Drug Quantity Management program has been developed to prevent stockpiling, misuse and/or overuse while providing a sufficient quantity for the indications of doxylamine and pyridoxine products. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per 365 Days[‡]
Bonjesta [®] (doxylamine succinate and pyridoxine hydrochloride tablets)	20/20 mg tablets	360 tablets [†]
Diclegis [®] (doxylamine succinate and pyridoxine hydrochloride delayed-release tablets, generic)	10/10 mg tablets	720 tablets [*]

[‡] This is enough drug for patients to complete 6 months of therapy. For coverage of additional quantities (for example, 9 months of therapy), a coverage review is required. [†] A quantity of 360 Bonjesta tablets per 365 days (six fills of 60 tablets/30 days) will be covered without prior authorization. ^{*} A quantity of 720 Diclegis tablets per 365 days (six fills of 120 tablets/30 days) will be covered without prior authorization.

CRITERIA

Bonjesta

1. If the patient has continued nausea and vomiting of pregnancy beyond 6 months, approve 60 tablets per 30 days for three fills to allow for a total treatment duration of 9 months.

Diclegis (generic)

1. If the patient has continued nausea and vomiting of pregnancy beyond 6 months, approve 120 tablets per 30 days for three fills to allow for a total treatment duration of 9 months.

REFERENCES

1. Bonjesta[®] tablets [prescribing information] Bryn Mawr, PA: Duchesnay USA; February 2022.
2. Diclegis[®] tablets [prescribing information] Bryn Mawr, PA: Duchesnay USA; June 2018.