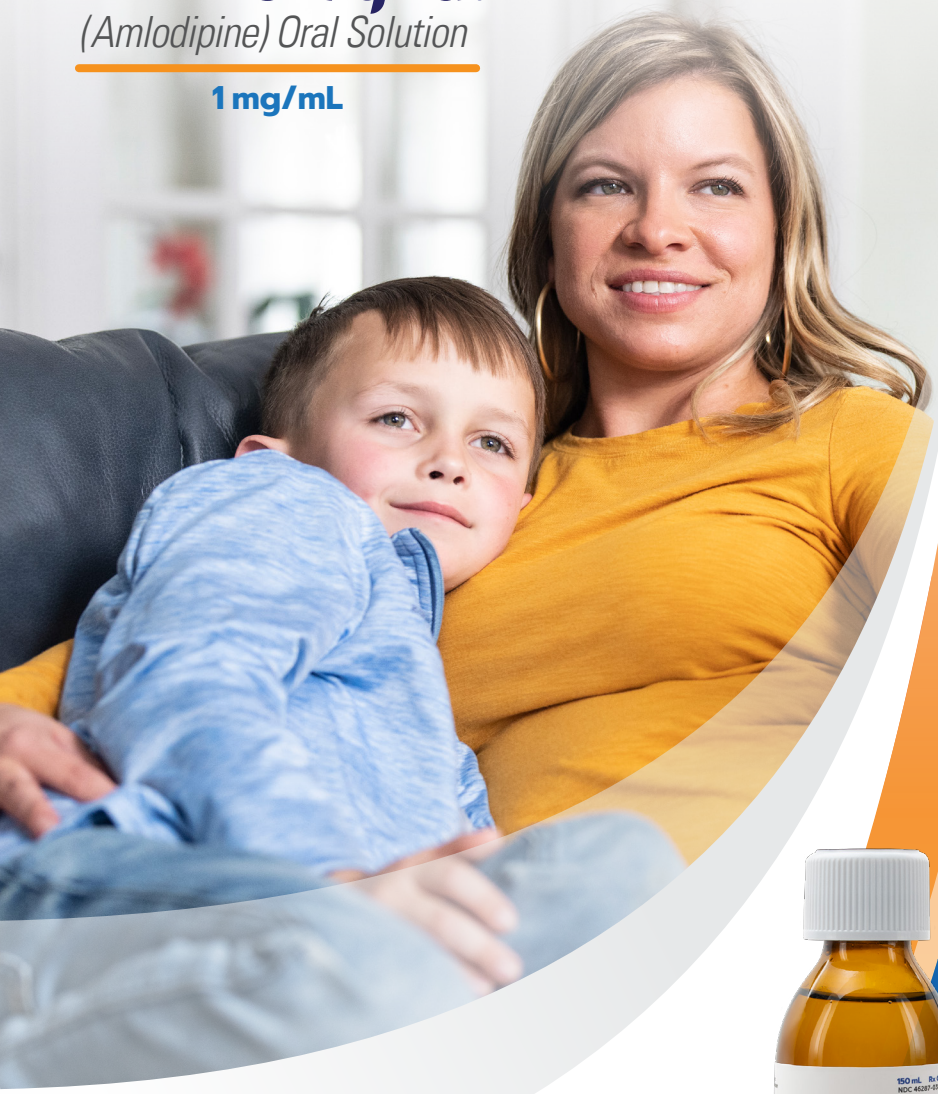
Norliqva®
(Amlodipine) Oral Solution
1 mg/mL



The First and Only FDA-approved Oral Solution of Amlodipine

For patients 6 years and older with dysphagia or issues swallowing tablets

norliqva.com

DYSPHAGIA & THE NEED FOR AN ORAL LIQUID SOLUTION

Dysphagia is the medical term used to describe difficulty swallowing. It can include difficulty starting a swallow (oropharyngeal dysphagia), issues in the throat (pharyngeal dysphagia), and the sensation of food being stuck (esophageal dysphagia).

Dysphagic Patients:

2x more likely to die while in the hospital

33% more likely to need nursing home care

3.8 days longer in the hospital on average

$6,243 higher hospital bills on average

It's important to optimize treatment plans for patients with dysphagia given these complications. Dysphagic patients who suffer from chronic heart failure, edema caused by heart or liver failure, and/or hypertension are often prescribed medication that is crushed/compounded from tablets into a liquid form.

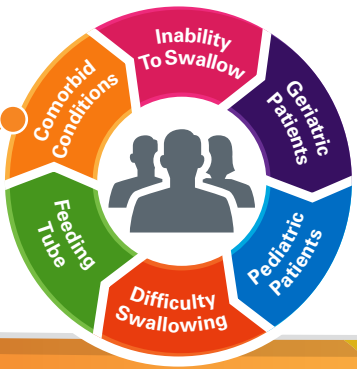
69%

OF OLDER PATIENTS REPORT MISSING DOSES OF A TABLET OR CAPSULE DUE TO DIFFICULTIES SWALLOWING

Unfortunately, liquids derived from crushed/compounded tablets raise concerns about patient safety and efficacy, and they have come under increasing scrutiny from the FDA.

Patients who may need an oral liquid

- Stroke
- Parkinson's Disease
- ALS
- Multiple Sclerosis
- Cerebral Palsy



READ THIS BEFORE YOU CRUSH/ COMPOUND ANOTHER TABLET

68% to 268% The range of potency compounded products exhibited in a 2006 FDA survey.[1]

Contamination In 2007, the CDC found compounded drugs have a higher risk of contamination.[1]

Costly Protocols Crushing can require expensive safety protocols that take up valuable staff time.

Short Shelf Life Crushed and compounded products can have variable and very costly, short shelf lives.

THE RISKS AND CONCERNS OF CRUSHING/COMPOUNDING

Patients who have difficulty swallowing are often given crushed/compounded formulations of the prescriptions. However, crushed/compounded formulations can exhibit a wide variation in potency due to non-uniformity of compounded materials. These dosing inconsistencies of compounded suspensions have long been a persistent challenge for pharmacists and patients.[2] Crushed/compounded formulations are not tested for safety or efficacy.

Due to fatalities related to contamination, the FDA recently released stricter guidance regarding crushing/compounding and recommended against using crushed/ compounded products considered "essentially copies of a commercially available drug product" without permission, especially if an FDA-approved alternative exists.[3]

Before you crush/compound consider the following:

- Check if the medication is a NIOSH listed product that is high risk and may cause harm.
- Check USP-800 guidelines for crushing/compounding hazardous products.
- Per FDA guidance, prescribe an approved liquid alternative if one exists.

1 Gudeman, Jennifer, Michael Jozwiakowski, John Chollet, and Michael Randell. "Potential Risks of Pharmacy Compounding." Drugs in R&D 13, no. 1 (2013): 1-8. doi:10.1007/s40268-013-0005-9.

2 Kindy K, Sun L, Crites A. Compounding pharmacies have been linked to deaths, illnesses for years. Washington Post. February 7, 2013. http://www.washingtonpost.com. Accessed October 2, 2017.

3 Food Drug Administration Center for Drug Evaluation & Research (2016). Guidance for Industry: Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act (FDA, Maryland) 1-8. doi:10.1007/ s40268-013-0005-9.

CONSIDER NORLIQVA® FOR YOUR PATIENTS WHO NEED IT

WHAT IS NORLIQVA®?

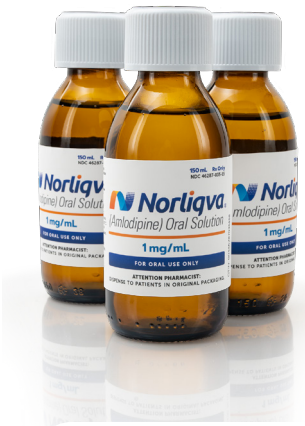
- **The first FDA-approved liquid solution of amlodipine for hypertension and coronary artery disease**
- **Approved for adults and children 6 years and older**
- **Kid-friendly mild peppermint flavor**
- **Requires no refrigeration or shaking for convenient use**

DOSING & ADMINISTRATION

NORLIQVA® is an oral solution: 1 mg/mL.

Adult recommended starting dose: 5 mg orally once daily with a maximum of 10 mg orally once daily. Small, fragile, or elderly patients, or patients with hepatic insufficiency may be started on 2.5 mg orally once daily.

Pediatric starting dose: 2.5 mg to 5 mg orally once daily.



THE RIGHT MEDICATION FOR THE RIGHT PATIENT

- Younger patients who resist or who cannot swallow tablets or capsules
- Older patients who suffer from dysphagia or problems swallowing
- Providers who need safe, compliant and easy-to-dose alternatives

Amlodipine Comparison Matrix	Norliqva®	Crushed/ Compounded Amlodipine
FDA-approved ready-made oral solution formulation for adults and children 6 and older	✓	✗
Tested to ensure potency and consistency in dosing	✓	✗
No need to shake, use immediately	✓	✗
Stable 36 month shelf life	✓	✗
Tested to ensure proper dosing for bioequivalence	✓	✗
Kid friendly mild peppermint flavor	✓	✗
Additional preparation required by pharmacist / patient / caregiver	✗	✓

Contact your wholesaler today to order NORLIQVA®

150mL bottle | NDC: 46287-035-15

Important Safety Information

Contraindications

NORLIQVA® is contraindicated in patients with sensitivity to amlodipine.

Norliqva®
(Amlodipine) Oral Solution
1 mg/mL

EasyPay
COPAY PROGRAM

Healthcare providers can help their patients pay as little as $0* on each prescription using the EasyPay Card.

To learn more, visit cmppharma.com/easypay

Terms and Conditions

* Void where prohibited by law. CMP Pharma reserves the right to rescind, revoke or amend this program without notice. Offer not valid for patients eligible for benefits under Medicaid (including Medicaid managed care), Medicare, TRICARE, Veterans Affairs, FEHBP, or similar state or federal programs. Offer void where prohibited, taxed, or otherwise restricted. Offer good only in the U.S.A. No generic substitution with this offer.

IMPORTANT SAFETY INFORMATION

Indications And Usage

NORLIQVA® is a calcium channel blocker for the treatment of:

HYPERTENSION

NORLIQVA® is indicated for the treatment of hypertension in adults and children 6 years of age and older, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

CORONARY ARTERY DISEASE

- Chronic Stable Angina
- Vasospastic Angina (Prinzmetal's or Variant Angina)
- Angiographically Documented Coronary Artery Disease In patients without heart failure or an ejection fraction <40%

Contraindications

NORLIQVA® is contraindicated in patients with sensitivity to amlodipine.

Warnings And Precautions

NORLIQVA® may cause the following conditions.

- Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis. However, acute hypotension is unlikely.
- Worsening angina and acute myocardial infarction can develop after starting or increasing the dose of NORLIQVA®, particularly in patients with severe obstructive coronary artery disease.
- Titrate slowly in patients with severe hepatic impairment.

Most common adverse reactions to amlodipine were edema, dizziness, flushing and palpitation which occurred in a dose related manner. Other adverse reactions not clearly dose-related but reported with an incidence >1.0% are fatigue and nausea.

Talk to your healthcare provider about other possible side effects with NORLIQVA®.

To report SUSPECTED ADVERSE REACTIONS, contact CMP Pharma, Inc. at 1-844-321-1443 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Drug Interactions

Do not exceed doses greater than 20 mg daily of simvastatin.

- CYP3A Inhibitors: Co-administration with CYP3A inhibitors (moderate and strong) results in increased systemic exposure to amlodipine and may require dose reduction.
- CYP3A Inducers: No information is available on the quantitative effects of CYP3A inducers on amlodipine. Blood pressure should be closely monitored when amlodipine is co-administered with CYP3A inducers.
- Simvastatin: Co-administration of simvastatin with amlodipine increases the systemic exposure of simvastatin. Limit the dose of simvastatin in patients on amlodipine to 20 mg daily
- Immunosuppressants: Amlodipine may increase the systemic exposure of cyclosporine or tacrolimus when co- administered.

Dosage And Administration

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Please see Full Prescribing Information at norliqva.com/prescribing-information

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