# FIRST®- Atenolol Rx

**Atenolol 2 mg/mL or 10 mg/mL in FIRST®- Grape Solution Compounding Kit**

## FOR PRESCRIPTION COMPOUNDING ONLY

**Cessation of Therapy with Atenolol.** Patients with coronary artery disease, who are being treated with atenolol, should be advised against abrupt discontinuation of therapy. Severe exacerbation of angina and the occurrence of myocardial infarction and ventricular arrhythmias, which may occur with or without preceding exacerbation of the angina pectoris, have been reported in angina patients following the abrupt discontinuation of therapy with beta-blockers. When discontinuation of atenolol is planned, the patients should be carefully observed and advised to limit physical activity to a minimum. If the angina worsens or acute coronary insufficiency develops, it is recommended that atenolol be promptly reinstituted, at least temporarily.

**See CONTRAINDICATIONS, WARNINGS and PRECAUTIONS and usage described in approved labeling for atenolol containing products for additional information.**

## DESCRIPTION

Each FIRST®- Atenolol Compounding Kit is comprised of atenolol powder, USP and FIRST®- Grape Solution containing artificial grape flavor, citric acid (anhydrous)*, D&C yellow #10, FD&C red #40, purified water, sodium benzoate, and sucralose.** When compounded, the final product provides a solution containing either 2 mg per mL or 10 mg per mL of atenolol in FIRST®- Grape Solution comparable to the active ingredient contained in *Atenolol for Oral Solution, USP.****

## How Supplied and Compounding Directions

| Size | 2 mg/mL 10 FL OZ | 10 mg/mL 5 FL OZ |
|---|---|---|
| NDC# | 65628-210-10 | 65628-211-05 |
| Atenolol Powder, USP | 0.6 g | 1.5 g |
| FIRST®- Grape Solution (Diluent) | 298 mL | 148 mL |

## TO THE PHARMACIST

***Everything you need to make this Rx is included...***




1. FIRST®- Atenolol Compounding Kit contains pre-measured atenolol powder, USP and FIRST®- Grape Solution.
2. **Important** - Hold the neck of the bottle containing atenolol powder and tap the bottom edges on a hard surface to loosen the powder. Remove the cap from the bottle.
3. Tap the top of the inner foil seal liner to loosen any powder which may have adhered to the liner. Carefully and slowly peel back the inner foil seal liner from the bottle.
4. Shake the FIRST®- Grape Solution for a few seconds. Remove the cap from the bottle. Carefully and slowly peel back the inner foil seal liner from the bottle.
5. Transfer about half the contents of the FIRST®- Grape Solution into the atenolol powder bottle. Close the atenolol powder bottle using the original powder bottle cap. Shake vertically for approximately 60 seconds.
6. Open the atenolol powder bottle and add the remaining FIRST®- Grape Solution into the atenolol powder bottle. Close the atenolol powder bottle using the original powder bottle cap. Shake vertically for an additional 60 seconds.
7. **Instruct the patient to shake the bottle well before each use.**

## CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS:

Atenolol is contraindicated in sinus bradycardia, heart block greater than first degree, cardiogenic shock, and overt cardiac failure.

Atenolol is contraindicated in those patients with a history of hypersensitivity to the atenolol or any of the drug product's components.

**Cardiac Failure.** Sympathetic stimulation is necessary in supporting circulatory function in congestive heart failure, and beta blockade carries the potential hazard of further depressing myocardial contractility and precipitating more severe failure.

In patients with acute myocardial infarction, cardiac failure which is not promptly and effectively controlled by 80 mg of intravenous furosemide or equivalent therapy is a contraindication to beta-blocker treatment.

**Patients Without a History of Cardiac Failure.** Continued depression of the myocardium with beta-blocking agents over a period of time can, in some cases, lead to cardiac failure. If cardiac failure continues despite adequate treatment, atenolol should be withdrawn.

**Concomitant Use of Calcium Channel Blockers.** Bradycardia and heart block can occur and the left ventricular end diastolic pressure can rise when beta-blockers are administered with verapamil or diltiazem. Patients with pre-existing conduction abnormalities or left ventricular dysfunction are particularly susceptible.

**Bronchospastic Diseases. PATIENTS WITH BRONCHOSPASTIC DISEASE SHOULD, IN GENERAL, NOT RECEIVE BETA BLOCKERS.** Because of its relative beta1 selectivity, however, atenolol may be used with caution in patients with bronchospastic disease who do not respond to, or cannot tolerate, other antihypertensive treatment. Since beta1 selectivity is not absolute, the lowest possible dose of atenolol should be used with therapy and a beta2-stimulating agent (bronchodilator) should be made available.

**Major Surgery.** Chronically administered beta-blocking therapy should not be routinely withdrawn prior to major surgery, however the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

**Diabetes and Hypoglycemia.** Beta-blockers may mask tachycardia occurring with hypoglycemia.

**Thyrotoxicosis.** Beta-adrenergic blockade may mask certain clinical signs (e.g., tachycardia) of hyperthyroidism. Abrupt withdrawal of beta blockade might precipitate a thyroid storm.

**Untreated Pheochromocytoma.** Atenolol should not be given to patients with untreated pheochromocytoma.

FIRST®- Atenolol Compounding Kit components have a two-year expiration date.*** Store FIRST®- Atenolol Compounding Kits at room temperature 15°–30°C (59°–86°F).

Based on real time temperature and humidity testing, *compounded* FIRST®- Atenolol product is stable for 60 days at room temperature 15°–30°C (59°–86°F) [see USP].*** Store the final *compounded* solution at room temperature 15°–30°C (59°–86°F).

Compendial difference: Loss on Drying (LOD) in Atenolol powder may exceed the current USP specification over the duration of the shelf-life following storage at room temperature. However, the chemical assay, organic impurities, and appearance meet USP specification, and the final reconstituted oral solution performance and quality are not impacted. Certificate of Analysis with LOD data on file.

**For oral use only.** Avoid contact with eyes. Keep container tightly closed. Keep out of reach of children. Protect from light. Protect from freezing. The beyond-use date of the compounded product, as dispensed, when stored at room temperature, is ***no later than 60 days.***

### How Supplied

**FIRST®- Atenolol Compounding Kits are available as follows:**

2 mg/mL 10 FL OZ (300 mL) as dispensed (NDC 65628-210-10)

10 mg/mL 5 FL OZ (150 mL) as dispensed (NDC 65628-211-05)

* Higher % in 10 mg/mL product than 2 mg/mL

** Certificate of analysis on file

*** Data and documentation on file

**Rx ONLY**

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U.S. Patent Pending

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Grape Flavor

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