FIRST® - Metoprolol Rx

Metoprolol Tartrate 10 mg/mL in FIRST®- Grape Solution Compounding Kit

FOR PRESCRIPTION COMPOUNDING ONLY

Ischemic heart disease. Do not abruptly discontinue metoprolol tartrate therapy in patients with coronary artery disease. Severe exacerbation of angina, myocardial infarction and ventricular arrhythmias have been reported in patients with coronary artery disease following the abrupt discontinuation of therapy with beta-blockers. Patients should be warned against interruption or discontinuation of therapy without the physician's advice.

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

DESCRIPTION

Each FIRST®- Metoprolol Compounding Kit is comprised of metoprolol tartrate 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 10 mg per mL of metoprolol tartrate in FIRST®- Grape Solution comparable to the active ingredient contained in *Metoprolol Tartrate for Oral Solution, USP*.**

How Supplied and Compounding Directions

Size	10 FL OZ	3 FL OZ
NDC#	65628-220-10	65628-230-03
Metoprolol Tartrate Powder, USP	3.0 g	0.9 g
FIRST®- Grape Solution (Diluent)	297 mL	89 mL

TO THE PHARMACIST

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

1. FIRST®- Metoprolol Compounding Kits contain pre-measured metoprolol tartrate powder, USP and FIRST®- Grape Solution.

2. **Important** - Hold the neck of the bottle containing metoprolol tartrate 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 the contents of the FIRST®- Grape Solution completely into the metoprolol tartrate powder bottle. Close the metoprolol tartrate powder bottle using the original powder bottle cap. Shake vertically for approximately 30 seconds.

6. **Instruct the patient to shake bottle well before each use.**

CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS:

Hypertension and angina. Metoprolol tartrate is contraindicated in sinus bradycardia, heart block greater than first degree, cardiogenic shock, and overt cardiac failure.

Hypersensitivity to metoprolol tartrate and related derivatives, or to any of the excipients; hypersensitivity to other beta-blockers (cross sensitivity between beta-blockers can occur).

Sick-sinus syndrome.

Severe peripheral arterial circulatory disorders.

Myocardial infarction. Metoprolol tartrate is contraindicated in patients with a heart rate <45 beats/min; second-degree and third-degree heart block; significant first-degree heart block (P-R interval ≥ 0.24 sec); systolic blood pressure <100 mm Hg; or moderate-to-severe cardiac failure.

Heart failure. Beta-blockers, like metoprolol tartrate, can cause depression of myocardial contractility and may precipitate heart failure and cardiogenic shock.

Use during 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.

Bradycardia. Bradycardia, including sinus pause, heart block, and cardiac arrest have occurred with the use of metoprolol tartrate. Patients with first-degree atrioventricular block, sinus node dysfunction, or conduction disorders may be at increased risk.

Exacerbation of bronchospastic disease. Patients with bronchospastic disease, should in general, not receive beta-blockers, including metoprolol tartrate.

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

Pheochromocytoma. Administration of beta-blockers alone in the setting of pheochromocytoma has been associated with a paradoxical increase in blood pressure due to the attenuation of beta-mediated vasodilatation in skeletal muscle.

Thyrotoxicosis. Metoprolol tartrate may mask certain clinical signs (e.g., tachycardia) of hyperthyroidism. Avoid abrupt withdrawal of beta blockade, which might precipitate a thyroid storm.

Risk of anaphylactic reactions. While taking beta-blockers, patients with a history of severe anaphylactic reaction to a variety of allergens may be more reactive to repeated challenge, either accidental, diagnostic, or therapeutic. Such patients may be unresponsive to the usual doses of epinephrine used to treat allergic reaction.

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

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

For oral use only. Avoid contact with eyes. Keep container tightly closed. Keep out of the 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®- Metoprolol Compounding Kits are available as follows:
10 FL OZ (300 mL) as dispensed (NDC 65628-220-10)
3 FL OZ (90 mL) as dispensed (NDC 65628-230-03)

* Certificate of analysis on file
** Data and documentation on file

Rx ONLY

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U.S. Patent Pending

Manufactured for:

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Grape Flavor

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REV 03