



Posicor advertisement.

[s.l.]: [s.n.], 1993

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NEW from Roche Laboratories...

ONCE-DAILY
Posicor[®]
mibefradil 2HCl 50-mg
100-mg
Tablets

For hypertension or angina

**The new tetralol class that
fits your cardiovascular
patients to a**



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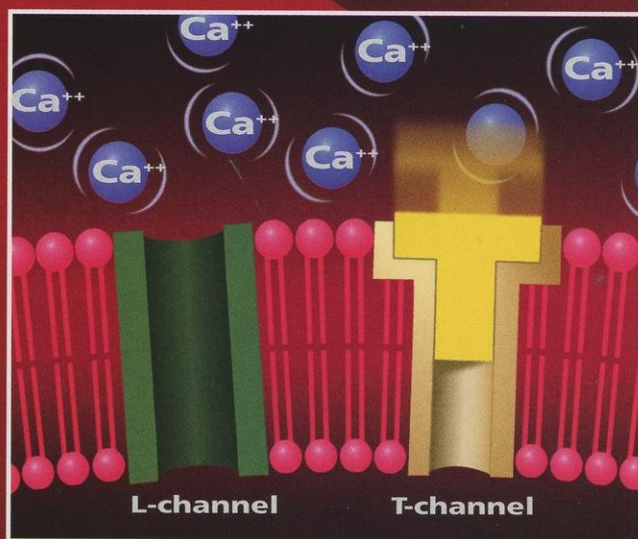
Pharmaceuticals

selectivi-T

of POSICOR

The first and only agent to selectively block T-type calcium channels^{*1}

- Current calcium antagonists act primarily on L-type calcium channels²
- T-type calcium channels are found in vascular smooth muscle cells, the sinoatrial node, Purkinje cells², and neurohormonal secretory cells³
- The first of a new class of calcium antagonist in 15 years,⁴ a tetralol derivative



Artist's rendition of T-channel blockade at smooth muscle cell membrane.

^{*}Based on animal and in vitro data, POSICOR has been shown to be a T-type calcium channel blocker; however, the clinical significance of this characteristic has not been established at this time.

References: 1. Mishra SK, Hermsmeyer K. Selective inhibition of T-type Ca^{2+} channels by RO 40-5967. *Circ Res.* 1994;75: 144-148. 2. Bean B. Pharmacology of calcium channels in cardiac muscle, vascular muscle, and neurons. *Am J Hypertens.* 1991;4:406S-411S. 3. Bean B. Classes of calcium channels in vertebrate cells. *Ann Rev Physiol.* 1989; 51:367-384. 4. IMS America.



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safety

of POSICOR

Well-tolerated safety profile

- The only calcium antagonist to induce a slight reduction in heart rate without a negative inotropic effect⁵ at therapeutic concentrations⁶
- Provides vasodilation without reflex tachycardia
- Safety regardless of age⁷, race, gender, and in patients with renal failure or diabetes, established in studies involving over 3400 patients

Coadministration of POSICOR with terfenadine, astemizole, or cisapride, and in patients with sick sinus syndrome or 2nd or 3rd degree AV block, without a pace-maker, is contraindicated.

Patients with a pretreatment heart rate below 50 bpm should be followed closely. As with all calcium channel blockers, caution should be exercised when treating patients with heart failure or compromised ventricular function. When POSICOR is coadministered with some drugs (e.g., quinidine, sotalol) it may be difficult to use serial ECGs for monitoring the effects of these other drugs.

References: 5. Frishman W. Calcium channel blockers. In: *Cardiovascular Pharmacotherapeutics*. New York, NY: McGraw-Hill Companies, Inc; 1997: chap 8. 6. Rousseau M, Hayashida W, van Eyck C, et al. Hemodynamic and cardiac effects of the selective T-type and L-type calcium channel blocking agent mibefradil in patients with varying degrees of left ventricular systolic dysfunction. *J Am Coll Cardiol*. 1996;28:972-979. 7. Bursztyn M, Kadr H, Tilvis R, et al. Mibefradil, a novel calcium antagonist, in elderly hypertensives: favorable hemodynamics and pharmacokinetics. Accepted for publication in *Am Heart J*.

Introducing the new tetralol class...

ONCE-DAILY

Posicor[®]
mibefradil 2HCl 50-mg
100-mg
Tablets

...in a class by itself

ability

effective management of hypertension

Unsurpassed antihypertensive efficacy

- Effective control of both systolic⁸ and diastolic⁹ blood pressure
- Consistent, smooth 24-hour control, including early morning hours^{9,10}

POSICOR vs Norvasc*

- Unsurpassed antihypertensive efficacy^{11,12} with significantly less leg edema (6.8% vs 16.7%, $P=0.011$)¹²

POSICOR vs Procardia XL†

- Unsurpassed antihypertensive efficacy^{13,14} with significantly less leg edema (3.2% vs 10.3%, $P=0.027$) and headache (0.8% vs 8.7%, $P=0.002$)¹³

POSICOR vs Cardizem CD‡

- Superior antihypertensive efficacy ($P<0.001$) with an unsurpassed side effect profile^{15,16}

* Norvasc (amlodipine besylate) is a registered trademark of Pfizer.

† Procardia XL (nifedipine GITS) is a registered trademark of Pfizer.

‡ Cardizem CD (diltiazem HCl) is a registered trademark of Hoechst Marion Roussel.

References: 8. Data on file (Ref. 074-007), Hoffmann-La Roche Inc., Nutley, New Jersey 07110. 9. Oparil S, Kobrin I, Abernethy D, et al. Dose-response characteristics of milbefradil, a novel calcium antagonist, in the treatment of essential hypertension. Accepted for publication in *Am J Hypertens*. 10. Schmitt R, Kleinbloesem C, Belz G, et al. Hemodynamic and humoral effects of the novel calcium antagonist RO 40-5967 in patients with hypertension. *Clin Pharmacol Ther*. 1992;52:314-323. 11. Viskoper R, Bernink P, Ziekenhuis M, et al. A randomized, double-blind trial comparing milbefradil and amlodipine: two long-acting calcium antagonists with similar efficacy but different tolerability profiles. Accepted for publication in *J Human Hypertens*. 12. Data on file (Ref. 074-008), Hoffmann-La Roche Inc., Nutley, New Jersey 07110. 13. Data on file (Ref. 074-009), Hoffmann-La Roche Inc., Nutley, New Jersey 07110. 14. Data on file (Ref. 074-010), Hoffmann-La Roche Inc., Nutley, New Jersey 07110. 15. Massie B, Chrysant S, Jain A, Weir M, Weiss R, Kobrin I. Antihypertensive effects of milbefradil: a double-blind comparison with diltiazem CD. *Clin Cardiol*. 1997;20:562-568. 16. Data on file (Ref. 074-015), Hoffmann-La Roche Inc., Nutley, New Jersey 07110.

Roche

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tolerability

comparable to placebo

Excellent tolerability profile at both doses

- Does not cause constipation¹⁷

Compare the tolerability of POSICOR to placebo

Adverse Event	Placebo (n=283)	POSICOR 50 mg (n=279)	POSICOR 100 mg (n=285)
Headache	6%	3%	8%
Leg Edema	3%	1%	4%
Rhinitis	0%	3%	3%
Abdominal Pain	1%	1%	2%
Light-headed Feeling	0%	1%	3%
Dyspepsia	1%	1%	2%

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Reference: 17. Data on file (Ref. 074-013), Hoffmann-La Roche Inc., Nutley, New Jersey 07110.

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