



 *Belay for Balance*



AZELIREN

Azelnidipine 8 mg and 16 mg Tablets

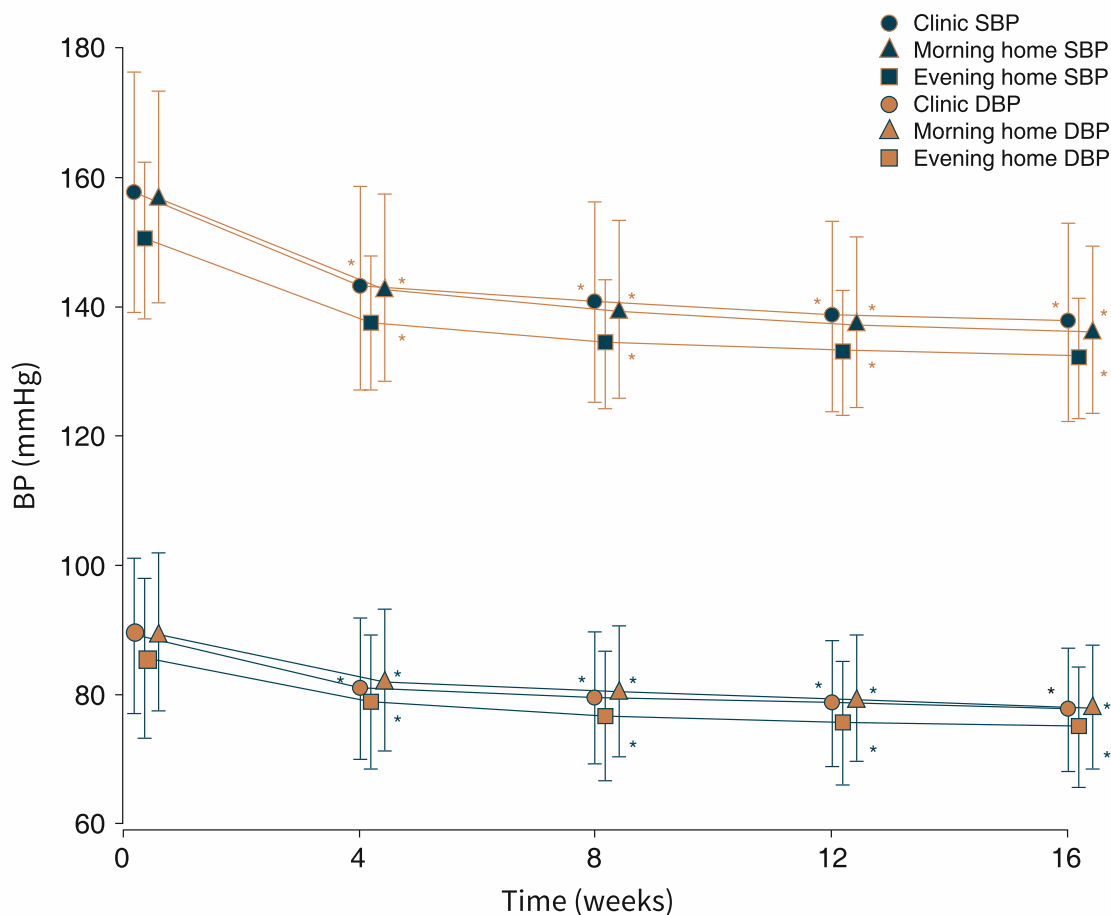


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EFFECTS OF AZELNIDIPINE ON MORNING HYPERTENSION

A total of 5,433 hypertensive patients were enrolled in the study. Data obtained from 4,852 of these patients were used for efficacy analysis.



Changes in clinic, morning home, and evening home blood pressure (BP) after azelnidipine treatment. * $p < 0.0001$ vs. baseline, according to Dunnett's test.

- After Azelnidipine treatment, clinic, morning home, and evening home BP measurements showed significant lowering of SBP and DBP by week 4 and persistence of the effect up to week 16. The mean SBP/DBP changes from baseline were $-18.7 \pm 19.9/-10.2 \pm 12.4$ mmHg (clinic), $-19.3 \pm 17.4/-10.2 \pm 10.8$ mmHg (morning home), and $-16.9 \pm 17.0/-9.4 \pm 10.6$ mmHg (evening home), and all improvements were significant.
- After azelnidipine treatment, pulse rates were also significantly lowered by week 4, and the effects persisted up to week 16.

Azelnidipine is one of the most useful antihypertensive drugs because of its reliable and persistent BP-lowering effects, in addition to its pulse rate-lowering effect.

AZELNIDIPINE AND AMLODIPINE: A COMPARISON OF THEIR EFFECTS AND SAFETY IN HYPERTENSIVE PATIENTS

Azelnidipine and amlodipine were administered at a dosage of 8–16 mg or 2.5–5 mg, once daily after breakfast.

Changes of blood pressure and pulse rate in azelnidipine or amlodipine group

		BASELINE	AFTER 8 WEEKS	Δ BP
Azelnidipine (n = 101)	SBP	149.63 ± 12.72	129.31 ± 10.56	−20.32 ± 13.08
	DBP	98.40 ± 3.18	85.52 ± 7.01	−12.88 ± 7.40
	PR	74.67 ± 6.55	73.57 ± 7.13	—
Amlodipine (n = 101)	SBP	149.32 ± 13.21	134.33 ± 11.65	−14.98 ± 14.62
	DBP	98.61 ± 3.54	88.81 ± 8.45	−9.79 ± 8.00
	PR	74.26 ± 8.26	73.18 ± 7.05	—

- The reductions of BP in the azelnidipine group were greater than amlodipine.

Fifty-six patients in total were enrolled in the ABPM study. Complete data were available in 40 of them, in which 19 were administered azelnidipine and 21 administered amlodipine.

Differences of Δ BP after treatment with azelnidipine or amlodipine

		AZELNIDIPINE (n = 19)	AMLODIPINE (n = 21)	P
24-h Average	Δ SBP	15.89 ± 7.20	4.67 ± 9.03	0.001
	Δ DBP	10.32 ± 5.57	4.14 ± 6.12	0.002
Day time	Δ SBP	14.47 ± 8.71	3.48 ± 10.12	0.001
	Δ DBP	9.68 ± 6.28	3.48 ± 6.20	0.005
Night time	Δ SBP	20.26 ± 7.28	7.71 ± 9.70	0.000
	Δ DBP	12.95 ± 7.11	5.43 ± 7.88	0.007

The 24-h average, day time and night time blood pressure reduction in the azelnidipine group were greater than in the amlodipine group.

Once-daily administration of azelnidipine effectively controlled blood pressure and had a stable action over 24 h. Azelnidipine had good safety and compliance similar to amlodipine.

Reference: Clin Exp Hypertens. 2010;32(6):372-6.

SBP: Systolic Blood Pressure, DBP: Diastolic Blood Pressure, PR: Pulse Rate



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DESCRIPTION:

AZELIREN (Azelnidipine) is a third-generation, new dihydropyridine calcium channel blocker (CCB) that is highly lipid soluble and has prolonged antihypertensive properties (its plasma half life is about 15–21 h).

INDICATION:

AZELIREN (Azelnidipine) is indicated for the treatment of Hypertension.

MECHANISM OF ACTION:

Azelnidipine reversibly blocks voltage-dependent Ca^{2+} influx through L-type calcium channels in the cell membrane. Normally, calcium induces smooth muscle contraction, contributing to hypertension. When calcium channels are blocked, the vascular smooth muscle does not contract, resulting in relaxation of vascular smooth muscle walls and decreased blood pressure.

DOSAGE:

- The normal dose for an adult is 8-16 mg of azelnidipine once daily, taken orally after breakfast. The maximum dosage is 16 mg/day.
- The initial dosage is to be 8 mg/day or less, to be adjusted as symptoms are monitored, up to 16 mg daily.

USP:



AZELIREN (Azelnidipine) has a gradual, long-lasting, and potent BP-lowering effect.

AZELIREN (Azelnidipine) significantly decreases Heart Rate in Hypertensive patients.

AZELIREN (Azelnidipine) significantly decreases Proteinuria in Hypertensive patients.

AZELIREN (Azelnidipine) has sustained action of lowering blood pressure over 24-hour period with once daily dose.

AZELIREN (Azelnidipine) treatment may have beneficial effects on glucose tolerance, insulin sensitivity and the inflammatory state.

Reference:

- 1) Hypertens Res Vol. 28, No. 12 (2005)
- 2) Journal of Diabetes Investigation Volume 4 Issue 2 March 2013
- 3) Drugs R D (2013) 13:75–85
- 4) Cardiovasc Diabetol. 2011; 10: 79.

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