Now available:

NEXICLON™ XR (clonidine) Extended-Release Suspension and Tablets, the first and only oral once-daily treatment that gradually releases clonidine over the course of the day.

NEXICLON XR (clonidine) is a central alpha-adrenergic agonist indicated for the treatment of hypertension and available in two unique extended-release formulations to suit the individual needs of patients:

- Scored tablets with 0.17 mg clonidine base
  - — Allows patients to split the tablet for more precise dose titration
- An oral suspension with 0.09 mg/mL clonidine base
  - — Ideal for patients who have difficulty taking pills or prefer taking liquid medications

Dosing guidelines:

Initial dose: 0.17 mg once daily
Elderly patients may benefit from a lower initial dose.

Initial dose is recommended to be administered at bedtime.

Maintenance dose: Increase in increments of 0.09 mg once daily at weekly intervals until the desired response is achieved.

Most commonly used therapeutic doses range from 0.17 mg to 0.52 mg once daily; doses higher than 0.52 mg are not recommended.

NEXICLON XR is supplied as clonidine base and contains the same active moiety (clonidine) that is found in Catapres® Tablets (clonidine hydrochloride immediate-release tablets). The recommended dose of NEXICLON XR for patients who are currently taking clonidine hydrochloride immediate-release tablets is provided in the table below. The dose of NEXICLON XR must be adjusted according to the patient's individual blood pressure response. Dose adjustments may be made at weekly intervals until the desired response is achieved.

	NEXICLON XR Extended-Release Oral Suspension 0.09 mg/mL	NEXICLON XR Extended-Release Tablets 0.17 mg	Equivalent Dose of Catapres® (clonidine HCl) Immediate-Release Tablets
Initial Dose	0.17 mg (2 mL) once daily	0.17 mg (1 x 0.17 mg tablet) once daily	0.1 mg twice daily
Maintenance Dose Titration Increments	0.09 mg (1 mL) once daily	0.09 mg (1/2 x 0.17 mg tablet) once daily	0.05 mg twice daily
Common Doses Used for Blood Pressure Effect	0.17 mg (2 mL) once daily	0.17 mg (1 x 0.17 mg tablet) once daily	0.1 mg twice daily
	0.34 mg (4 mL) once daily	0.34 mg (2 x 0.17 mg tablet) once daily	0.2 mg twice daily
	0.52 mg (6 mL) once daily	0.52 mg (3 x 0.17 mg tablet) once daily	0.3 mg twice daily

Each mL of NEXICLON XR Oral Suspension contains 0.087 mg of clonidine base. For labeling purposes, the description of the concentration has been rounded off to 0.09 mg/mL. For example, a 2 mL dose of NEXICLON XR Oral Suspension contains 0.174 mg of clonidine, which has been rounded off to a dose description of 0.17 mg.

NEXICLON™ XR (clonidine)

Please see accompanying Full Prescribing Information or visit www.nexiclonxr.com for additional product information.

INDICATION

NEXICLON™ XR (clonidine) Extended-Release Oral Suspension and NEXICLON™ XR (clonidine) Extended-Release Tablets are indicated in the treatment of hypertension. NEXICLON XR may be employed alone or concomitantly with other antihypertensive agents.

IMPORTANT SAFETY CONSIDERATIONS

Contraindications

NEXICLON XR should not be used in patients with known hypersensitivity to clonidine (rash, angioedema).

Warnings and Precautions

Patients should not discontinue therapy without consulting a physician. Dose reduction should be performed gradually over a 2- to 4-day period to avoid withdrawal symptomatology. Rare instances of hypertensive encephalopathy, cerebrovascular accidents, and death have been reported after clonidine withdrawal.

Monitor closely and titrate slowly in patients with severe coronary insufficiency, conduction disturbances, recent myocardial infarction, cerebrovascular disease, or chronic renal failure.

Patients who engage in potentially hazardous activities, such as operating machinery or driving, should be advised of a possible sedative effect of clonidine.

In perioperative use, NEXICLON XR may be administered up to 28 hours prior to surgery and resumed the following day.

Adverse Reactions

There is very little experience with NEXICLON XR in controlled trials Based on this limited experience, the adverse event profile of NEXICLON XR appears similar to that of immediate-release clonidine formulation. The most commonly expected adverse reactions are dry mouth, drowsiness, and dizziness.

Drug Interactions

No drug interaction studies have been conducted with NEXICLON XR; however the following have been reported with other oral formulations of clonidine:

- Clonidine may potentiate the CNS-depressive effects of alcohol, barbiturates, or other sedating drugs.
- Tricyclic antidepressants may reduce the hypotensive effect of clonidine, necessitating an increase in clonidine dose.
- Drugs known to affect sinus node function or AV nodal conduction (e.g., digitalis, calcium channel blockers, and beta-blockers): There may be additive effects such as bradycardia and AV block.

Use in Specific Populations

Pregnancy Category C. Clonidine is secreted in human milk.
Safety and effectiveness in pediatric patients have not been established.
Dose may need adjustment in patients with renal impairment. Elderly patients may benefit from a lower initial dose.

Please see Full Prescribing Information for additional product information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.