CROSTEEN

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Atorvastatin Calcium Tablets

COMPOSITION

CROSTEEN-10

Each film-coated tablet contains:
Atorvastatin calcium
equivalent to Atorvastatin…… 10 mg

INDICATIONS

Therapy with lipid-altering agents should be only one component of multiple risk factor intervention in individuals at significantly increased risk for atherosclerotic vascular disease due to hypercholesterolemia. Drug therapy is recommended as an adjunct to diet when the response to a diet restricted in saturated fat and cholesterol and other non pharmacologic measures alone has been inadequate. In patients with CHD or multiple risk factors for CHD, atorvastatin can be started simultaneously with diet.

- **Prevention of Cardiovascular Disease**
  In adult patients without clinically evident CHD, but with multiple risk factors for CHD such as age, smoking, hypertension, low HDL-C, or a family history of early CHD,**CROSTEEN** is indicated to:
  - Reduce the risk of myocardial infarction
  - Reduce the risk of stroke
  - Reduce the risk for revascularization procedures and angina

In patients with type 2 diabetes, and without clinically evident CHD, but with multiple risk factors for CHD such as retinopathy, albuminuria, smoking, or hypertension, **CROSTEEN** is indicated to:

- Reduce the risk of myocardial infarction
- Reduce the risk of stroke

In patients with clinically evident CHD, **CROSTEEN** is indicated to:

- Reduce the risk of non-fatal myocardial infarction
- Reduce the risk of fatal and non-fatal stroke
- Reduce the risk for revascularization procedures
- Reduce the risk of hospitalization for CHF
- Reduce the risk of angina

- **Hypercholesterolemia**

CROSTEEN is indicated:

As an adjunct to diet to reduce elevated total cholesterol, LDL-cholesterol, apo B and triglyceride levels and to increase HDL-C in patients with primary hypercholesterolaemia (heterozygous familial and nonfamilial) and mixed dyslipidaemia (Fredrickson Types IIa and IIb).

- As adjunctive therapy to diet for the treatment of patients with elevated serum triglyceride levels (Fredrickson Type IV).
- For the treatment of patients with primary dysbetalipoproteinaemia (Fredrickson Type III) who do not respond adequately to diet.
- To reduce total cholesterol and LDL-C in patients with homozygous familial hypercholesterolaemia as an adjunct to other lipid lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable.
- As an adjunct to diet to reduce total cholesterol, LDL-C and apo B levels in boys and menarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolaemia, if after an adequate trial of diet therapy, the following findings are present:
  - LDL-C remains ≥ 190 mg/dl or
  - LDL-C remains ≥ 160 mg/dl and
    - there is a positive family history of premature cardiovascular disease or
    - two or more other cardiovascular disease (CVD) risk factors are present in the pediatric patient

Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol only when the response to diet and other nonpharmacological measures has been inadequate [see National Cholesterol Education Program (NCEP) Guidelines, summarized in the table below].

TABLE. NCEP GUIDELINES FOR LIPID MANAGEMENT .

Risk category	LDL goal (mg/dl)	LDL level at which to consider drug therapy (mg/dl)
CHD or CHD risk equivalents* (10-yr risk>20%)	<100	≥ 130 (100-129: drug optional)
2+ risk factors ** (10-yr risk ≤ 20%)	<130	10-yr risk 10%-20%: ≥ 130 10-yr risk <10%: ≥ 160
0-1 risk factor **	<160	≥ 190 (160-189; LDL-lowering drug optional)

*Coronary heart disease or peripheral vascular disease (including symptomatic carotid artery disease).

** Other risk factors for CHD include: age (males ≥ 45 years, females ≥ 55 years or premature menopause without estrogen replacement therapy); family history of premature CHD; current cigarette smoking; hypertension, confirmed HDL-C ≤ 40 mg/dL (≤ 0.91 mmol/L); and diabetes mellitus. Subtract 1 risk factor if HDL-C is ≥ 60 mg/dL (≥ 1.6 mmol/L).

After the LDL-C goal has been achieved, if the triglyceride level is still ≥ 200 mg/dl, non HDL-C (total cholesterol minus HDL-C) becomes a secondary target of therapy. Non HDL-C goals are set 30 mg/dl higher than LDL-C goals for each risk category.

Prior to initiating therapy with atorvastatin, secondary causes for hypercholesterolemia (e.g., poorly controlled diabetes mellitus, hypothyroidism, nephrotic syndrome, dysproteinemias, obstructive liver disease, other drug therapy, and alcoholism) should be excluded, and a lipid profile performed to measure total-C, LDL-C, HDL-C, and TG. For patients with TG <400 mg/dL (<4.5 mmol/L), LDL-C can be estimated using the following equation: LDL-C = total-C - (0.20 × [TG] + HDL-C). For TG levels >400 mg/dL (>4.5 mmol/L), this equation is less accurate and LDL-C concentrations should be determined by ultracentrifugation.

DOSAGE AND ADMINISTRATION

The patient should be placed on a standard cholesterol-lowering diet before receiving atorvastatin and should continue on this diet during treatment with atorvastatin.

- **Hypercholesterolaemia (Heterozygous Familial and Nonfamilial) and Mixed Dyslipidaemia (Fredrickson Types IIa and IIb)**
  The recommended starting dose of atorvastatin is 10 or 20 mg once daily. Patients who require a large reduction in LDL (more than 45%) may be started at 40 mg once daily. The dosage range is 5 to 80 mg once daily. Atorvastatin can be administered as a single dose at any time of the day, with or without food. Therapy should be individualized according to the goal of therapy and response. After initiation and/or up-titration of atorvastatin, lipid levels should be analysed within 2 to 4 weeks and the dosage adjusted accordingly.
- **Heterozygous Familial Hypercholesterolaemia in Pediatric Patients (10-17 years of age)**
  The recommended starting dose of atorvastatin is 10 mg/day; the maximum recommended dose is 20 mg/day (doses greater than 20 mg have not been studied in this patient population). Doses should be individualized according to the recommended goal of therapy. Adjustments should be made at intervals of 4 weeks or more.
- **Homozygous Familial Hypercholesterolaemia**
  The dosage of atorvastatin in these patients is 10 to 80 mg daily. Atorvastatin should be used as an

adjunct to other lipid-lowering treatments (eg LDL apheresis) in these patients or if such treatments are unavailable.

- Concomitant Lipid Lowering Therapy
  Atorvastatin may be used in combination with a bile acid binding resin for additive effect. The combination of HMG-CoA reductase inhibitors and fibrates should generally be avoided.
- Dosage in patients with Renal Insufficiency
  Renal disease does not affect the plasma concentrations nor LDL-C reduction of atorvastatin; thus, dosage adjustment in patients with renal dysfunction is not necessary.
- **Dosage in Patients Taking Cyclosporine, Clarithromycin or a combination of Ritonavir plus Saquinavir or Lopinavir plus Ritonavir**
  In patients taking cyclosporine, therapy should be limited to **CROSTEEN-10** once daily. In patients taking clarithromycin or in patients with HIV taking a combination of ritonavir plus saquinavir or lopinavir plus ritonavir, for doses of atorvastatin exceeding 20 mg appropriate clinical assessment is recommended to ensure that the lowest dose necessary of atorvastatin is employed.

CONTRAINDICATIONS

- Hypersensitivity to any component of this medication
- Active liver disease or unexplained persistent elevations of serum transaminases exceeding three times the upper limit of normal
- Pregnancy and Lactation

PACKAGING INFORMATION

CROSTEEN-10 BLISTER of 10 tablets

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