

Front

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

ATORVASTATIN CALCIUM TABLETS USP 10 MG ATRONA-10

Each Film Coated Tablet Contains:

Atorvastatin Calcium USP

Eq. to Atorvastatin 10 mg

Excipients q.s.

Colours Titanium Dioxide

ATORVASTATIN CALCIUM TABLETS USP 20 MG ATRONA-20

Each Film Coated Tablet Contains:

Atorvastatin Calcium USP

Eq. to Atorvastatin 20 mg

Excipients q.s.

Colours Titanium Dioxide

ATORVASTATIN CALCIUM TABLETS USP 40 MG ATRONA-40

Each Film Coated Tablet Contains:

Atorvastatin Calcium USP

Eq. to Atorvastatin 40 mg

Excipients q.s.

Colours Titanium Dioxide

PHARMACOLOGY: Atorvastatin is a competitive inhibitor of HMG-CoA reductase. It is a completely synthetic compound. HMG-CoA reductase catalyzes the reduction of 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) to mevalonate, which is the rate-limiting step in hepatic cholesterol biosynthesis. Inhibition of the enzyme decreases de novo cholesterol synthesis, increasing expression of low-density lipoprotein receptors (LDL receptors) on hepatocytes. This increases LDL uptake by the hepatocytes, decreasing the amount of LDL-cholesterol in the blood. Like other statins, atorvastatin also reduces blood levels of triglycerides and slightly increases levels of HDL-cholesterol.

INDICATIONS: ATRONA belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines.

ATRONA is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed. If you are at an increased risk of heart disease, ATRONA can also be used to reduce such risk even if your cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.

RECOMMENDED DOSAGE:

The recommended starting dose of Atorvastatin tablets is 10 or 20 mg once daily.

The maximum dose of Atorvastatin tablets is 80 mg once daily for adults and 20 mg once daily for children.

CONTRAINDICATIONS:

The following medicines are known to interact with Atorvastatin in your body:

- 1. Medicines used to alter the way your immune system works, e.g. ciclosporin
- 1. Certain antibiotics or antifungal medicines, e.g. erythromycin, clarithromycin, telithromycin, ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, rifampin, fusidic acid
- 1. Other medicines to regulate lipid levels, e.g. gemfibrozil, other fibrates, colestipol
- 1. Some calcium channel blockers used for angina or high blood pressure, e.g. amlodipine, diltiazem,; medicines to regulate your heart rhythm e.g. digoxin, verapamil, amiodarone
- 1. Medicines used in the treatment of HIV e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir, the combination of tipranavir/ritonavir etc.

Side

- 1. Some medicines used in the treatment of hepatitis C e.g. telaprevir
- 1. Other medicines known to interact with ATRONA include ezetimibe (which lowers cholesterol), warfarin (which reduces blood clotting), oral contraceptives, stiripentol (an anti-convulsant forepilepsy), cimetidine (used for heartburn and peptic ulcers), phenazone (a painkiller), colchicines (used to treat gout) and antacids (indigestion products containing aluminium or magnesium)
- 1. Medicines obtained without a prescription: St John's Wort

ADVERSE REACTIONS:

Stop taking Atorvastatin and call your doctor at once if you have any of these serious side effects:

Unexplained muscle pain, tenderness, or weakness; confusion, memory problems; fever, unusual tiredness, and dark colored urine; swelling, weight gain, urinating less than usual or not at all; increased thirst, increased urination, hunger, dry mouth, fruity breath odor, drowsiness, dry skin, blurred vision, weight loss; or nausea, upper stomach pain, itching, loss of appetite, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes).

Less serious side effects may include:

Mild muscle pain; diarrhea; or mild nausea.

WARNING AND PRECAUTIONS:

Do not use Atorvastatin without the advice of a doctor:

- 1. If you have had a previous stroke with bleeding into the brain, or have small pockets of fluid in
- 1. The brain from previous strokes
- 1. If you have kidney problems
- 1. If you have an under-active thyroid gland (hypothyroidism)
- 1. If you have had repeated or unexplained muscle aches or pains, a personal history or family
- 1. History of muscle problems
- 1. If you have had previous muscular problems during treatment with other lipid-lowering
- 1. Medicines (e.g. other '-statin' or '-fibrate' medicines)
- 1. If you regularly drink a large amount of alcohol
- 1. If you have a history of liver disease
- 1. If you are older than 70 years.

Pregnancy and breast-feeding:

- 1. Do not take ATRONA if you are pregnant, or if you are trying to become pregnant.
- 1. Do not take ATRONA if you are able to become pregnant unless you use reliable contraceptive measures.
- 1. Do not take ATRONA if you are breast-feeding.

Driving and using machines:

- 1. Normally this medicine does not affect your ability to drive or operate machines.

SYMPTOMS OF OVER-DOSAGE AND ITS TREATMENT:

If you take too many tablets by mistake then consult your doctor.

STORAGE: Store below 30°C. Protect from Moisture.

Keep all medicines out of reach of children.

- PRESENTATION:**
1. ATRONA-10 : An Alu-Alu Blister of 10 Tablets.
 2. ATRONA-20 : An Alu-Alu Blister of 10 Tablets.
 3. ATRONA-40 : An Alu-Alu Blister of 10 Tablets.

Mfg. Lic. No.: G/25/1905

MANUFACTURED BY:

 **zota**
healthcare ltd.

Plot No. 169, Surat Special Economic Zone,
Sachin, Surat-394 230. (Gujarat), India.

ZHPS207R00



ATRONA 40
(Atorvastatin Calcium Tablets USP 40mg)

RWANDA SUBMISSION

Module - 1

1.4.4 Mock-ups and Specimens

- Enclosed.

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