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۱×۱۰ گولیاں

زیٹیب®

ایزیٹیمائب ۱۰ ملی گرام

اینٹی ھائپرلپیڈیمک

خوراک:
زیٹیب کی تجویز کردہ خوراک ایک گولی روزانہ ہے جو کہ دن میں کسی بھی وقت کھانے کے ساتھ یا کھانے کے بغیر لی جا سکتی ہے۔

بچوں کے لیے:
ڈاکٹری ہدایات کے مطابق استعمال کریں۔

ھدایات:
* دوا کو خشک اور ٹھنڈی جگہ پر رکھیں۔
* دوا کو گرمی، روشنی اور نمی سے محفوظ رکھیں۔
* دوا صرف ڈاکٹری نسخہ کے مطابق استعمال کریں۔
* تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

پیشکش:
زیٹیب ۱۰ ملی گرام گولیاں (۱×۱۰) الیو۔ایلو سٹرپ پیک میں دستیاب ہیں۔

Manufactured by:
Schazoo Zaka (Pvt) Ltd.
Lalpur Wala, 20-Km Lahore-Jaranwala Road,
Distt. Sheikhupura, Pakistan.

Zetab®

1 x 10 Tablets

Ezetimibe 10 mg

COMPOSITION:
Each tablet contains:
Ezetimibe Sch. Specs. 10mg

CLINICAL PHARMACOLOGY:
Mechanism of action:
Ezetimibe is lipid lowering compound that selectively inhibits the intestinal absorption of cholesterol and related phytosterols. Ezetimibe has a mechanism of action that differs from those of other classes of cholesterol reducing compounds (HMG-CoA reductase inhibitors, bile acid sequestrants (resins), fibric acid derivatives, and plant stanols).
Ezetimibe does not inhibit cholesterol synthesis in the liver, or increase bile acid excretion. Instead, ezetimibe localizes and appears to act at the brush border of the small intestine and inhibits the absorption of cholesterol, leading to a decrease in the delivery of intestinal cholesterol to the liver. This causes a reduction of hepatic cholesterol stores and an increase in clearance of cholesterol from the blood; this distinct mechanism is complementary to that of HMG-CoA reductase inhibitors.

Pharmacokinetics:
- **Absorption:** After oral administration, ezetimibe is absorbed and extensively conjugated to a pharmacologically active phenolic glucuronide (ezetimibe-glucuronide). After a single 10mg dose of ezetimibe to fasted adults, mean ezetimibe peak plasma concentration (C_{max}) of 3.4 to 5.5ng/ml were attained within 4 to 12 hours (T_{max}). Ezetimibe-glucuronide mean C_{max} values of 45 to 71ng/ml were achieved between 1 to 2 hours (T_{max}). There was no substantial deviation from dose proportionality between 5 and 20mg.
- **Distribution:** Ezetimibe and ezetimibe-glucuronide are highly bound (>90%) to human plasma proteins.
- **Metabolism and Excretion:** Ezetimibe is primarily metabolized in the small intestine and liver via glucuronide conjugation (a phase II reaction) with subsequent biliary and renal excretion. Ezetimibe and ezetimibe-glucuronide are the major drug derived compounds detected in plasma, constituting approximately 10% to 20% and 80% to 90% of the total drug in plasma respectively. Both ezetimibe and ezetimibe-glucuronide are slowly eliminated from plasma with a half-life of approximately 22 hours for both ezetimibe and ezetimibe-glucuronide.

INDICATIONS:
Primary Hypercholesterolemia:
Ezetimibe, administered with an HMG-CoA reductase inhibitor (statin) or

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alone, is indicated as adjunctive therapy to diet for the reduction of elevated total cholesterol, low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo-B) and triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C) in patients with primary (heterozygous familial and non-familial) hypercholesterolemia.

Homozygous Familial Hypercholesterolemia (HoFH):
Ezetimibe, administered with a statin, is indicated for the reduction of elevated total-C and LDL-C levels in patients with HoFH. Patients may also receive adjunctive treatment (e.g. LDL apheresis).

Homozygous Sitosterolemia (Phytosterolemia):
Ezetimibe is indicated for the reduction of elevated sitosterols and campesterol levels in patients with homozygous familial sitosterolemia.

DOSAGE & ADMINISTRATION:
The patient should be on an appropriate lipid-lowering diet and should continue on this diet during treatment with **Zetab**.
The recommended dose of **Zetab** is 1 tablet (10mg) once daily, used alone or with a statin. **Zetab** can be administered at any time of the day, with or without food.

Use in Elderly:
No dosage adjustment is required for elderly patients.

Use in Pediatric Patients:
Children and adolescents >10 years: No dosage adjustment is required.
Children <10 years: Treatment with **Zetab** is not recommended.

Use in Hepatic Impairment:
No dosage adjustment is required in patients with mild hepatic insufficiency. Treatment with **Zetab** is not recommended in patients with moderate or severe liver dysfunction.

Use in Renal Impairment:
No dosage adjustment is required in patients with Renal Impairment.

Co-administration with bile acid sequestrants:
Dosing of **Zetab** should occur either > 2 hours before or > 4 hours after administration of a bile acid sequestrant.

Hepatic insufficiency: Due to unknown effects of the increased exposure to ezetimibe in patients with moderate or severe hepatic insufficiency, ezetimibe is not recommended in these patients.
Liver enzymes: When ezetimibe is co-administered with an HMG-CoA reductase inhibitor, liver function tests should be performed at initiation of therapy and according to the recommendations of the HMG-CoA reductase inhibitor.

PREGNANCY & LACTATION:
Zetab should be given in Pregnancy and Lactation only if the potential benefit justifies the potential risk to the fetus.

DRUG INTERACTIONS:
Ezetimibe has no significant effect on a series of probe drugs (caffeine, dextromethorphan, tolbutamide, and IV midazolam) known to be metabolized by cytochrome P450.
Antacids: A single dose of antacid administration has no significant effect on the oral bioavailability of total ezetimibe.
Fenofibrate: Concomitant administration of fenofibrates increase the mean Cmax and AUC values of total ezetimibe approximately 64% and 48%, respectively.
Pharmacokinetics of fenofibrate were not significantly affected by ezetimibe (10mg once daily).
Cholestyramine: Concomitant administration of cholestyramine decrease the mean AUC values of total ezetimibe and ezetimibe approximately 55% and 80%, respectively.
Warfarin: Concomitant administration of ezetimibe (10mg) has no significant effect on bioavailability of warfarin and prothrombin.
Digoxin: Concomitant administration of ezetimibe (10mg) has no significant effect on bioavailability of digoxin and the ECG parameters.
HMG-CoA Reductase inhibitors: Concomitant administration of ezetimibe (10mg) has no significant effect on bioavailability of atorvastatin, simvastatin, pravastatin, lovastatin, or fluvastatin.

SIDE EFFECTS:
Zetab is generally well-tolerated. Adverse reactions have usually been mild and transient. The most frequent adverse effects are fatigue, abdominal pain, sinusitis, diarrhea, pharyngitis, back pain, arthralgia, and coughing.

OVERDOSAGE:
In case of overdosage, treatment should be symptomatic and supportive.

STORAGE CONDITIONS:
* Store in a cool and dry place.
* Protect from heat, light and moisture.
* Keep all medicines out of the reach of children.

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