

SIMVA

(Simvastatin) Tablets, USP

COMPOSITION:

Each film coated tablet contains: Simvastatin USP ... 10mg.
Each film coated tablet contains: Simvastatin USP ... 20mg.
[USP Specs.]

DESCRIPTION: SIMVA (Simvastatin) is a lipid-lowering agent derived synthetically from a fermentation product of aspergillus terreus.

INDICATIONS: In patient with coronary heart disease, it reduces the risk of coronary death and non-fatal myocardial infarction. It is also indicated in the treatment of hypercholesterolemia particularly in type IIa and IIb.

ADVERSE EFFECTS: SIMVA is generally well-tolerated. The most common adverse effect of therapy is gastro-intestinal disturbance. Other adverse effects include headache, skin rashes, dizziness, blurred vision, insomnia and dysgeusia. Reversible increase in serum-aminotransferase concentration may occur so liver function should be monitored.

DRUG INTERACTIONS: There is an increased risk of myopathy if certain drugs such as immunosuppressants, fibric acid derivatives or nicotinic acid are given concurrently. Increase bleeding time and increase in prothrombin time have been reported in patients taking simvastatin with coumarin anticoagulants.

PRECAUTIONS: SIMVA should not be used in

- 1) acute liver disease.
- 2) Unexplained persistent raised serum-aminotransferase concentration.
- 3) Pregnancy 4) Severe renal impairment.

DOSAGE AND ADMINISTRATION: The patient should be put on a standard low cholesterol diet before starting SIMVA. It is given in an initial dose of 5mg to 10mg at night. The dose may be adjusted at intervals of not less than 4 weeks upto maximum of 40mg once daily at night.

CORONARY HEART DISEASE: Starting dose is 20mg/day as a single dose in evening. If low density lipoprotein cholesterol level falls below 75mg/dl or total cholesterol level falls below 140mg/dl consideration should be given to reducing the dose of the SIMVA.

HYPERLIPIDEMIA: Initial dose is 10mg/day as a single dose in the evening. For mild to moderate hypercholesterolemia the initial dose is 5mg/day.

CONCOMITANT THERAPY: SIMVA is effective alone or in combination with bile acid sequestrants.

RENAL INSUFFICIENCY: Because SIMVA does not undergo significant renal excretion, adjustment of dose is not necessary in patient with renal insufficiency. In patient with severe renal insufficiency (creatinine clearance <30ml/min) dosage above 10mg/day should be carefully considered.

INSTRUCTIONS: Store below 30° C. Protect from heat, light and moisture. Keep out of the reach of children.

PRESENTATION: SIMVA (Simvastatin) tablets 10mg & 20mg are available in blister pack of 10's x 2.

سموا ٹیبلیٹس
(سمواسٹاٹن)

اجزاء ترکیب: سموا ٹیبلیٹس میں 10 ملی گرام یا 20 ملی گرام سمواسٹاٹن فی ٹیبلیٹ ہے۔
فوائد: سموا ٹیبلیٹس میں بڑھتے ہوئے کولیسٹرول کی مقدار کو کم کرتی ہے۔

خوراک اور طریقہ استعمال:

بالغ افراد: عمومی خوراک 5 سے 10 ملی گرام روزانہ ہے جو رات کے وقت لینی چاہئے۔ بچوں میں سموا کا استعمال ممنوع ہے۔
احتیاط: حاملہ خواتین اور دودھ پلانے والی مائیں سموا کا استعمال نہ کریں۔ ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات: 3 ماہ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
طریقہ فراہمی: سموا 10 ملی گرام اور 20 ملی گرام ٹیبلیٹس کے بیسٹریک میں دستیاب ہے۔



Manufactured by:
NABIQASIM INDUSTRIES (PVT.) LTD.
17/24, Korangi Industrial Area, Karachi-Pakistan.

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