APPROVED PATIENT INFORMATION LEAFLET: SIMVASTATIN 10/20/40 mg AUSTELL

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM

SIMVASTATIN 10 mg AUSTELL TABLETS

SIMVASTATIN 20 mg AUSTELL TABLETS

SIMVASTATIN 40 mg AUSTELL TABLETS

Read all of this leaflet carefully before you start taking this medicine.

- **Keep this leaflet. You may need to read it again.**
- **If you have further question, please ask your doctor or your pharmacist.**
- **This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

WHAT SIMVASTATIN AUSTELL CONTAINS

Simvastatin 10 mg Austell:

Each film coated tablet contains simvastatin 10 mg.

Simvastatin 20 mg Austell:

Each film coated tablet contains simvastatin 20 mg.

Simvastatin 40 mg Austell:

Each film coated tablet contains simvastatin 40 mg.

The tablets contain the following as preservatives:

Butylated hydroxytoluene 0.02% m/m

Ascorbic acid 2.04 % m/m.

The other ingredients are lactose, maize starch, pregelatinised starch, sodium starch glycollate, colloidal silicon dioxide, butylated hydroxy toluene, isopropyl alcohol, citric acid monohydrate, ascorbic acid, purified water, microcrystalline cellulose, magnesium stearate, hypromellose, purified talc, titanium dioxide, ferric oxide yellow, ferric oxide red & polyethylene glycol (PEG 400).

WHAT SIMVASTATIN AUSTELL IS USED FOR

SIMVASTATIN AUSTELL is indicated in patients with established coronary heart disease and hypercholesterolaemia unresponsive to diet.

BEFORE TAKING SIMVASTATIN AUSTELL

Do not take SIMVASTATIN AUSTELL tablets:

- If you are hypersensitive to Simvastatin or any other ingredients present in the tablet.
- If you suffer from liver diseases
- If your serum amino transferase concentration is raised.
- If you suffer from renal impairment
- You have rare inherited disease called porphyria

Warnings:

The active metabolite of SIMVASTATIN AUSTELL is fetotoxic and teratogenic in rats, and it should therefore not be used in female patients of child-bearing potential. Use in paediatric patients is not recommended, as safety and efficacy have not been established.

Interactions:

"If you are taking other medicines on a regular basis, concomitant use of the medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional, for advice"

"If you are pregnant or breast feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice"

Please consult your doctor or a pharmacist if you are taking any of the following:

- Cyclosporine, itraconazole, ketoconazole, erythromycin, clarithromycin, HIV protease inhibitors, and nefazodone.
- Fibric acid derivatives or Nicotinic acid.
- Coumarin anticoagulants
- Mibefradil

Also tell your doctor about all other medicines you are taking, including non-prescription medicines, nutritional supplements, or herbal products. Also tell your prescriber or health care professional if you are a frequent user of drinks with caffeine or alcohol, if you smoke, or if you use illegal drugs. These may affect the way your medicine works. Check with your health care professional before stopping or starting any of your medicines

HOW TO TAKE SIMVASTATIN AUSTELL

The patient must follow a cholesterol-lowering diet before initiation of, and while on SIMVASTATIN AUSTELL therapy.

Hypercholesterolaemia

Adults: Initial dose: 10 mg daily as a single dose in the evening.

The dose of SIMVASTATIN AUSTELL_should be reduced if LDL-cholesterol levels fall below 1.94 mmol/l, or total plasma cholesterol levels fall below 3,6 mmol/l.

Coronary heart disease

Adults: Initial dose: 20 mg/day as a single dose in the evening.

Dosage adjustments:

If required, the dose should be adjusted at intervals of not less than 4 weeks, up to a maximum of 80 mg daily as a single dose in the evening.

SIMVASTATIN AUSTELL can be taken with meals or on an empty stomach.

Dosage in renal insufficiency

does not undergo significant renal excretion, therefore modification SIMVASTATIN AUSTELL of dose should be necessary with mild to moderate renal insufficiency. In patients with severe renal insufficiency SIMVASTATIN AUSTELL therapy should be closely monitored and doses above 10 mg/day should be implemented with caution

Concomitant therapy

SIMVASTATIN AUSTELL is effective alone or in combination with bile acid sequestrants. When both medicines are prescribed, SIMVASTATIN AUSTELL should be given 1 hour before or 4 hours after cholestyramine administration (See INTERACTIONS). A maximum daily dose of 10 mg SIMVASTATIN AUSTELL is recommended in patients taking cyclosporine, fibrates or niacin concomitantly (See INTERACTIONS).

"Do not share medicines prescribed for you with others"

"In the event of over dosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control center"

POSSIBLE SIDE EFFECTS

"Not all side-effects reported for this medicine are included in this leaflet. If your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice"

If any of the following happen, stop taking Simvastatin tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

Gastro-intestinal

Constipation, diarrhoea, nausea, vomiting, flatulence, dyspepsia, abdominal pain, cramps and pancreatitis.

Haematological

Anaemia, neutropenia.

Skin and appendages

Skin rash, alopecia.

Musculoskeletal

- *Frequent*: Myalgia, muscle cramps.
- *Less Frequent*: Myopathy, myositis, rhabdomyolysis presenting as muscle pain with elevated creatine phosphokinase and myoglobinuria leading to renal failure.

Neurological

Headache, dizziness, fatigue, aesthaenia, paraesthesia, peripheral neuropathy.

Hypersensitivity reactions

Less frequent: reactions may include angioedema, lupus-like syndrome, polymyalgia rheumatica, vasculitis, thrombocytopenia, increased erythrocyte sedimentation rate,

eosinophilia, arthritis, arthralgia, urticaria, photosensitivity, fever, flushing, malaise and dyspnoea. Other Mass gain has been reported.

STORING AND DISPOSING OF SIMVASTATIN AUSTELL

Keep this medicine in a dry place at or below 25 °C.

Keep blister packs in carton until required for use.

Do not transfer the medicine to any other container.

If your doctor tells you to stop the treatment, return any left over to the pharmacist.

Do not share medicines prescribed for you with others.

"KEEP ALL MEDICINES OUT OF REACH OF CHILDREN."

PRESENTATION OF SIMVASTATIN AUSTELL

SIMVASTATIN 10 mg AUSTELL:

Blister packs (White opaque PVDC coated PVC film and Aluminium foil) of 3 x 10 or 2 x 14 tablets.

SIMVASTATIN 20 mg AUSTELL:

Blister packs (White opaque PVDC coated PVC film and Aluminium foil) of 3 x 10 or 2 x14 tablets.

SIMVASTATIN 40 mg AUSTELL:

Blister packs (White opaque PVDC coated PVC film and Aluminium foil) of 3 x 10 or 2 x 14 tablets.

IDENTIFICATION OF SIMVASTATIN AUSTELL

SIMVASTATIN 10 mg AUSTELL:

Pinkish Brown, oval, biconvex, film-coated tablets with ‘BL’ embossing on one side and ‘10’ embossing on the other side.

SIMVASTATIN 20 mg AUSTELL:

Peach coloured, oval, biconvex, film-coated tablets with ‘BL’ embossing on one side and ‘20’ embossing on the other side.

SIMVASTATIN 40 mg AUSTELL:

Dull pink coloured, oval, biconvex, film-coated tablets with ‘BL’ embossing on one side and ‘40’ embossing on the other side.

REGISTRATION NUMBER/REFERENCE NUMBER

SIMVASTATIN 10 mg AUSTELL: A38/7.5/0477

SIMVASTATIN 20 mg AUSTELL: A38/7.5/0478

SIMVASTATIN 40 mg AUSTELL: A38/7.5/0479

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