

Safety Data Sheet

Pravastatin sodium tablets, USP

Strength: 10/20/30/40mg. **Pack Size:** 90 and 500 Tablets per bottle
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Revision No.: 02

EMERGENCY OVERVIEW

Each Pravastatin Sodium Tablets, USP intended for oral administration contains Pravastatin Sodium and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

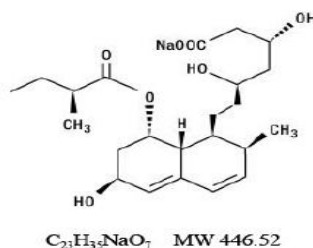
Section 1. Identification

Identification of the product

Product name Pravastatin Sodium Tablets, USP

Formula C₂₃H₃₅NaO₇

Chemical Name 1-Naphthalene-heptanoic acid, 1,2,6,7,8,8a-hexahydro-β,δ,6-trihydroxy-2-methyl-8-(2-methyl-1-oxobutoxy)-, monosodium salt, [1S-[1α(βS*,δS*),2α,6α,8β(R*),8aα]]-



Manufacturer / supplier identification

Company: Cadila Healthcare Ltd. Ahmedabad, India

Address: Sarkhej – Bavla. N.H. 8A, Moraiya. Tal. Sanand.
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**Recommended use /
Therapeutic Category** Pravastatin sodium tablets are one of a class of lipid-lowering compounds, the HMG-CoA reductase inhibitors, which reduce cholesterol biosynthesis.

**Restriction on Use /
Contraindications:** Hypersensitivity to any component of this medication. Active liver disease or unexplained, persistent elevations of serum transaminases. HMG-CoA reductase inhibitors, like some

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other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function.

Section 2. Hazard(s) Information

Dose and Administration

Adult Patients:

The recommended starting dose is 40 mg once daily. If a daily dose of 40 mg does not achieve desired cholesterol levels, 80 mg once daily is recommended.

Padiatric Patients:

Children (Ages 8 to 13 years, Inclusive):

The recommended starting dose is 20mg once daily in children 8 to 13 years of age.

Adolescents (Ages 14 to 18 years, Inclusive):

The recommended starting dose is 40mg once daily in adolscents 14 to 18 years of age.

Pravastatin sodium tablets can be administered orally as a single dose at any time of the day, with or without food. Since the maximal effect of a given dose is seen within 4 weeks, periodic lipid determinations should be performed at this time and dosage adjusted according to the patient's response to therapy and established treatment guidelines.

Adverse Effects

Pravastatin is generally well tolerated; adverse reactions have usually been mild and transient.

Over Dose Effect

To date, there has been limited experience with overdosage of pravastatin.

Medical Conditions

Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): predisposing factors include advanced age (≥ 65), uncontrolled hypothyroidism, and renal impairment. Patients should be advised to promptly report to their physician any unexplained and/or persistent muscle pain, tenderness, or weakness. Pravastatin therapy should be discontinued if myopathy is diagnosed or suspected.

Liver enzyme abnormalities: persistent elevations in hepatic transaminases can occur. Check liver enzyme tests before initiating therapy and as clinically indicated thereafter. (5.2)

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Pregnancy Comments

Pravastatin sodium tablets should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the patient becomes pregnant while taking this class of drug, therapy should be discontinued immediately and the patient apprised of the potential hazard to the fetus.

Pravastatin was not teratogenic in rats at doses up to 1000 mg/kg daily or in rabbits at doses of up to 50 mg/kg daily. These doses resulted in 10X (rabbit) or 120X (rat) the human exposure based on surface area (mg/meter²). Rare reports of congenital anomalies have been received following intrauterine exposure to other HMG-CoA reductase inhibitors.

Pregnancy Category

X

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Pravastatin sodium	Not Found	81131-70-6
Inactive Ingredients :		
Croscarmellose sodium	Not Found	9004-32-4
Lactose anhydrous	Not Found	63-42-3
Magnesium stearate	Not Found	557-04-0
Microcrystalline cellulose	Not Found	9004-34-6
Polyoxyl 35 castor oil	Not Found	61791-12-6
Sodium carbonate anhydrous	Not Found	497-19-8

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Section 4. First-aid measure

General

Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive medical attention

Overdose Treatment

If an overdose occurs, it should be treated symptomatically with laboratory monitoring and supportive measures should be instituted as required.

Section 5. Fire - fighting measures

Flash point

Not Found

Upper Flammable Limit:

Not Found

Auto-Ignition Temperature:

Not Found

Lower Flammable Limit:

Not Found

Extinguishing Media

Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.

Fire and Explosion Hazard

This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build-up of static electricity.

Fire Fighting Procedure

As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

Spill Response

Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

Section 7. Handling and Storage

Storage

Store at 20° to 25°C (68° to 77°F) keep tightly closed (protect from moisture). protect from light.

Incompatibilities:

No Data available.

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Section 8. Exposure controls / personal protection

Respiratory Protection	Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.
Skin Protection	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.
Eye protection	Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.
Engineering Control	Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Section 9. Physical and chemical properties

Appearance	Pravastatin Sodium Tablets USP, 10 mg are white to off-white, oval-shaped, biconvex uncoated tablets debossed with the logo of 'ZC46' on one side and plain on the other side. Pravastatin Sodium Tablets USP, 20 mg are white to off-white, oval-shaped, biconvex uncoated tablets debossed with the logo of 'ZC45' on one side and plain on the other side. Pravastatin Sodium Tablets USP, 40 mg are white to off-white, oval-shaped, biconvex uncoated tablets debossed with the logo of 'ZC44' on one side and plain on the other side. Pravastatin Sodium Tablets USP, 80 mg are white to off-white, oval-shaped, biconvex uncoated tablets debossed with the logo of 'ZC43' on one side and plain on the other side.		
Solubility in water	No Data Available	Odour	Odourless
Boiling point	No Data Available	Melting Point	No Data Available
Evaporation rate	No Data Available	Vapour density	No Data Available
Reactivity in water	No Data Available	Evaporation rate	No Data Available
% Volatile by volume	No Data Available	Specific gravity	No Data Available
		Vapour pressure	No Data Available

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Other information

Pravastatin sodium is white to yellowish white powder or crystalline powder, hygroscopic in nature. It is a relatively polar hydrophilic compound with a partition coefficient (octanol/water) of 0.59 at a pH of 7.0. It is freely soluble in water and in methanol. Soluble in ethanol.

Section 10. Stability and Reactivity

Condition to avoid

Avoid exposure to extreme heat, light and moisture.

Stable

Stable under normal ambient and anticipated storage and handling conditions.

Decomposition Products

No Data Available

Hazardous Reaction

No data available.

Incompatibilities:

No Data available

Section 11. Toxicological information

General

Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.

Target organ

Eye contact, Skin contact and inhalation is not great risk as this product is tablet.

Other

In dogs treated with Pravastatin Sodium (10, 30 or 75 mg/kg/day) for 1 year, dark brown discoloration of the liver and concentric lamellar bodies in the cytoplasm of hepatocytes were observed in association with clinical chemistry changes indicative of liver damage (elevated alkaline phosphatase, gamma glutamyl transferase, and alanine amino transferase; decreased albumin) and altered drug metabolism at the highest dose, which is approximately 6 times the maximum recommended human dose (MRHD) of 400 mg/day on a mg/m^2 basis. Gross liver changes not clearly accompanied by biochemical evidence of hepatotoxicity were noted at 30 mg/kg/day, or approximately 2.4 times the MRHD on mg/m^2 basis

Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil

Section 13. Disposal Consideration

Dispose the waste in accordance with all applicable Federal, State and local laws.

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Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is 077751

Section 16. Other information

None

Date of issue: 28/05/2015

Supersedes edition of: 01

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions.
It does not represent a guarantee of the properties of the product.