EMERGENCY OVERVIEW

PRAVASTATIN SODIUM TABLETS contain 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 of the substance

**Identification of the product**

**Product name:** PRAVASTATIN SODIUM TABLETS

**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*),8aa]]-

**Therapeutic Category**

Pravastatin sodium tablets are one of a class of lipid-lowering compounds, the HMG-CoA reductase inhibitors, which reduce cholesterol biosynthesis.

**Manufacturer / supplier identification**

**Company:** Cadila Healthcare Ltd. Ahmedabad, India

**Contact for information:** Tel.: +91 79 6868100 Fax: +91 79 3750319

**Emergency telephone No.** Tel.: +91 79 6868100

Section 2. Composition / information on ingredients

**Component**

**Exposure Limit**

**CAS No.**

**Principle Component:**

Pravastatin sodium Not Found 81131-70-6

**Inactive Ingredients:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure Limit</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Croscarmellose sodium</td>
<td>Not Found</td>
<td>9004-32-4</td>
</tr>
<tr>
<td>Lactose anhydrous</td>
<td>Not Found</td>
<td>63-42-3</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Not Found</td>
<td>557-04-0</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>Not Found</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Polyoxyl 35 castor oil</td>
<td>Not Found</td>
<td>61791-12-6</td>
</tr>
<tr>
<td>Sodium carbonate anhydrous</td>
<td>Not Found</td>
<td>497-19-8</td>
</tr>
</tbody>
</table>
Material Safety data sheet

PRAVASTATIN SODIUM TABLETS

<table>
<thead>
<tr>
<th>Strength</th>
<th>Pack Size</th>
<th>Revision No.:</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mg.</td>
<td>90 and 500 Tablets per bottle</td>
<td>00</td>
</tr>
<tr>
<td>20 mg.</td>
<td>90, 500 and 1000 Tablets per bottle</td>
<td></td>
</tr>
<tr>
<td>40 mg.</td>
<td>90 and 500 Tablets per bottle</td>
<td></td>
</tr>
<tr>
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<td></td>
</tr>
</tbody>
</table>

Section 3. Health Hazards 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.

**Pediatric Patients:**
- **Children (Ages 8 to 13 Years, Inclusive):** The recommended dose is 20 mg once daily in children 8 to 13 years of age.
- **Adolescents (Ages 14 to 18 Years):** The recommended starting dose is 40 mg once daily in adolescents 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.

**Contraindications**
Hypersensitivity to any component of this medication. Active liver disease or unexplained, persistent elevations of serum transaminases. HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function.

**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 4. First aid measures

**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.
Material Safety data sheet

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Section 5. Fire – fighting measures

<table>
<thead>
<tr>
<th>Flash point</th>
<th>Not Found</th>
<th>Upper Flammable Limit:</th>
<th>Not Found</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto-Ignition Temperature:</td>
<td>Not Found</td>
<td>Lower Flammable Limit:</td>
<td>Not Found</td>
</tr>
<tr>
<td>Extinguishing Media</td>
<td>Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.</td>
<td>Fire and Explosion Hazard</td>
<td>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.</td>
</tr>
</tbody>
</table>

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. Storage / Spill / Disposal Measures

Storage

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

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.

Disposal

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

Section 7. Exposure controls and 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.
Section 8. Physical and chemical properties

Appearance

Pravastatin Sodium capsules, 25 mg are white to off white granular powder filled in size ’4’ hard gelatin capsules with pink colored cap printed with “ZA-31” in black ink and white colored body printed with “25 mg” in black ink.

Pravastatin Sodium capsules, 50 mg are white to off white granular powder filled in size ’3’ hard gelatin capsules with pink colored cap printed with “ZA-32” in black ink and white colored body printed with “50 mg” in black ink.

Pravastatin Sodium capsules, 100 mg are white to off white granular powder filled in size ’1’ hard gelatin capsules with pink colored cap printed with “ZA-33” in black ink and white colored body printed with “100 mg” in black ink.

Odour

Odourless

Melting Point

No Data Available

Vapour density

No Data Available

Solubility in water

No Data Available

Evaporation rate

No Data Available

Specific gravity

No Data Available

Boiling point

No Data Available

Reactivity in water

No Data Available

Vapour pressure

No Data Available

% Volatile by volume

No Data Available

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 9. Physical Hazards

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 10. Toxicological information

Handling of formulated product is not expected to cause any adverse 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/m² 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/m² basis.

Section 11. Ecological information

No data available on Ecotoxicity

Section 12. Other information

None

Date of issue: 04/08/06


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.