SAFETY DATA SHEETS

This SDS packet was issued with item:

078360007

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078552129 078817413

Material Safety data sheet

WARFARIN SODIUM TABLETS, USP

Strength: 1.0/2.0/2.5/3.0/4.0/5.0/6.0/7.5/10.0 mg. **Pack Size:** 100/1000 Tablets per bottle **Revision No.:** 00

EMERGENCY OVERVIEW

WARFARIN SODIUM TABLETS, USP contain Warfarine 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:	Warfarin Sodium Tablets USP
Formula:	C19H15NaO4
Chemical Name:	3-(α-acetonylbenzyl)-4-hydroxycoumarin and is a racemic mixture of the R- and S-enantiomers
Therapeutic Category	Anticoagulant, which acts by inhibiting vitamin K-dependent coagulation factors

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 :		
Warfarin Sodium, USP 0.5 mg or 1 mg or 2 mg or 5 mg or 10 mg or 20 mg.	Not Found	129-06-6
Inactive Ingredients :		
Hydroxypropyl cellulose	Not Found	9004-64-2
Lactose monohydrate	Not Found	67392-87-4
Magnesium stearate	Not Found	557-04-0
Pregelatinized starch	Not Found	113-15-5
Permitted Colors	Not Found	

Section 3. Health Hazards Information

Dose and Administration

The dosage and administration of warfarin sodium tablets must be individualized for each patient according to the particular
patient's PT/INR response to the drug.

Venous Thromboembolism (including pulmonary embolism):
Available clinical evidence indicates that an INR of 2.0-3.0 is sufficient for prophylaxis and treatment of venous thromboembolism and minimizes the risk of hemorrhage associated with higher INRs.

Post-Myocardial Infarction:
In post-myocardial infarction patients, warfarin sodium tablets therapy should be initiated early (2-4 weeks post-infarction) and dosage should be adjusted to maintain an INR of 2.5-3.5 long-term.

Mechanical and Bioprosthetic Heart Valves:
In patients with mechanical heart valve(s), long term prophylaxis with warfarin to an INR of 2.5-3.5 is recommended.

Initial Dosage:
It is recommended that warfarin sodium tablets therapy be initiated with a dose of 2 to 5 mg per day with dosage adjustments based on the results of PT/INR determinations.

Maintenance:
Most patients are satisfactorily maintained at a dose of 2 to 10 mg daily.

Adverse Effects

- Fatal or nonfatal hemorrhage from any tissue or organ. Hemorrhagic complications may present as paralysis; paresthesia; headache, chest, abdomen, joint, muscle or other pain; dizziness; shortness of breath, difficult breathing or swallowing; unexplained swelling; weakness; hypotension; or unexplained shock.
- Necrosis of skin and other tissues.
- Adverse reactions reported infrequently include: hypersensitivity/allergic reactions, systemic cholesterol microembolization, purple toes syndrome, hepatitis, cholestatic hepatic injury, jaundice, elevated liver enzymes, vasculitis,
- Edema, fever, rash, dermatitis, including bullous eruptions, urticaria, abdominal pain including cramping, flatulence/bloating, fatigue, lethargy, malaise, asthenia, nausea, vomiting, diarrhea, pain, headache, dizziness, taste perversion, pruritus, alopecia, cold intolerance, and paresthesia including feeling cold and chills.

Over Dose Effect

Suspected or overt abnormal bleeding (e.g., appearance of blood in stools or urine, hematuria, excessive menstrual bleeding, melena, petechiae, excessive bruising or persistent oozing from superficial injuries) are early manifestations of anticoagulation beyond a safe and satisfactory level.

Medical Conditions

Warfarin sodium tablets are indicated for the prophylaxis and/or treatment of venous thrombosis and its extension, and pulmonary embolism. Warfarin sodium tablets are indicated for the prophylaxis and/or treatment of the thromboembolic complications associated with atrial fibrillation and/or cardiac valve replacement. Warfarin sodium tablets are indicated to reduce the risk of death, recurrent myocardial infarction, and thromboembolic events such as stroke or systemic embolization after myocardial infarction.

Contraindications	Anticoagulation is contraindicated in any localized or general physical condition or personal circumstance in which the hazard of hemorrhage might be greater than the potential clinical benefits of anticoagulation, such as: – **Pregnancy** – **Hemorrhagic tendencies or blood dyscrasias Recent or contemplated surgery of:** (1) central nervous system; (2) eye; (3) traumatic surgery resulting in large open surfaces. – **Bleeding tendencies associated with active ulceration or overt bleeding of:** (1) gastrointestinal, genitourinary or respiratory tracts; (2) cerebrovascular hemorrhage; (3) aneurysms-cerebral, dissecting aorta; (4) pericarditis and pericardial effusions; (5) bacterial endocarditis.
Pregnancy Comments	Warfarin sodium tablets are contraindicated in women who are or may become pregnant because the drug passes through the placental barrier and may cause fatal hemorrhage to the fetus in utero. Furthermore, there have been reports of birth malformations in children born to mothers who have been treated with warfarin during pregnancy. Embryopathy characterized by nasal hypoplasia ,Central nervous system abnormalities, Ventral midline dysplasia, characterized by optic atrophy, and eye abnormalities have been observed. Mental retardation, blindness, and other central nervous system abnormalities have been reported in association with second and third trimester exposure.
Pregnancy Category	**X**

Section 4. First aid measures

General	Remove from exposure. Remove contiminated Clothing. Person devloping serious hypersensitivity reaction must receive medical attention
Overdose Treatment	Excessive anticoagulation, with or without bleeding, may be controlled by discontinuing warfarin sodium tablets therapy and if necessary, by administration of oral or parenteral vitamin K1. In emergency situations of severe hemorrhage, clotting factors can be returned to normal by administering 200 to 500 mL of fresh whole blood or fresh frozen plasma, or by giving commercial Factor IX complex.

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. Storage / Spill / Disposal Measures

Storage	Store at 20°-25°C (68°-77°F) Dispense in a tight, light-resistant container.
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

Warfarin Sodium Tablets, 1 mg are pink, oval, flat, beveled edge, uncoated tablets debossed with the logo of 'WAR', '1' and bisect on one side and plain on other side.

Warfarin Sodium Tablets, 2 mg are lavender, oval, flat, beveled edge, uncoated tablets debossed with the logo of 'WAR', '2' and bisect on one side and plain on other side.

Warfarin Sodium Tablets, 2.5 mg are green, oval, flat, beveled edge, uncoated tablets debossed with the logo of 'WAR', '21/2' and bisect on one side and plain on other side.

Warfarin Sodium Tablets, 3 mg are tan, oval, flat, beveled edge, uncoated tablets debossed with the logo of 'WAR', '3' and bisect on one side and plain on other side.

Warfarin Sodium Tablets, 4 mg are blue, oval, flat, beveled edge, uncoated tablets debossed with the logo of 'WAR', '4' and bisect on one side and plain on other side.

Warfarin Sodium Tablets, 5 mg are peach, oval, flat, beveled edge, uncoated tablets debossed with the logo of 'WAR', '5' and bisect on one side and plain on other side.

Warfarin Sodium Tablets, 6 mg are teal, oval, flat, beveled edge, uncoated tablets debossed with the logo of 'WAR', '6' and bisect on one side and plain on other side.

Warfarin Sodium Tablets, 7.5 mg are yellow, oval, flat, beveled edge, uncoated tablets debossed with the logo of 'WAR', '71/2' and bisect on one side and plain on other side.

Warfarin Sodium Tablets, 10 mg are white to off white, oval, flat, beveled edge, uncoated tablets debossed with the logo of 'WAR','10' and bisect on one side and plain on 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
Percentage Volatile by volume	No Data Available	**Specific gravity**	No Data Available
Vapour pressure	No Data Available		
Other information	Not Applicable		

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

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	Not Applicable

Section 11. Ecological information

No data available on Ecotoxicity

Section 12. Other information

None

Date of issue: 28/02/06 **Supersedes edition of:** New Edition

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.