

# Material Safety Data Sheet

## Warfarin Sodium Tablets, USP

**Strength:** 1/2/2.5/3/4/5/6/7.5/10 mg per Tablet    **Pack Size:** 100/1000 Tablet Per bottle (for 1/2/2.5/3/4/6/7.5/10 mg)  
90/100/1000 Tablet Per bottle (for 5 mg)

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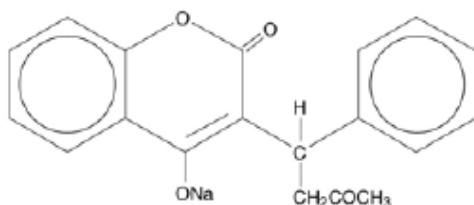
### EMERGENCY OVERVIEW

Each Warfarin sodium tablets intended for oral administration contains Warfarin 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:**  $C_{19}H_{15}NaO_4$   
**Chemical Name:** 3-( $\alpha$ -acetylbenzyl)-4-hydroxycoumarin and is a racemic mixture of the *R*- and *S*-enantiomers  
**Therapeutic Category:** Anticoagulant



Warfarin Sodium

##### 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.
<b>Principle Component :</b>		
Warfarin Sodium USP	Not Found	129-06-6
<b>Inactive Ingredients :</b>		
Hydroxypropyl cellulose	Not Found	9004-64-2

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Lactose Monohydrate	Not Found	67392-87-4
Magnesium Stearate	Not Found	577-04-0
Pregelatinized Starch	Not Found	113-15-5
Permitted colors	Not Found	NA

### Section 3. Health Hazards Information

#### Dose and Administration

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

#### Venous Thromboembolism

Adjust the warfarin dose to maintain a target INR of 2.5 (INR range, 2 to 3) for all treatment durations. The duration of treatment is based on the indication as follows:

- For patients with a DVT or PE secondary to a transient (reversible) risk factor, treatment with warfarin for 3 months is recommended.
- For patients with an unprovoked DVT or PE, treatment with warfarin is recommended for at least 3 months. After 3 months of therapy, evaluate the risk-benefit ratio of long-term treatment for the individual patient.
- For patients with two episodes of unprovoked DVT or PE, long-term treatment with warfarin is recommended. For a patient receiving long-term anticoagulant treatment, periodically reassess the risk-benefit ratio of continuing such treatment in the individual patient.

#### Atrial Fibrillation

In patients with non-valvular AF, anticoagulate with warfarin to target INR of 2.5 (range, 2 to 3).

- In patients with non-valvular AF that is persistent or paroxysmal and at high risk of stroke (i.e., having any of the following features: prior ischemic stroke, transient ischemic attack, or systemic embolism, or 2 of the following risk factors: age greater than 75 years, moderately or severely impaired left ventricular systolic function and/or heart failure, history of hypertension, or diabetes mellitus), long-term anticoagulation with warfarin is recommended.
- In patients with non-valvular AF that is persistent or paroxysmal and at an intermediate risk of ischemic stroke (i.e., having 1 of the following risk factors: age greater than 75 years, moderately or severely impaired left ventricular systolic function and/or heart failure, history of hypertension, or diabetes mellitus), long-term anticoagulation with warfarin is recommended.
- For patients with AF and mitral stenosis, long-term anticoagulation with warfarin is recommended.
- For patients with AF and prosthetic heart valves, long-term anticoagulation with warfarin is recommended; the target INR may be increased and aspirin added depending on valve type and position, and on patient factors.

#### Mechanical and Bioprosthetic Heart Valves

- For patients with a bileaflet mechanical valve or a Medtronic Hall (Minneapolis, MN) tilting disk valve in the aortic position who are in sinus rhythm and without left atrial enlargement, therapy with warfarin to a target INR of 2.5 (range, 2 to 3) is recommended.
- For patients with tilting disk valves and bileaflet mechanical valves in the mitral position, therapy with warfarin to a target INR of 3 (range, 2.5 to 3.5) is

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recommended.

- For patients with caged ball or caged disk valves, therapy with warfarin to a target INR of 3 (range, 2.5 to 3.5) is recommended.
- For patients with a bioprosthetic valve in the mitral position, therapy with warfarin to a target INR of 2.5 (range, 2 to 3) for the first 3 months after valve insertion is recommended. If additional risk factors for thromboembolism are present (AF, previous thromboembolism, left ventricular dysfunction), a target INR of 2.5 (range, 2 to 3) is recommended.

### Post-Myocardial Infarction

- For high-risk patients with MI (e.g., those with a large anterior MI, those with significant heart failure, those with intracardiac thrombus visible on transthoracic echocardiography, those with AF, and those with a history of a thromboembolic event), therapy with combined moderate-intensity (INR, 2 to 3) warfarin plus low-dose aspirin ( $\leq 100$  mg/day) for at least 3 months after the MI is recommended.

### Recurrent Systemic Embolism and Other Indications

Oral anticoagulation therapy with warfarin has not been fully evaluated by clinical trials in patients with valvular disease associated with AF, patients with mitral stenosis, and patients with recurrent systemic embolism of unknown etiology. However, a moderate dose regimen (INR 2 to 3) may be used for these patients.

### Initial and Maintenance Dosing

The appropriate initial dosing of warfarin sodium varies widely for different patients. Not all factors responsible for warfarin dose variability are known, and the initial dose is influenced by:

- Clinical factors including age, race, body weight, sex, concomitant medications, and comorbidities

Genetic factors (CYP2C9 and VKORC1 genotypes)

### Adverse Effects

Hemorrhage ,Necrosis of skin and other tissues ,Systemic atheroemboli and cholesterol microemboli ,Other adverse reactions to warfarin sodium include: Immune system disorders: hypersensitivity/allergic reactions (including urticaria and anaphylactic reactions) ,Vascular disorders: vasculitis ,Hepatobiliary disorders: hepatitis elevated liver enzymes. Cholestatic hepatitis has been associated with concomitant administration of warfarin sodium and ticlopidine.

Gastrointestinal disorders: nausea, vomiting, diarrhea, taste perversion, abdominal pain, flatulence, bloating ,Skin disorders: rash, dermatitis (including bullous eruptions), pruritus, alopecia ,Respiratory disorders: tracheal or tracheobronchial calcification

General disorders: chills

### Over Dose Effect

Bleeding (e.g., appearance of blood in stools or urine, hematuria, excessive menstrual bleeding, melena, petechiae, excessive bruising or persistent oozing from superficial injuries, unexplained fall in hemoglobin) is a manifestation of excessive anticoagulation.

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<b>Medical Conditions</b>	<p>Before you take warfarin sodium, tell your healthcare provider if you: have bleeding problems ,fall often have liver or kidney problems have high blood pressure ,have a heart problem called congestive heart failure ,have diabetes ,plan to have any surgery or a dental procedure have any other medical conditions are pregnant or plan to become pregnant. are breastfeeding. You and your healthcare provider should decide if you will take warfarin sodium and breastfeed. Tell all of your healthcare providers and dentists that you are taking warfarin sodium. They should talk to the healthcare provider who prescribed warfarin sodium for you before you have <b>any</b> surgery or dental procedure. Your warfarin sodium may need to be stopped for a short time or your may need your dose adjusted.Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some of your other medicines may affect the way warfarin sodium works. Certain medicines may increase your risk of bleeding. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.</p>
<b>Contraindications</b>	<p>Pregnancy, except in women with mechanical heart valves ,Hemorrhagic tendencies or blood dyscrasias ,Recent or contemplated surgery of the central nervous system (CNS) or eye, or traumatic surgery resulting in large open surfaces ,Bleeding tendencies associated with certain conditions ,Threatened abortion, eclampsia, and preeclampsia ,Unsupervised patients with potential high levels of non-compliance ,Spinal puncture and other diagnostic or therapeutic procedures with potential for uncontrollable bleeding ,Hypersensitivity to warfarin or any component of the product ,Major regional or lumbar block anesthesia ,Malignant hypertension .</p>
<b>Pregnancy Comments</b>	<p>Warfarin sodium tablets are contraindicated in women who are pregnant except in pregnant women with mechanical heart valves, who are at high risk of thromboembolism, and for whom the benefits of warfarin sodium may outweigh the risks.</p>
<b>Pregnancy Category</b>	<p><b>Pregnancy Category D</b> for women with mechanical heart valves and <b>Pregnancy Category X</b> for other pregnant populations</p>

### Section 4. First aid measures

<b>General</b>	<p>Remove from exposure. Remove contaminated clothing. Person developing serious hypersensitivity reaction must receive medical</p>
<b>Overdose Treatment</b>	<p>The treatment of excessive anticoagulation is based on the level of the INR, the presence or absence of bleeding, and clinical circumstances. Reversal of warfarin sodium anticoagulation may be obtained by discontinuing warfarin sodium therapy and, if necessary, by administration of oral or parenteral vitamin K<sub>1</sub>.</p> <p>The use of vitamin K<sub>1</sub> reduces response to subsequent warfarin sodium therapy and patients may return to a pretreatment thrombotic status following the rapid reversal of a prolonged INR. Resumption of warfarin sodium administration reverses the effect of vitamin K, and a therapeutic INR can again be obtained by careful dosage adjustment. If rapid re-anticoagulation is indicated, heparin may be preferable for</p>

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initial therapy.

Prothrombin complex concentrate (PCC), fresh frozen plasma, or activated Factor VII treatment may be considered if the requirement to reverse the effects of warfarin sodium is urgent. A risk of hepatitis and other viral diseases is associated with the use of blood products; PCC and activated Factor VII are also associated with an increased risk of thrombosis. Therefore, these preparations should be used only in exceptional or life-threatening bleeding episodes secondary to warfarin sodium overdose.

### Section 5. Fire – fighting measures

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

<b>Spill Response</b>	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.
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### Section 7. Handling and Storage

<b>Storage</b>	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from light.
	Dispense in a tight, light-resistant container as defined in the USP.

### Section 8. Exposure controls and personal protection

<b>Respiratory Protection</b>	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.
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<b>Skin Protection</b>	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.
<b>Eye protection</b>	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.
<b>Protective Clothing</b>	Protective clothing is not normally necessary, however it is good practice to use apron.

### Section 9. Physical and chemical properties

<b>Appearance</b>	Warfarin Sodium Tablets USP, 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 USP, 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 USP, 2.5 mg are green, oval, flat, beveled edge, uncoated tablets debossed with the logo of 'WAR', '2½' and bisect on one side and plain on other side
	Warfarin Sodium Tablets USP, 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 USP, 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 USP, 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 USP, 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 USP, 7.5 mg are yellow, oval, flat, beveled edge, uncoated tablets debossed with the logo of 'WAR', '7½' and bisect on one side and plain on other side
	Warfarin Sodium Tablets USP, 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

<b>Solubility in water</b>	very soluble	<b>Odour</b>	Odourless
<b>Boiling point</b>	No Data Available	<b>Melting Point</b>	No Data Available
<b>Evaporation rate</b>	No Data Available	<b>Vapour density</b>	No Data Available
<b>Reactivity in water</b>	No Data Available	<b>Evaporation rate</b>	No Data Available
<b>Percentage Volatile by volume</b>	No Data Available	<b>Specific gravity</b>	No Data Available
<b>Vapour pressure</b>	No Data Available	<b>Other information</b>	Not Applicable

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### Section 10. Stability and Reactivity

<b>Condition to avoid</b>	Avoid exposure to extreme heat, light and moisture.	<b>Stable</b>	Stable under normal ambient and anticipated storage and handling conditions.
<b>Decomposition Products</b>	No Data Available	<b>Hazardous Reaction</b>	No data available.
<b>Incompatibilities</b>	No data available.		

### Section 11. Toxicological information

<b>General</b>	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.
<b>Target organ</b>	Eye contact, Skin contact and inhalation is not great risk as this product is tablet.
<b>other</b>	Not Applicable

### Section 12. Ecological information

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

### Section 13. Disposal Consideration

<b>Disposal</b>	Dispose the waste in accordance with all applicable Federal, State and local laws.
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### Section 14. Transport Information

May be shipped normally as a non hazardous material.

### Section 15. Regulatory Information

ANDA no.- 44-663

### Section 16. Other information

None

**Date of issue:** 19/06/2012

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.