

INDICATIONS AND USAGE **warfarin sodium tablets**
Fdaer Pharmaceuticals, USA Inc.

INDICATIONS AND USAGE
Warfarin sodium tablets are indicated for the treatment of thrombotic disorders and for the prevention of thromboembolism in certain patients.

Warnings
See full prescribing information for complete list of warnings and precautions.

- 1. Hemorrhage
- 2. Interactions with other drugs and foods
- 3. Bleeding risk
- 4. Laboratory monitoring
- 5. Pregnancy, lactation, and fertility
- 6. Contraindications

How to Use
See full prescribing information for complete list of directions for use.

Usual Dosage
See full prescribing information for complete list of usual dosages.

Contraindications
See full prescribing information for complete list of contraindications.

Warnings and Precautions
See full prescribing information for complete list of warnings and precautions.

Adverse Reactions
See full prescribing information for complete list of adverse reactions.

Drug Interactions
See full prescribing information for complete list of drug interactions.

How to Use
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4 CONTRAINDICATIONS

- **Prognosis**
 - **Worshiper**
 - **Worshiper**
 - **Worshiper**

5 WARNING AND PRECAUTIONS

- **5.1 Warnings**
 - **5.1.1 Pregnancy**
 - **5.1.2 Breastfeeding**

6 TISSUE REACTION

- **6.1 Tissue Reaction**
 - **6.1.1 Tissue Reaction**

6.2 Epidermal Allergic and Contact Dermatitis

- **6.2 Epidermal Allergic and Contact Dermatitis**
 - **6.2.1 Epidermal Allergic and Contact Dermatitis**

6.3 Use in Pregnant Women with Mechanical Heart Valves

- **6.3 Use in Pregnant Women with Mechanical Heart Valves**
 - **6.3.1 Use in Pregnant Women with Mechanical Heart Valves**

6.4 Other Clinical Settings with Increased Risk

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 - **6.4.1 Other Clinical Settings with Increased Risk**

6.5 Management Factors Affecting Risk

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 - **6.5.1 Management Factors Affecting Risk**

6.6 Adverse Reactions

- **6.6 Adverse Reactions**
 - **6.6.1 Adverse Reactions**

7 DRUG INTERACTIONS

- **7 Drug Interactions**
 - **7.1 Cytochrome P450 Interactions**
 - **7.2 Drug-Drug Interactions**

7.3 Drugs that Increase Bleeding Risk

- **7.3 Drugs that Increase Bleeding Risk**
 - **7.3.1 Drugs that Increase Bleeding Risk**

Table 1: Example of CYP450 Interactions with Warfarin

Drug	Interaction	Effect
Valproic acid	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Phenytoin	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Amiodarone	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Fluconazole	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Rifampin	Induces CYP2C9	Decreases warfarin plasma levels, decreasing bleeding risk
St. John's Wort	Induces CYP3A4	Decreases warfarin plasma levels, decreasing bleeding risk
Chlorzoxiprone	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Fluoxetine	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Trimethoprim-sulfamethoxazole	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Simvastatin	Inhibits CYP3A4	Increases warfarin plasma levels, increasing bleeding risk
Erythromycin	Inhibits CYP3A4	Increases warfarin plasma levels, increasing bleeding risk
Clarithromycin	Inhibits CYP3A4	Increases warfarin plasma levels, increasing bleeding risk
Fluorouracil	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Acetaminophen	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Salicylic acid	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Aspirin	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Ibuprofen	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Nitroglycerin	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Isosorbide dinitrate	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Diazepam	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Valproic acid	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
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Salicylic acid	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Aspirin	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Ibuprofen	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Nitroglycerin	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Isosorbide dinitrate	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk
Diazepam	Inhibits CYP2C9	Increases warfarin plasma levels, increasing bleeding risk

7.4 Adverse and Antagonist

- **7.4 Adverse and Antagonist**
 - **7.4.1 Adverse and Antagonist**

8 USE IN SPECIFIC POPULATIONS

- **8 Use in Specific Populations**
 - **8.1 Pregnancy**
 - **8.2 Lactation**
 - **8.3 Fertility and Risk of Reproductive Potential**
 - **8.4 Fertility**

100 Tablets
2/0/14



NDC 45880-015-01 is a bottle of 100 tablets
Warfarin Sodium Tablets USP, 5 mg
N, white
100 Tablets
2/0/14



NDC 45880-016-01 is a bottle of 100 tablets
Warfarin Sodium Tablets USP, 5 mg
N, white
100 Tablets
2/0/14



NDC 45880-017-01 is a bottle of 100 tablets
Warfarin Sodium Tablets USP, 5 mg
N, white
100 Tablets
2/0/14



NDC 45880-018-01 is a bottle of 100 tablets
Warfarin Sodium Tablets USP, 5 mg
N, white
100 Tablets
2/0/14



NDC 45880-019-01 is a bottle of 100 tablets
Warfarin Sodium Tablets USP, 5 mg
N, white
100 Tablets
2/0/14



WARFARIN SODIUM					
NDC 45880-015-01					
Product Information					
Product Name	WARFARIN SODIUM TABLETS				
Product Code	NDC 45880-015-01				
Form of Administration	Tablets				
Active Ingredient/Active Moiety					
Ingredient Name	Strength	Quantity	Units		
Warfarin Sodium	5 mg	100	Tablets		
Product Characteristics					
Color	White	Shape	Round		
Imprint	None	Score	None		
Contains	None				
Packaging					
#	Item Code	Package Description	Marketing Start	Marketing End	
1	45880-015-01	100 (1) 5 mg Warfarin Sodium Tablets	2014-01-01	2014-01-01	
2	45880-015-02	100 (1) 5 mg Warfarin Sodium Tablets	2014-01-01	2014-01-01	
Marketing Information					
Marketing Status	Approved	Marketing Start	2014-01-01	Marketing End	None

WARFARIN SODIUM					
NDC 45880-016-01					
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Product Code	NDC 45880-016-01				
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Product Characteristics					
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Contains	None				
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Marketing Information					
Marketing Status	Approved	Marketing Start	2014-01-01	Marketing End	None

WARFARIN SODIUM					
NDC 45880-018-01					
Product Information					
Product Name	WARFARIN SODIUM TABLETS				
Product Code	NDC 45880-018-01				
Form of Administration	Tablets				
Active Ingredient/Active Moiety					
Ingredient Name	Strength	Quantity	Units		
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Product Characteristics					
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Marketing Information					
Marketing Status	Approved	Marketing Start	2014-01-01	Marketing End	None

WARFARIN SODIUM					
NDC 45880-019-01					
Product Information					
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Product Code	NDC 45880-019-01				
Form of Administration	Tablets				
Active Ingredient/Active Moiety					
Ingredient Name	Strength	Quantity	Units		
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