

Information For the User  
Nicoumalone 1 mg Tablet

# Nicotyle tablet

**Brand Name:** Nicotyle Tablet

**Composition:**

Each uncoated tablet contains:  
Nicoumalone IP 1 mg

**Therapeutic Indication:**

Indicated for the prevention and treatment of thromboembolic disorders  
Used in conditions such as deep vein thrombosis (DVT), pulmonary embolism (PE), atrial fibrillation with embolic risk, and for mechanical prosthetic heart valves  
Helps reduce the risk of stroke and systemic embolism in high-risk patients

**Mechanism of Action:**

Nicoumalone is an oral anticoagulant that acts as a vitamin K antagonist  
It inhibits the synthesis of vitamin K-dependent clotting factors II, VII, IX, and X in the liver  
This results in delayed blood clot formation and prevention of thrombus growth or recurrence

**Dosage & Administration:**

Initial dose and maintenance dose should be individualized based on INR (International Normalized Ratio) monitoring  
Usual starting dose: 1 mg to 4 mg daily  
Target INR range typically between 2.0 to 3.0 depending on clinical indication  
Tablet should be taken at the same time daily with or without food  
Frequent INR monitoring is essential during therapy

**Contraindications:**

Hypersensitivity to Nicoumalone or any component of the formulation  
Active bleeding or bleeding disorders  
Severe hepatic or renal impairment  
Pregnancy (Category X – teratogenic risk)  
Recent surgery involving the central nervous system, eyes, or trauma with potential bleeding risk

**Warnings & Precautions:**

Regular INR monitoring is mandatory to avoid under- or over-anticoagulation  
Avoid concomitant use with NSAIDs, antiplatelet agents, or other anticoagulants unless prescribed  
Maintain consistent dietary vitamin K intake  
Caution in elderly, patients with liver disease, and those at risk of falls or bleeding

**Drug Interactions:**

Interacts with antibiotics, antifungals, antiepileptics, and certain foods rich in vitamin K (e.g., spinach, broccoli)  
May potentiate or diminish anticoagulant effect – monitor INR closely when starting or stopping any medicine

**Side Effects:**

Common: bleeding, bruising, nausea

Less common: rash, hair thinning, elevated liver enzymes

Serious: major bleeding, skin necrosis, purple toe syndrome

**Storage:**

Store in a cool, dry, and dark place below 25°C

Protect from light and moisture

Keep out of reach of children

**Packaging:**

Nicotyle Tablet is available in blister or strip packs

**Schedule:**

Schedule H Prescription Drug – To be sold by retail on the prescription of a registered medical practitioner only

Manufactured in India for:



**Cafoli Lifecare Pvt. Ltd.**

**(An ISO 9001: 2015 Certified Co.)**

Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113

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