

Information For the User  
Nicoumalone 3 mg Tablet

# Nicotyle 3 tablet

**Brand Name:** Nicotyle 3 Tablet

**Composition:**

Each uncoated tablet contains:  
Nicoumalone IP 3 mg

**Therapeutic Indication:**

Indicated for the prevention and treatment of thromboembolic disorders such as deep vein thrombosis (DVT) pulmonary embolism (PE) atrial fibrillation with risk of embolism and for patients with mechanical prosthetic heart valves  
Also used in patients with previous thromboembolic episodes to prevent recurrence

**Mechanism of Action:**

Nicoumalone is an oral anticoagulant that acts as a vitamin K antagonist  
It inhibits the hepatic synthesis of vitamin K-dependent clotting factors II VII IX and X  
This leads to reduced thrombin generation and inhibition of clot formation

**Dosage & Administration:**

Initial and maintenance doses must be individualized and guided by INR monitoring  
Usual starting dose: 2 to 4 mg once daily  
Maintenance dose varies as per patient response and INR target (typically between 2.0 to 3.0)  
Take the tablet at the same time each day with or without food  
Regular INR monitoring is mandatory especially during initiation dose adjustment or with interacting drugs

**Contraindications:**

Hypersensitivity to Nicoumalone or any component of the formulation  
Active bleeding or conditions with a high risk of bleeding  
Severe liver or kidney impairment  
Pregnancy (contraindicated due to risk of fetal harm)  
Recent or planned surgeries involving the eye brain or spine

**Warnings & Precautions:**

Frequent INR monitoring is required to maintain therapeutic range and avoid complications  
Avoid alcohol and significant dietary changes especially foods high in vitamin K  
Use with caution in elderly patients and those with liver disease hypertension or risk of falls  
Inform all healthcare providers before any invasive procedure or dental work

**Drug Interactions:**

Numerous interactions with antibiotics NSAIDs antifungals antiplatelets and other anticoagulants  
Changes in INR may also occur with herbal products or food supplements  
Always consult your doctor before starting or stopping any medicine

**Side Effects:**

Common: minor bleeding nausea bruising

Less common: rash headache dizziness

Serious: major bleeding hematuria gastrointestinal 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 3 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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