

Information For the User
Nicoumalone 2 mg Tablet

Nicotyle 2 tablet

Brand Name: Nicotyle 2 Tablet

Composition:

Each uncoated tablet contains:
Nicoumalone IP 2 mg

Therapeutic Indication:

Indicated for the prevention and treatment of thromboembolic disorders
Used in deep vein thrombosis (DVT), pulmonary embolism (PE), atrial fibrillation with risk of embolism, and in patients with prosthetic heart valves
Helps prevent stroke, systemic embolism, and recurrence of venous thrombosis

Mechanism of Action:

Nicoumalone is a vitamin K antagonist that inhibits the synthesis of clotting factors II, VII, IX, and X
By blocking these vitamin K-dependent clotting factors in the liver, it reduces the blood's ability to form clots
Provides effective long-term oral anticoagulation with INR-based dose adjustment

Dosage & Administration:

Initial dose and maintenance dose must be based on INR monitoring
Usual starting dose: 2 mg to 4 mg daily
Target INR: generally between 2.0 and 3.0 depending on clinical condition
Take the tablet at the same time each day, with or without food
Frequent INR monitoring is essential during treatment

Contraindications:

Hypersensitivity to Nicoumalone or any excipient
Active bleeding or bleeding tendency
Severe hepatic or renal dysfunction
Pregnancy (Category X – teratogenic)
Recent or planned surgery involving high bleeding risk (CNS, eye, etc.)

Warnings & Precautions:

Frequent INR monitoring is necessary to maintain therapeutic range
Avoid abrupt changes in diet, especially foods high in vitamin K (green leafy vegetables)
Use caution with concurrent medications that affect coagulation or liver enzymes
Caution advised in elderly, fall-risk patients, and those with liver disease

Drug Interactions:

Significant interactions with antibiotics, antifungals, NSAIDs, antiplatelets, and certain anticonvulsants
Consult physician before starting or stopping any medicine
Monitor INR when changing medications

Side Effects:

Common: minor bleeding, bruising, nausea

Less common: rash, elevated liver enzymes

Rare but serious: major bleeding, skin necrosis, purple toe syndrome

Storage:

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

Protect from direct light and moisture

Keep out of reach of children

Packaging:

Nicotyle 2 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

TM: Trademark Applied for