

Information For the User
Nicoumalone 4 mg Tablet

Nicotyle 4 tablet

Brand Name: Nicotyle 4 Tablet

Composition:

Each uncoated tablet contains:
Nicoumalone IP 4 mg

Therapeutic Indication:

Indicated for the prevention and treatment of thromboembolic disorders including deep vein thrombosis pulmonary embolism atrial fibrillation with embolic risk and for patients with mechanical prosthetic heart valves

Also used to reduce the risk of stroke and systemic embolism in high-risk cardiovascular patients

Mechanism of Action:

Nicoumalone is an oral anticoagulant that functions as a vitamin K antagonist
It inhibits the synthesis of vitamin K-dependent clotting factors II VII IX and X in the liver
This leads to reduced thrombin formation and decreased clot formation and propagation

Dosage & Administration:

Initial and maintenance doses must be individualized based on INR monitoring

Usual starting dose ranges from 2 mg to 4 mg once daily

Maintenance dose adjusted to maintain INR in the therapeutic range usually between 2.0 to 3.0 depending on the indication

Take the tablet at the same time each day with or without food

Frequent INR monitoring is essential especially during initiation and dose changes

Contraindications:

Hypersensitivity to Nicoumalone or any excipient

Active internal bleeding severe hepatic dysfunction severe renal impairment

Pregnancy due to teratogenic effects and bleeding risk to the fetus

Recent or planned major surgery especially involving the eye spine or brain

Warnings & Precautions:

Regular INR monitoring is mandatory to ensure therapeutic efficacy and avoid bleeding complications

Avoid significant changes in diet especially foods rich in vitamin K

Inform healthcare providers before any invasive procedures or dental work

Use with caution in elderly debilitated patients or those with liver disease hypertension or bleeding tendencies

Drug Interactions:

Many drugs interact with Nicoumalone including NSAIDs antibiotics antifungals antiplatelets and some herbal supplements

These interactions may increase or decrease INR levels

Consult a doctor before starting or stopping any medication

Side Effects:

Common: easy bruising bleeding gums epistaxis nausea

Less common: rash dizziness headache

Serious: major bleeding GI bleeding hematuria skin necrosis purple toe syndrome

Storage:

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

Protect from direct sunlight and moisture

Keep out of reach of children

Packaging:

Nicotyle 4 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