

# Voalant Tablet 5mg

Warfarin Sodium Clathrate 5.45mg, equivalent to Warfarin Sodium 5mg

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## What Voalant is used for

Voalant is used to prevent and/or to treat blood clots forming in blood vessels. It helps to reduce the tendency of blood to form clots in the legs, lungs, brain or heart, and to prevent formation or reoccurrence of blood clots after heart attack.

## How Voalant works

Voalant contains warfarin sodium that belongs to a group of medicines called anticoagulants. It increases the times it takes for your blood to clot and prevent excessive clotting.

## Before you use Voalant

### When you must not use it:

Do not use Voalant if you:

- are allergic to warfarin sodium, or any ingredients in this medication.
- are pregnant or plan for a pregnancy.
- have a bleeding tendency or bruise easily.
- have any scheduled operations/surgeries, even minor.
- Have high blood pressure that is not controlled by medicines.
- Suffer from severe liver insufficiency or liver cirrhosis.
- have certain conditions such as:
  - stomach or intestinal bleeding or ulcers;
  - bleeding in the lungs or kidneys, bladder or urethra;
  - cerebral haemorrhage (bleeding in the brain);
  - heart infection;

- swelling of the heart membrane or fluid in the heart;
- brain aneurysm (swelling of an artery that supplies blood to the brain).
- have tendency to fall due to neurological or other health-related conditions.
- have dementia, psychoses, alcoholism or another situation where the anticoagulant treatment cannot be administrated safely.
- are taking medicines that may increase your risk of bleeding or other medicines that stop the blood from clotting.
- have a physical condition which might have a risk of bleeding such as recent stroke.

Do not take Voalant together with miconazole oral gel.

Ask your doctor or pharmacist for advice before taking any medicine.

### Before you start to use it:

Talk to your doctor or pharmacist before taking Voalant if you:

- have liver or kidney problems.
- have thyroid problems.
- have ever had a stomach ulcer or bleeding in the stomach or intestines.
- have a condition making you prone to blood clots (thrombophilia).
- have a high risk of injury or falling.
- had recent ischaemic stroke (caused by blockage of blood vessels in the brain).
- are about to have surgery and your doctor may have to change your dose or stop your warfarin treatment.
- are taking any medicines that may increase your risk of bleeding or prevent blood clotting.
- observe signs of over-anticoagulation during treatment such as sudden unexplained

bruising, nosebleeds or haematuria.

## Taking other medicines

Please tell your doctor or pharmacist if you are taking any other medicines, including medicines obtained without a prescription, herbal medicines or natural products.

Some commonly used medicines and products that may interfere with Voalant include:

- Miconazole
- Fibrinolytic drugs to treat or prevent blood clots (e.g. alteplase, streptokinase)
- Non-steroidal anti-inflammatory drugs (NSAIDs) (e.g. aspirin, ibuprofen), antiplatelet drugs, medicines to treat heart problems (e.g. amiodarone, propafenone), fungal infections (e.g. fluconazole), to lower cholesterol in blood (e.g. bezafibrate, gemfibrozil), to treat gout (e.g. allopurinol), to treat asthma (e.g. zafirlukast) - prolonged bleeding time
- Medicines to treat epilepsy (e.g. phenobarbital, carbamazepine), tuberculosis (e.g. rifampicin), immunosuppressant (e.g. azathioprine), oral contraceptives, vitamin K, reduce the effect of warfarin
- Some types of medicines used to prevent blood clotting (e.g. warfarin, dicoumarol, phenprocoumon, acenocoumarol and fluindione). The effect of these medicines may be stronger when used with glucosamine. Patients treated with such combinations should therefore be monitored extra carefully when initiating or ending glucosamine therapy.

For temporary relief of pain or fever while taking warfarin, preparations containing only paracetamol as the active ingredient can be used.

Please consult your doctor if you are taking the following herbal medicines:

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- Ginkgo, dong quai and danshen - may potentiate the effect of warfarin
- St. John's wort and ginseng - may reduce the effect of warfarin

Do not drink large amounts of alcohol while taking Voalant. Cranberry juice and other cranberry products may potentiate the effect of warfarin and therefore concomitant use should be avoided.

### *Pregnancy and lactation*

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Voalant during pregnancy. Voalant may harm your unborn baby. Use effective measures to avoid pregnancy while taking Voalant.

Voalant is unlikely to harm your baby during breast-feeding, if taken at the correct dose.

### **How to use Voalant**

#### **How much to use?**

The administration and dosage of Voalant is individualized according to your response (PT/INR) to the medicine.

Take Voalant exactly according to the instructions given to you by your doctor. Do not change your dose without talking to your doctor. Try to take your tablets at the same time each day. Check with your doctor or pharmacist if you are not sure.

Your doctor will do blood tests during your treatment and may change your dose depending on the results. It is very important to have blood test at regular intervals to see how long it takes your blood to clot, and it is necessary to follow the dosing instructions and attend the blood test.

### **When to use it?**

Use as directed by your doctor or pharmacist.

### **How long to use it?:**

The time period for taking Voalant depends on your doctor's instruction.

### **If you forget to use it:**

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

Tell your doctor that you have forgotten a dose when you next see them or when you have your blood test.

### **If you take too much (overdose):**

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

### **While you are using Voalant**

#### **Things you must do:**

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentist and pharmacist treating you that you are taking Voalant
- Tell your doctor immediately if you become pregnant while taking this medication.

#### **Things you must not do:**

- Do not take any medication without consulting your doctor.
- Do not give Voalant to anyone else, even if they have same symptoms or conditions as you.

- Do not stop using this medication unless directed by your doctor.

### **Things to be careful of:**

Drastic changes in dietary habits should be avoided as the amount of vitamin K in food may affect therapy with warfarin. A balanced diet with a constant amount of vitamin K is recommended.

### *Driving and using machines*

This medicine should not affect your ability to drive or operate machinery. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

### **Side effects**

Like all medicines, Voalant can cause side effects, although not everybody gets them.

Stop taking this medicine and see a doctor or go to a hospital immediately if you have:

- a rare allergic reaction such as swelling of the face, tongue, lips and throat, difficulty breathing, severe itching of your skin with raised lumps. You may need urgent medical treatment.

Some side effects could be serious.

Tell your doctor straight away if you have any of the following side effects:

- any unexpected bleeding or signs of bleeding (as this could mean that your clotting levels are too low and that your dose needs to be adjusted):
  - unexplained nose bleeds, bleeding gums;
  - unexplained bruising or pinpoint red spots on your skin;
  - heavy bleeding or oozing from cuts and wounds;
  - dark red or brown urine (this may be due to bleeding in the bladder or kidneys);
  - black tarry stools (signs of bleeding from the stomach, intestine or rectum);
  - coughing up blood;

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- (in women) unusually heavy periods or bleeding from the vagina;
- blurred vision, slurred speech, loss of movement, numbness, dizziness, headache, feeling or being sick, fits, loss of consciousness. These could be signs of a bleed in the brain.
- painful, blue-purple coloured toes.
- yellowing of the skin and white of eyes (jaundice).
- severe pain in the upper abdomen (a sign of inflammation of the pancreas).
- a painful skin rash. On rare occasions warfarin can cause serious skin conditions, including one called calciphylaxis that can start with a painful skin rash but can lead to other serious complications. This adverse reaction occurs more frequently in patients with chronic kidney disease.

Frequency 'not known' - Impairment of renal function occurring with excessive anticoagulation and presence of blood in urine (anticoagulant-related nephropathy).

Tell your doctor or pharmacist if any of the following side effects persist or get worse:

- feeling sick or being sick, diarrhoea
- hair loss
- skin rash
- fever
- drop in number of red blood cells, blood haemoglobin (shown in blood tests).

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers→

Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## Storage and disposal of Voalant

### Storage:

Store in the original package and at room temperature below 30°C. Protect from light and moisture. Keep out of reach of children.

### Disposal:

The expiry date of Voalant is printed on the carton and blister. Do not use if after expiry date. Medicines should not be disposed of via wastewater or household waste. If your doctor tells you to stop taking Voalant or the expiry date has passed, ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## Product Description

### What it looks like?:

Voalant Tablets 5mg is a 8.5mm round bioconvex tablets pale orange tablets, engraved with the "WAF5" on one side and "UL" on the other side.

## Ingredients in Voalant

### Active ingredients:

Warfarin Sodium Clathrate 5.45mg (equivalent to Warfarin Sodium 5mg)

### Inactive ingredients:

Lactose anhydrous, Pregelatinized Corn Starch, FD & C Yellow No.6 Aluminum Lake, Magnesium Stearate, Purified Water.

### Manufacturer:

U-Liang Pharmaceutical Co., Ltd  
No.10, Kuang-Fu Rd.,  
Hu-Kou Hsiang, Hsin Chu Hsien,  
Taiwan R.O.C

### Product Registration Holder:

Nano Medic Care Sdn Bhd  
No.1-6 & 1-12, 1<sup>st</sup> Floor,  
Jalan Indah 2, Taman Indah,  
84000 Muar Johor  
MALAYSIA

**MAL number:** MAL\_\_\_\_\_A

### Date of revision:

July 2024

### Serial Number:

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