4. Possible side effects

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

Stop taking warfarin and see a doctor or go to a hospital straight away if you notice the following serious side effect - you may need urgent medical treatment:

- **Allergic reaction** - the signs may include swelling of your face, lips, tongue or throat, difficulty breathing or swallowing, severe itching of your skin with raised lumps.

If you fall or injure yourself during treatment, especially if you hit your head. Please seek urgent medical attention. You may need to be checked by a doctor, as you may be at increased risk of bleeding.

If you get any of the above, stop taking warfarin and see a doctor or go to a hospital straight away.

Tell your doctor or go to a hospital straight away if you get any of the following side effects. Your doctor may decide to stop your warfarin treatment:

- Any bleeding at all as this is a sign that your clotting levels are low: Examples of bleeding that have been noted with the use of warfarin are:
  - nose bleeds without any obvious reason
  - loss of consciousness, fits, numbness, headache, confusion, dizziness, feeling or being sick, slurred speech, blurred vision. These could be signs that there is a bleed in your brain
  - change in the colour of your urine - a dark red or brown urine might be due to bleeding in your kidneys or bladder
  - black or red stools can mean you have internal bleeding
  - red or purple swollen patches on your skin that look like bruises
  - painful red patches of skin that have blood filled blisters that turn black
- feeling sick (nausea) or being sick (vomiting), fever, pain, swelling or tenderness in your stomach or back or difficulty in breathing and chest pain
- yellowing of the skin and whites of the eyes (jaundice)
- purple painful toes
- 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.

The following side effects have also been reported

- Damage to the kidneys - symptoms include: feeling sick or being sick, diarrhoea, dehydration, peeing less than usual, confusion, drowsiness.

If you get any of the above, please tell your doctor or go to hospital straight away.

Tell your doctor if you get any of these side effects:

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

If you get any of the above, please tell your doctor.

Adverse effects with no known frequency:

Impairment of renal function occurring with excessive anticoagulation and presence of blood in urine (anticoagulant-related nephropathy). Osteoporosis (bone thinning) which may increase the risk of a fracture (broken bone).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store warfarin

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Do not use after the expiry date (month, year) stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- Once you open the bottle, it can only be used for 28 days. Write the date you open the bottle on the label.
- Do not use warfarin suspension if you notice anything wrong with the medicine. Talk to your pharmacist.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What warfarin suspension contains

- The active ingredient is warfarin sodium. This medicine contains 1mg of warfarin sodium in each 1ml of suspension
- The other ingredients are propylene glycol (E1520), benzoic acid (E210), xanthan gum (E415), polysorbate 80 (E433), citric acid (E330), disodium phosphate (E339), aluminium magnesium silicate, liquid maltitol (E965), masking flavour and purified water.

What warfarin suspension looks like and contents of the pack

A white to off-white suspension.

It comes in a brown glass bottle holding 150ml of suspension, packed in a cardboard box with a 10ml purple syringe and an adaptor.

Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

This leaflet was last revised in August 2025.

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V2

Rosemont® Package Leaflet: Information for the User

Warfarin Sodium 1mg/1ml Oral Suspension

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed only for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet

1. What warfarin is and what it is used for
2. What you need to know before you take warfarin
3. How to take warfarin
4. Possible side effects
5. How to store warfarin
6. Contents of the pack and other information

1. What warfarin is and what it is used for

The name of your medicine is Warfarin Sodium 1mg/1ml Oral Suspension (called warfarin in this leaflet). Warfarin belongs to a group of medicines called anticoagulants. It is used to thin your blood and prevent your blood from clotting.

If you are seeing another doctor or are going to the hospital, tell them that you are taking warfarin. They may want to contact your doctor.

2. What you need to know before you take warfarin

Do not take warfarin if:

- you are allergic to warfarin or any of the other ingredients of this medicine (listed in Section 6). An allergic reaction can include swelling of your face, lips, tongue or throat, difficulty breathing or swallowing, severe itching of your skin with raised lumps
- you have severe uncontrollable bleeding
- you have had a stroke as a result of bleeding from a blood vessel in the brain
- you are pregnant, planning to become pregnant or have just had a baby in the last 48 hours (please see Section 2 “Pregnancy and breast-feeding”)
- you have had surgery in the last 72 hours or are about to have surgery in the next 72 hours
- you are taking medicines that may increase your risk of bleeding or other medicines that stop the blood from clotting (please see Section 2 'Take special care with warfarin' and 'Taking other medicines').

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor before taking warfarin.

Warnings and precautions

Talk to your doctor or pharmacist before taking warfarin to check if any of the following apply to you. You may need to be more closely monitored by your doctor:

- you are an older person (over 65)
- you drink large amounts of alcohol
- you have diarrhoea and are being sick
- you have any sudden illness or have recently been ill (such as having the flu or feeling run down)
- you have raised blood pressure that is not controlled by medicines
- you have liver or kidney problems
- you have ever had a stomach ulcer or bleeding
- you have a condition making you prone to blood clots (thrombophilia)
- you have had a stroke
- you have an infection of the lining of your heart (bacterial endocarditis)
- you have anaemia, bruise easily or have an illness that causes bleeding
- you have heart disease including congestive heart failure
- you have problems with circulation of blood to the brain (cerebrovascular disease)
- you have a tumour or cancer
- you have thyroid problems
- you have had a recent wound or injury
- you have low vitamin K levels
- you have low levels of a substance called “Protein C” or “Protein S”. These stop blood clotting
- you take part in sports activities, particularly those with a high risk of injury or falling
- you are taking any medicines that may increase your risk of bleeding such as non-steroidal anti-inflammatories (NSAIDs) e.g. aspirin or other medicines that stop the blood from clotting
- you are going to have surgery. The doctor may have to change your dose or stop your warfarin treatment
- you are changing your diet or have recently lost or gained a lot of weight. Keep your diet and level of activity as close to normal as possible (please see Section 2 “Taking warfarin with food and drink” for more information).

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking warfarin. You may need to be more closely monitored by your doctor.

Continued overleaf

Rosemont®

ARTWORK VERSION: 2 Date: 13.08.2025 Operator: SBL

PRINT VERSION: Date: Operator:

JOB INFORMATION

Product Name: Warfarin Sodium Oral Suspension (UK)

Strength: 1mg/1ml
Pack Size: 150ml
Bottle Size: 150ml
Design Icon: N/A

New Item Code: J1BD1RBJ7
Previous Item Code: J1BD1RBJ6
Supplier Code: N/A
Change Control No.: DEV-00899

JOB SPECIFICATION

Keyline Ref: UKL412 LFT
Dimensions: 300 x 210mm
Folded Size: 150 x 30mm
Tabbed: No
Pharmacode: 153
EAN Code: N/A
No. of Colours: 1
Page Number: 1 of 2

MAIN BODY TEXT

Font Type: Univers LT Std Roman, Univers LT Std Bold
Font Size: 7 pt

COLOURS

Print Colours: Black

TECHNICAL NON PRINTING COLOURS

Keyline (Non-Printing), Cirrus_Info_Box

APPROVALS

Third Party Approval

Name:
Sign:
Date:

Regulatory Approval

Name:
Sign:
Date:

Other medicines and warfarin
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines and vitamin supplements. This is because warfarin can affect the way some other medicines work. Also some other medicines can affect the way warfarin works. Other medicines can make you more likely to bleed or you may need to take more warfarin because of what you are already taking.

Do not take warfarin and tell your doctor if you are taking any of the following medicines:
- alteplase, reteplase, streptokinase, tenecteplase, urokinase (fibrinolytic drugs to treat or prevent blood clots)
- other medicines used to thin your blood (anticoagulants) or stop clotting such as clopidogrel, dipyridamole, dabigatran, bivalirudin, heparins, fondaparinux, rivaroxaban, eptifibatide, tirofiban, abciximab and prostacyclin. If you are changing to warfarin from another anticoagulant you should tell your doctor
- medicines to treat depressions such as SSRIs (selective serotonin reuptake inhibitors), for example, fluoxetine and citalopram or SNRIs (selective noradrenaline reuptake inhibitors) such as venlafaxine
- sulfinpyrazone – used for gout
- St. John's Wort - a herbal remedy used for depression.

Do not take warfarin and tell your doctor if you are taking any of the above medicines. If you are not sure, talk to your doctor or pharmacist.

The following medicines may increase the effect of your warfarin. Tell your doctor or pharmacist if you are taking:
- medicines for gout, pain and inflammation called non-steroidal anti inflammatory drugs (NSAIDs) such as aspirin, indometacin, celecoxib
- glucosamine (for osteoarthritis)
- medicines for heart problems such as amiodarone, propafenone or quinidine
- medicines that reduce high levels of fats (lipids) in your blood such as bezafibrate or gemfibrozil or lower your cholesterol levels such as fluvastatin
- colestyramine - used for itching and diarrhoea in some illnesses
- vitamin K which can be found in vitamin supplements and enteral feeds
- medicines to help you sleep such as chloral hydrate or triclofos which relax your muscles
- anabolic steroids such as stanozolol or corticosteroids such as zafirlukast
- medicines for pain and inflammation in illnesses like rheumatism and arthritis such as paracetamol, allopurinol or phenylbutazone
- medicines for infection such as cefamanadole, chloramphenicol, ciprofloxacin, co-trimoxazole, erythromycin, clarithromycin, metronidazole, neomycin, sulfamethoxazole or tetracyclines
- medicines for fungal infections such as fluconazole, ketoconazole or miconazole
- medicines for diabetes such as glibenclamide
- medicines for thyroid problems
- cimetidine, omeprazole or sucralfate – used for stomach ulcers or too much stomach acid
- tamoxifen, capecitabine, erlotinib - used to treat cancer
- danazol - used for menstrual problems or endometriosis
- methylphenidate - used for hyperactivity disorder
- disulfiram - used for alcohol addiction
- dextropropoxyphene – used for pain
- tramadol - used for pain.

If any of the above apply to you (or you are not sure) talk to your doctor or pharmacist before taking warfarin.

The following medicines may decrease the effect of your warfarin. Tell your doctor or pharmacist if you are taking:
- barbiturates (sedatives)
- medicines for epilepsy such as phenobarbital, phenytoin, primidone or carbamazepine
- medicines for arthritis such as azathioprine
- rifampicin – used for infections like TB (tuberculosis)
- griseofulvin – used for fungal infections
- orlistat - used to help weight loss
- phenazone – used for pain
- oral contraceptives (the "pill")
- aminogluthethimide - used for cancer.

The following medicines may have varying effects on warfarin. Tell your doctor or pharmacist if you are taking:
- corticosteroids - used for inflammation and many other diseases
- nevirapine, ritonavir - used for HIV infection.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking warfarin.

Warfarin with food, drink and alcohol
- Do not drink large amounts of alcohol while you are taking warfarin.
- It is best not to have cranberry juice or any other cranberry products. This is because cranberry may increase the effects of warfarin and cause bleeding.
- If you have been advised to have cranberry products for medical reasons (such as bladder infections), talk to your anticoagulant clinic or health advisor before taking this medicine. They may ask you to stop using or reduce the amount of cranberry or monitor you more often while you are taking warfarin.
- It is important to keep your diet as close to normal as possible while taking warfarin. This is because making changes in your diet may affect how your body responds to warfarin. This is particularly likely to happen with foods which contain large amounts of vitamin K such as leafy green vegetables.

Pregnancy, breast-feeding and fertility
- Do not take this medicine if you are pregnant, planning to become pregnant or have just had a baby in the last 48 hours.
- You should use a barrier method of contraception such as a condom. See your doctor straight away if you get pregnant while taking this medicine. This is because warfarin can harm your unborn child. Your doctor can give you another medicine instead of warfarin.
- Breast-feeding, while taking this medication, is unlikely to harm your baby, if warfarin is taken at the correct dose.

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Driving and using machines
This medicine should not affect your ability to drive or operate machinery.

Warfarin Sodium 1mg/1ml Oral Suspension contains liquid maltitol, propylene glycol and benzoic acid:
- Liquid maltitol (a type of sugar). If your doctor has told you that you cannot tolerate some sugars, talk to your doctor before taking this medicine.
- Propylene glycol. This medicine contains 39.6mg propylene glycol in each ml. If you are pregnant or breast-feeding or if you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.
- Benzoic acid. This medicine contains 0.8mg benzoic acid in each ml, which may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- This medicine contains less than 1 mmol sodium (23 mg) per 1ml, that is to say essentially 'sodium-free'.

3. How to take warfarin

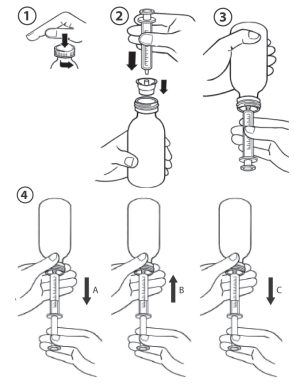
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- **Shake the bottle well before use to make sure you get the correct dose.**
- **If you find it difficult to measure the dose or take the medicine accurately, you may need the help of a carer.**
- **It is important that the dose is measured correctly.**

- This medicine contains 1 milligram (1mg) of Warfarin in each 1 millilitre (1ml) of suspension.
- Take this medicine by mouth.
- Try to take your dose at the same time each day.

Measuring your dose
Your pack contains a plastic syringe to measure the right amount of liquid prescribed for you. Always use this syringe to measure out your dose. The numbers up the side show how many millilitres (mls) of liquid you have inside the syringe.



1. Open the bottle: press the cap and turn it anticlockwise (figure 1).
2. Insert the syringe adaptor into the bottle neck (figure 2).
3. Take the syringe and put it in the adaptor opening (figure 2).
4. Turn the bottle upside down (figure 3).
5. Fill the syringe with a small amount of solution by pulling the piston down (figure 4A). Then push the piston upward in order to remove any possible bubbles (figure 4B). Finally, pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 4C).
6. Turn the bottle the right way up.
7. Remove the syringe from the adaptor. Put the end of the syringe into your mouth and push the piston slowly back in to take the medicine.
8. Wash the syringe with water and let it dry before you use it again.
9. Close the bottle with the plastic screw cap.

How much to take
The usual doses are given below. The correct dose will be decided by your doctor based on your response (INR) to the medicine. Follow your doctor's instructions carefully.

Adults
- On days one and two, the usual starting dose is 10mg (10ml), taken at the same time each day
- On days 3 and onwards, the usual dose is 3mg to 9mg (3ml to 9ml), taken at the same time each day
- If you are an older person (over 65) your doctor may give you a lower dose.

Children
Warfarin is not recommended for use in children.

Blood tests
Your doctor will do blood tests during your treatment and may change your dose depending on the results.

If you take more warfarin than you should
If you take more of this medicine than you should, talk to a doctor or go to your nearest hospital straight away. Take the medicine pack with you.

If you forget to take warfarin
- If you forget a dose and remember within two or three hours, you can still take that dose
- If you forget your dose for longer than three hours, do not take that dose. Instead, wait until the next dose is due
- Do not take a double dose to make up for a forgotten dose
- Tell your doctor that you have forgotten a dose when you next see them or when you have your blood test.

If you stop taking warfarin
Do not stop taking warfarin unless your doctor tells you to. It may be dangerous to do so.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Continued overleaf

Rosemont®

ARTWORK VERSION: 2
Date: 13.08.2025
Operator: SBL

PRINT VERSION:
Date:
Operator:

JOB INFORMATION
Product Name: Warfarin Sodium Oral Suspension (UK)
Strength: 1mg/1ml
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Bottle Size: 150ml
Design Icon: N/A
New Item Code: J1BD1RBJ7
Previous Item Code: J1BD1RBJ6
Supplier Code: N/A
Change Control No.: DEV-00899

JOB SPECIFICATION
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Font Size: 7 pt

COLOURS
Print Colours: Black

TECHNICAL NON PRINTING COLOURS
Keyline (Non-Printing), Zirrus_Info_Box

APPROVALS

Third Party Approval	
Name:	
Sign:	
Date:	
Regulatory Approval	
Name:	
Sign:	
Date:	