

MAFORAN TABLET

Warfarin Sodium (as Warfarin Sodium Clathrate) (1mg, 2mg, 3mg and 5mg)

What is in this leaflet

1. What is Maforan Tablet used for
2. How it works
3. Before you use Maforan Tablet
4. How to use Maforan Tablet
5. While you are using it
6. Side Effects
7. Storage and Disposal of Maforan Tablet
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What Maforan Tablet is used for

Maforan 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 recurrence of blood clots after heart attack.

How Maforan Tablet works

Maforan is a type of anticoagulant drug. "Anti" means against, and "coagulant" refers to blood clotting. Anticoagulants help reduce the occurrence of clotting in the blood. Maforan blocks some of the reabsorption of vitamin K by your liver. Vitamin K is needed to build clotting factors that help blood clot and stop bleeding. Vitamin K can be found naturally in foods such as green and leafy vegetables and some vegetable oils. Maforan begins to reduce blood clotting within 24 hours of taking this medication. The full effect can take 72 to 96 hours to occur.

Before you use Maforan Tablet

- When you must not use it

Do not use Maforan if you are allergic to warfarin sodium or any of the ingredients in this medicine.

Do not take Maforan together with Miconazole oral gel.

Pregnant and breastfeeding

If you are pregnant, think you may be pregnant or are planning to have baby, ask your doctor or pharmacist

for advice before taking this medicine.

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

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

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 Maforan if you:

- have kidney or liver problem
- 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, nose bleeds 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 Maforan 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 contraceptive, 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:

- Ginkgo, dong quai and dashen 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 Maforan. Cranberry juice and other cranberry products may potentiate the effect of warfarin and therefore concomitant use should be avoided.

MAFORAN TABLET

Warfarin Sodium (as Warfarin Sodium Clathrate) (1mg, 2mg, 3mg and 5mg)

How to use Maforan Tablet

- How much to use

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

Take Maforan 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

Continue taking Maforan for as long as your doctor recommends

- 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 use 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 it

- Things you must do

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

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor
- Do not take any new medicines without consulting your doctor or pharmacist
- Do not give Maforan to anyone else, even if they have the same symptoms or condition as you.

- 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 has no known effect on the ability to drive or operate machines. 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, Maforan 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 need 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 (sign of bleeding from the stomach, intestine or rectum);
 - coughing up blood;
 - (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

MAFORAN TABLET

Warfarin Sodium (as Warfarin Sodium Clathrate) (1mg, 2mg, 3mg and 5mg)

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

Storage and Disposal of Maforan Tablet

- Storage

Do not store above 30°C.

Protect from light.

Keep out of reach of children

- Disposal

The expiry date of Maforan 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 Maforan 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

Maforan 1 mg Tablet

White flat round tablet with a bisect and debossed with “MAFORAN”, “1” on one side, plain on the other.

Maforan 2 mg Tablet

Orange flat round tablet with a bisect and debossed with “MAFORAN”, “2” on one side, plain on the other.

Maforan 3 mg Tablet

Dark blue flat round tablet with a bisect and debossed with “MAFORAN”, “3” on one side, plain on the other.

Maforan 5 mg Tablet

Pink flat round tablet with a bisect and debossed with “MAFORAN”, “5” on one side, plain on the other.

- Ingredients

- Active ingredient:

Warfarin Sodium (as Warfarin Sodium Clathrate)

- Inactive ingredients:

Microcrystalline cellulose

Lactose monohydrate

Sodium starch glycolate

Poloxamer

Povidone

Colloidal silicon dioxide

Talcum

Magnesium stearate

Colorants:

Sunset yellow (2mg)

Brilliant Blue (3mg)

Erythrosine lake (5mg)

- MAL Number

Maforan 1 mg Tablet

(MAL20086013ARZ)

Maforan 2mg Tablet

(MAL20086014ARZ)

Maforan 3mg Tablet

(MAL20086015ARZ)

Maforan 5mg Tablet

(MAL18086118ARZ)

Manufacturer

Packed and released by:

GoodScience Sdn. Bhd.

No.7, Jalan KPK 4/3, Kawasan Perindustrian Kundang, Kundang Jaya 48020 Rawang, Selangor, Malaysia

Manufactured by:

Sriprasit Pharma Co., Ltd.

216 Moo 6, Suanluang, Krathum Baen, Samut Sakhon 74110, Thailand

Product Registration Holder

GoodScience Sdn. Bhd.

No.7, Jalan KPK 4/3, Kawasan Perindustrian Kundang, Kundang Jaya 48020 Rawang, Selangor, Malaysia

Date of revision

07/01/2025

Serial number

NPRA (R2) 19/236