

Package leaflet: Information for the user

Dindevan 25mg Tablets

phenindione

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, pharmacist or nurse.
- This medicine has been prescribed for you only. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Dindevan 25mg Tablets. It will be referred to as ‘Dindevan Tablets’ for ease hereafter.

What is in this leaflet

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

1. What Dindevan Tablets are and what they are used for

Phenindione belongs to a group of medicines called anticoagulants. These medicines increase the time it takes for your blood to clot. Phenindione is used to prevent and treat blood clots in the veins and arteries, for example, clots in the legs, lungs, brain or heart.

2. What you need to know before you take Dindevan Tablets

Do not take Dindevan Tablets

- if you are allergic to Phenindione or any of the other ingredients of this medicine (listed in section 6)
- if you have severe liver or kidney problems
- if you are pregnant or trying for a baby
- if you within the last 72 hours have had an operation or you have given birth within the last 48 hours
- if you are currently breast-feeding
- if you suffer from any unusual bruising or bleeding
- if you suffer from uncontrolled high blood pressure
- if you have an infection of the tissues lining the heart called bacterial endocarditis
- if you have a rare problem of sugar intolerance
- if your doctor has told you that you have bleeding within the brain (hemorrhagic stroke).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Dindevan Tablets

- if you have a painful skin rash. On rare occasions Dindevan Tablets can cause serious skin conditions, including one called calciphylaxis that can start with a painful skin rash but can lead to serious complications. This adverse reaction occurs more frequently in patients with chronic kidney disease
- if you are elderly
- if you have recently lost or gained a lot of weight
- if you have any short term illness
- if you have a problem with your kidneys, or liver which is not classed as severe
- if you are being sick or have diarrhoea
- if you are changing your diet which may result in an increase or decrease of Vitamin K
- if you have protein C or S deficiency (blood clotting disorders)
- if you have a disease of the brain and blood vessels (cerebrovascular disease)
- if you have major heart disease
- if you have low levels of iron in the blood (which may lead to pale appearance of the eyes and skin)
- if you have had a major injury
- if you have ulcers in your stomach
- if you have bleeding in the stomach or intestines
- if you have either an increase or decrease in the levels of thyroid hormone
- if you have cancer
- if you have decreased blood supply to a part of the brain (ischemic stroke)
- if you are going to have surgery. The doctor may have to change your dose or stop your phenindione treatment
- if you have stopped smoking.

Tell your doctor if any of the above applies to you as they may alter the effect of Dindevan Tablets and require an adjustment of the dose.

Other medicines and Dindevan Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Dindevan Tablets may affect or be affected by any of the medicines below which are used to treat the following conditions:

- Heart problems e.g., amiodarone and propafenone
- Prevent the formation of blood clots e.g., clopidogrel, bivalirudin, dabigatran, heparin, fondaparinux, rivaroxaban, danaparoid
- Clot dissolving medications (e.g., streptokinase, alteplase)
- Problems with platelet aggregation (blood cells sticking together) e.g., dipyridamole, eptifibatide, tirofiban and abciximab, prostacyclin
- Depression e.g., amitriptyline, nortriptyline, citalopram, venlafaxine
- Pain and inflammation e.g., paracetamol, aspirin, ibuprofen, piroxicam, flurbiprofen, indometacin, sulindac, azapropazone, diflunisal, corticosteroids
- High levels of lipids (fats) in the blood and drugs which lower cholesterol levels e.g. clofibrate
- Infection e.g., antibiotics such as ciprofloxacin, metronidazole, norfloxacin, co-trimoxazole, erythromycin, tetracyclines, cefamandole, chloramphenicol, rifampicin, neomycin, aztreonam, sulfamethoxazole
- Fungal infections, e.g., miconazole
- Stomach ulcers or excessive production of stomach acid e.g., cimetidine, sucralfate, cholestyramine.

- Diabetes e.g., tolbutamide, phenformin and glucagon
- Various inflammatory problems such as asthma e.g., prednisolone, zafirlukast
- Gout e.g., allopurinol, sulfinpyrazone
- Cancer e.g., ipilimumab, dasatinib and imatinib
- Difficulty in sleeping e.g., phenobarbital
- Osteoarthritis pain (glucosamine)
- Chronic alcoholism e.g., disulfiram
- Thyroid problems e.g., thyroxine
- Epilepsy e.g., barbiturates, carbamazepine, primidone, phenytoin
- Pain killers (Dextropropoxyphene)
- Joint and muscular pain (Fepirzone, oxyphenbutazone and phenylbutazone)
- Obesity e.g., orlistat
- Stress (ACTH, released in the body in response to biological stress).
- Some types of medicines used to prevent blood clotting (e.g., warfarin, dicoumarol, phenprocoumon, acenocoumarol and fluidione). 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.

If you are taking the following, tell your doctor

- Oral contraceptives
- Anabolic steroids such as stanozolol (used to promote muscle growth)
- Vitamin supplements e.g., Vitamin K or Cod Liver Oil (or other dietary intake high in fats or oils).

The dose of Dindevan Tablets will need to be checked regularly if any other medicines are also used at the same time. Many medications interact with Phenindione, so please inform your doctor if you are taking any other medicines including over the counter medicines, herbal (St. John's Wart) or vitamin preparations.

Regular blood tests:

You will have regular blood tests to see how long it takes for your blood to clot. These blood tests are very important to make sure you are taking the right dose. Blood tests will be more frequent if you have had your dose of phenindione changed, if you have started or stopped taking other medicines or have liver or kidney problems.

Dindevan Tablets with food, drink and alcohol

- Do not drink large amounts of alcohol when taking Dindevan Tablets. Discuss this with your doctor if you are worried about anything
- Avoid drinking Cranberry juice
- Some foods like liver, broccoli, brussels sprouts and green leafy vegetables may interfere with the action of Phenindione
- Avoid taking any food supplements when taking Phenindione.

Pregnancy and breast-feeding

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

Pregnancy

Dindevan Tablets should not be taken if you are pregnant, think you are pregnant or are planning to become pregnant. If you think you may have become pregnant, contact your doctor as soon as possible. Dindevan Tablets can have an adverse effect on the unborn child, and alternative medicines are available.

Breast-feeding

Speak to your doctor before taking this medicine if you are breast-feeding.

Driving and using machines

Dindevan Tablets should not affect your ability to drive or use machines.

Dindevan Tablets contains lactose which is a form of sugar.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This medicine also contains tartrazine (E102) which may cause allergic reactions.

3. How to take Dindevan Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Read the label on the container to see how many Dindevan Tablets to take, and how often to take them.

The recommended dose is:

Adults:

- Usual starting dose of 200mg (8 tablets) on the first day
- After the first day, the dose is usually reduced to 100mg (4 tablets) a day.
- From **the third day of treatment**, the doctor will adjust your dose up or down depending on the results of the blood test which will be performed at the start and at regular intervals during your treatment.

Method of Administration

- Swallow the tablets whole with a drink of water
- Try to take the tablets at the same time each day
- Do not take more tablets than the doctor tells you to.

The dose recommendations are for **adults only**.

Use in children

Dindevan Tablets are not suitable for use in children.

If you have to go to another doctor, to hospital or to a dentist, tell them that you are being treated with Dindevan Tablets and ask them to contact your own doctor.

If you take more Dindevan Tablets than you should

If you take too many Dindevan Tablets, you may experience bruising, lump of blood, blood in the urine, rectal bleeding and bleeding into any internal organ. Tell your doctor or go to your nearest Hospital Casualty/Accident and Emergency Department immediately. Take any remaining tablets and this leaflet with you so that the medical staff will know what you have taken.

If you forget to take your Dindevan Tablets

If you miss a dose and remember within two or three hours, you can still take that dose. If you forget for a longer time, do not take that dose to catch up, but take your next dose when it is due. Remember to tell your doctor when you see him/her next and have your blood test. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Dindevan Tablets

Do not stop taking your tablets except on your doctor's advice as your condition may worsen.

Keep healthcare professionals informed

Carry your anticoagulant record card with you at ALL times. Always tell any doctors, surgeons, nurses, dentists or pharmacists that you go to, that you are taking Dindevan Tablets.

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

4. Possible side effects

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

Stop taking Dindevan Tablets and tell your doctor immediately if you experience any of the following side effects, because you may need urgent medical treatment:

- Allergic reactions: the signs may include swelling of your face, lips, tongue or throat, difficulty breathing or swallowing, skin rashes, dark red or black areas on the skin as the skin may be dying or scaling of the skin. Also bluish discolouration of the skin including toes may occur. This is a rare complication, most likely to occur during the first several days of therapy with Dindevan Tablets and often in association with large starting doses
- Unusual bleeding or bruising more easily, getting more infections, feeling weak or tired more than usual, jaundice (yellowing of the skin or whites of the eyes), problems with your kidneys or liver and hair loss.

The following side-effects have been reported:

Not known (frequency cannot be estimated from the available data)

- Blood disorders (your doctor will do tests to check this).
- Loose stools (Diarrhoea)
- Loss of consciousness, fits, numbness, headache, dizziness, feeling or being sick, slurred speech, blurred vision. These could be signs that there is bleeding or formation of blood clots in your brain
- Difficulty in breathing and chest pain due to collection of blood in the chest
- Bleeding from cuts and wounds or the nose
- Vomiting of blood
- Black or red stools which might be due to bleeding from the stomach, intestine or rectum
- Severe stomach or back pain
- Taste disturbance
- Fever

- Unusual bleeding from the stomach, intestine or rectum
- Pancreatitis presenting as severe stomach or back pain
- Dark red or brown coloured urine which might be due to bleeding in your kidneys or bladder.
- Your urine may turn pink or orange

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Dindevan Tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the "Use Before" date which is stated on the carton and label. The "Use Before" date refers to the last day of that month.

Store in original package/container in order to protect from light.

Do not store above 25°C.

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 protect the environment.

6. Contents of the pack and other information

What Dindevan Tablets contains

The active substance is Phenindione. Each tablet contains 25mg of Phenindione. The other ingredients are maize starch, lactose, anhydrous citric acid powder, magnesium stearate, dispersed green 15217 [Tartrazine Lake (E102), Brilliant Blue FCF Lake (E133) and Alumina BP] and purified water.

What Dindevan Tablets looks like and contents of the pack

Green, round, flat, bevel edged uncoated tablets scored on one side, engraved D25 on the scored side. The tablets are packaged in either plastic pots (polypropylene containers) containing 28, 100 or 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This leaflet was last revised in January 2024.