WARFARIN 5 BIOTECH

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:
S4

Warfarin 5 Biotech, 5 mg, tablets
Warfarin sodium
Warfarin 5 Biotech contains sugar (sucrose: 8,0 mg per tablet and lactose: 139,0 mg per tablet).

Read all of this leaflet carefully before you start taking Warfarin 5 Biotech
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- Warfarin 5 Biotech has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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

1. What Warfarin 5 Biotech is and what it is used for
Warfarin 5 Biotech contains the active ingredient warfarin which belongs to a group of medicines called anticoagulants. It is used to decrease the clotting ability of the blood and therefore helps to prevent harmful clots from forming in the blood vessels. Warfarin 5 Biotech is used to prevent and treat blood clots forming in the legs, lungs, brain or heart.

2. What you need to know before you take Warfarin 5 Biotech
Do not take Warfarin 5 Biotech
- if you are hypersensitive (allergic) to warfarin sodium or any of the other ingredients of Warfarin 5 Biotech listed in section 6.1
- if you recently had a stroke caused by bleeding in the brain
- if you have a bleeding situation
- if you have any bleeding disorder or disease
- if you had surgery within the last 72 hours or are going to have surgery in the next 72 hours
- if you have a peptic ulcer or other stomach disease that causes you to bleed internally
- if you have a severe wound
- if you have a prosthetic heart valve
- if you an infection of the heart valves
- if your kidney or liver function is impaired
- if you have high blood pressure
- if you had an aneurysm (blood vein or artery that formed a sac or burst)
- if you have inflammation (swelling) of the pericardium, which is the fluid-filled sac that surrounds your heart (pericarditis)
- if you have an abnormal amount of fluid between the heart and pericardium (pericardial perfusion)
- if you had or are going to have surgery that involves your eyes, brain, back or nerves or any other major surgeries
- if you had a baby in the last 48 hours
- if you have severe arthritis (inflammation of the joints) affecting five or more joints at the same time
- if you have a Vitamin C deficiency
- if you have the possibility of losing your baby (threatened abortion)
- if you are younger than 18 years of age, because safety has not been established
- if you are taking other medicines that increase your risk of bleeding
- if you are taking other medicines to treat and prevent blocking of a blood vessel by a blood clot
- if you are pregnant or may become pregnant or breast feeding, you baby.

Warnings and precautions
Take special care with Warfarin 5 Biotech
- if you have a genetic disorder called protein C deficiency making you prone to blood clots (thrombophilia);
- you should not stop your treatment with Warfarin 5 Biotech abruptly. Your doctor will decrease your dose gradually over three to four weeks;
- if you have a Vitamin K deficiency;
- medicines like Warfarin 5 Biotech, which work against vitamin K, might put you at risk for weaker bones (increased risk in fractures). You need extra attention to avoid this problem;
- if you suffer from dietary deficiency, are on antibiotic treatment, suffer from vascular disease, diabetes or have allergic disorders;
- if you had recent ischaemic stroke (caused by blockage of blood vessels in the brain);
- if you had an infection of the heart lining (bacterial endocarditis);
- if you previously had gastrointestinal bleeding;
- if you have a higher risk of bleeding for example if you are over 65 years of age or are unsteady on your feet and more likely to fall and injure yourself;
- very high blood pressure which is not controlled by medicines;
- problems with circulation of blood to the brain (cerebrovascular disease);
- if you have severe heart disease, liver or kidney problems;
- if you have anaemia (low haemoglobin causing extreme tiredness, breathlessness, poor resistance to infection);
- if you have a tumour or cancer;
- if you had trauma, had a recent wound or injury;
- if you use any anti-platelet medicines (such as clopidrogel, aspirin), because that can increase the risk of bleeding;
- if you have the condition calciphylaxis, where calcium builds up inside the blood vessels of the fat and skin;
- if you have an overactive thyroid gland;
- if you experience a painful and prolonged erection called priapism. This problem seems to be linked to a lack of protein C, and it often happens alongside another issue called warfarin-induced skin necrosis;
- if you experience a painful spot on the skin, which may look red or bleed at first. Later, it can form blisters and turn black from tissue death. People with lack of protein C levels seem to be at the highest risk;
- Be cautious if you have "wet" age-related eye disease that can blur your central vision and are taking Warfarin 5 Biotech because it could make you bleed inside your eye and lead to vision loss.

Regular blood tests:
You will have regular blood tests to see how long it takes 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 warfarin changed, if you have started or stopped taking other medicines, or have liver or kidney problems.

Warfarin 5 Biotech may be affected by:
A number of things affect blood clotting and can therefore affect your Warfarin 5 Biotech treatment. It is important to follow the advice given below:
The following increases the effect of Warfarin 5 Biotech
- Weight loss
- Sudden illness such as the flu or feeling run down
- Stopping smoking, thus seek medical advice before you give up smoking
- Cranberry juice and cranberry products (and possibly grapefruit juice)
- Large amounts of alcohol

The following decreases the effect of Warfarin 5 Biotech
- Weight gain
- Stomach upset, diarrhoea
- Being sick (vomiting)

Keep your healthcare professionals informed:
Carry your anticoagulation record card with you at ALL times. Always tell any doctors, surgeons, nurses, dentists or pharmacists that you go to that you are taking Warfarin. You should also have received a booklet which includes more information about Warfarin along with a list of symptoms which need to be checked by your doctor immediately.

Surgical operations:
Tell your doctor you are taking Warfarin 5 Biotech.
Due to the risk of bleeding, your doctor may need to lower your dose before an operation or removal of teeth. You should stop taking Warfarin 5 Biotech 3 to 5 days before and after surgery where there is a risk of severe bleeding. Make sure you tell your doctor or dentist you are taking Warfarin 5 Biotech. Depending on the reason you are using warfarin, Warfarin 5 Biotech may have to be replaced by another medicine (heparin).

Children and adolescents
Warfarin 5 Biotech should not be given to children 18 years and younger as the safety and effectiveness have not been established.

Other medicines and Warfarin 5 Biotech
Always tell your healthcare provider if you are taking any other medicine.
(This includes all complementary or traditional medicines.)
Tell your doctor if you are taking any of the following medicines:
Do not take Warfarin 5 Biotech and tell your doctor if you are taking:
- Fibrinolytic medicines to treat or prevent blood clots, such as alteplase, reteplase, tenecteplase, streptokinase and urokinase
- St John's wort (Hypericum perforatum) an herbal remedy for depression.

Check with your doctor first before taking these medicines:
- Clopidogrel (antiplatelet medicines to prevent or break down blood clots)
- non-steroidal-anti-inflammatory drugs (NSAIDs) for pain and inflammation including aspirin, ibuprofen, celecoxib, diclofenac, indomethacin, meloxicam
- sulfinpyrazone (for gout)
- Thrombin inhibitors (delaying blood clotting) such as bivalirudin, dabigatran
- dipyridamole (antiplatelet drugs to prevent or break down blood clots)
- heparin or medicines containing heparin, bivalirudin, fondaparinux, dabigatran, rivaroxaban, danaparoid, prostacyclin (other anticoagulants)
- Glycoprotein IIb/IIIa receptor antagonists such as eptifibatide, tirofiban and abciximab (antiplatelet drugs to prevent or break down blood clots)
- SSRI and SNRI anti-depressants such as citalopram, fluoxetine, paroxetine, venlafaxine
- glucosamine (for osteoarthritis)

Medicines which increase the effect of Warfarin 5 Biotech:
- prolonged, regular use of paracetamol (for pain or inflammation)
- antibiotics such as amoxicillin, levofloxacin and tetracycline
- allopurinol (for gout)
- capecitabine, erlotinib, tamoxifen (for types of cancer)
- disulfiram (for alcohol dependence)
- ketoconazole, fluconazole, itraconazole, miconazole (for fungal infections)
- omeprazole (for stomach ulcers)
- propafenone, amiodarone, quinidine (for heart disorders)
- methylphenidate (for attention deficit disorder)
- zafirlukast (for asthma)
- bezafibrate, ciprofibrate, fenofibrate, gemfibrozil (to reduce high blood fats)
- statins such as fluvastatin to lower cholesterol (but this does not include pravastatin)
- erythromycin, sulfamethoxazole, metronidazole (for bacterial infections)
- orlistat (for obesity)
- Vitamin K (in vitamin supplements or in cod liver oil).

Medicines which decrease the effect of Warfarin 5 Biotech:
- barbiturates (sedatives)
- primidone, phenytoin, carbamazepine (to treat epilepsy)
- griseofulvin (for fungal infections)
- oral contraceptives (the 'Pill')
- rifampicin (for tuberculosis)
- azathioprine (for inflammatory bowel disease and rheumatoid arthritis and to prevent organ rejection)
- sucralfate (for stomach ulcers)
- cholestyramine (for lowering cholesterol)
- vitamin K (an increase in the amount of your vitamin K intake could reduce the effect of Warfarin 5 Biotech).

Medicines which have varying effects on Warfarin 5 Biotech:
- corticosteroids (for inflammation and many other diseases)
- nevirapine, ritonavir (for HIV infection).

Warfarin 5 Biotech with food, drink and alcohol
Patients should seek medical advice before undertaking any major changes in diet or using food supplements while taking Warfarin 5 Biotech.
Do not drink either cranberry juice or grapefruit juice or products containing it whilst taking Warfarin 5 Biotech.
Acute ingestion of a large amount of alcohol may inhibit the metabolism of Warfarin 5 Biotech and increase INR. Conversely, chronic heavy alcohol intake may induce the metabolism of Warfarin 5 Biotech.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving Warfarin 5 Biotech.

Do not take Warfarin 5 Biotech if you are pregnant, may become pregnant or have had a baby within the last 48 hours.
Woman of child-bearing age who are taking Warfarin 5 Biotech should use contraception medicine during their treatment with Warfarin 5 Biotech and for at least 1 month after the final dose of Warfarin 5 Biotech.

Do not breastfeed your infant while taking Warfarin 5 Biotech.

Driving and using machines
It is not always possible to predict to what extent Warfarin 5 Biotech may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Warfarin 5 Biotech affects them.

Warfarin 5 Biotech contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Warfarin 5 Biotech contains sucrose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Warfarin 5 Biotech
Do not share medicines prescribed for you with any other person.

Always take Warfarin 5 Biotech exactly as you doctor, or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Never take more or less tablets than your recommended dose. Your doctor or healthcare provider should check your progress with Warfarin 5 Biotech at regular visits.
A blood test must be taken regularly to see how fast your blood is clotting. This test is called INR (international normalised ratio) test.

Adults:
The usual starting dose of Warfarin 5 Biotech is 5 mg once a day. Then, your dose may be adjusted, depending on your condition and results of your blood tests.

Try to take the Warfarin 5 Biotech at the same time each day.

Your doctor will tell you how long your treatment with Warfarin 5 Biotech will last. Do not stop treatment early. If you have the impression that the effect of Warfarin 5 Biotech is too strong or too weak, tell your doctor or pharmacist.

If you take more Warfarin 5 Biotech than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms of taking too much Warfarin 5 Biotech include bleeding, black tarry stools, blood in urine, heavy bleeding or oozing from cuts and wounds or unusually heavy menstrual bleeding.

Activated charcoal should be used if you have symptoms 1 hour after taking too much (50 g for adults and 1g/kg for children) Warfarin 5 Biotech.

If you forget to take Warfarin 5 Biotech
Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects
Warfarin 5 Biotech can have side effects.
Not all side effects reported for Warfarin 5 Biotech are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Warfarin 5 Biotech, please consult your healthcare provider for advice.

If any of the following happens, stop taking Warfarin 5 Biotech and tell your doctor immediately or go the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to Warfarin 5 Biotech. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- an artery in the brain bursting and causing bleeding in the brain (cerebral haemorrhage)
- bleeding that occurs within the skull of head but outside the actual brain tissue (cerebral subdural haematoma)
- escape of blood from a ruptured blood vessel (haemorrhage)
- haemothorax (blood collects between your chest wall and your lungs)
- bleeding in the gastrointestinal tract, from the mouth to the rectum. When there is a lot of blood loss over a short time, symptoms may include vomiting red blood, vomiting black blood, bloody stool, or black stool (Gastrointestinal haemorrhage, rectal haemorrhage, haematemesis).
- severe pain in the upper abdomen (a sign of inflammation of the pancreas) (pancreatitis)
- the production of dark sticky faeces containing partly digested blood, as a result of internal bleeding or the swallowing of blood (melaena).
- damage to your liver that results in dark urine (hepatic dysfunction)
- 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.
- if you have a bone disease that occurs when the body loses too much bone, makes too little bone, or both. As a result, bones become weak and may break from a fall or, in serious cases, from sneezing or minor bump (osteoporosis)
- if you have blood in your urine (haematuria)
- drop in number of red blood cells, blood haemoglobin (shown in blood tests).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Less frequent side effects:
- lower-than-normal number of leukocytes (white blood cells) in the blood
- too many granulocytes (certain type of white blood cells) in the blood
- reduced blood clotting (by inhibiting vitamin K synthesis), may also increase the risk of bleeding
- diarrhoea
- nausea
- vomiting
- feeling bloated
- loss of appetite
- stomach pain
- kidney damage (leading to swelling in different parts of the body, abnormal amount of protein in the urine or difficulty passing urine).

Side effects with unknown frequency
- fever
- low number of red blood cells (anaemia)
- bleeding from the nose (epistaxis)
- yellowing of the skin and white of eyes (jaundice)
- skin rash
- hair loss
- a rash of purple spots on the skin caused by internal bleeding from small blood vessels (purpura)
- painful skin lesion seen in patients with moderate to severe kidney problems
- skin redness
- skin necrosis (also called warfarin-induced skin necrosis-condition in which skin and tissue death occurs)
- arm or leg become severely damaged and may die to problems with the veins in that limb
- sores or white spots in your mouth or throat.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you
can help provide more information on the safety of Warfarin 5 Biotech.

5. How to store Warfarin 5 Biotech
Store all medicines out of reach of children.
Store at or below 25 °C.
Store in the original package
Do not use after the expiry date stated on the carton.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What Warfarin 5 Biotech contains
The active substance is 5 mg warfarin sodium
The other ingredients are lactose monohydrate, sucrose, maize starch, purified water, pregelatinized starch, magnesium stearate and erythrosine aluminium lake (E127).

What Warfarin 5 Biotech looks like and contents of the pack
Pink coloured, circular, flat faced bevelled edged uncoated tablets with breakline on one side and plain on the other side.

Warfarin 5 Biotech are packed in Opaque blisters. Each blister contains 10 or 14 tablets, which are placed in an outer carton containing 10 or 2 blisters.

Holder of Certificate of Registration
Biotech Laboratories (Pty) Ltd.
Ground Floor, Block K West, Central Park,
400 16th Road, Randjespark, Halfway House
Midrand, 1685
South Africa
Tel: +27 (0) 11 848 3050

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WARFARIN 5 BIOTECH

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS:
S4

Warfarin 5 Biotech, 5 mg, tablette
Warfarien natrium
Warfarin 5 Biotech bevat suiker (sukrose: 8,0 mg per tablet en laktose: 139,0 mg per tablet).

Lees die hele pamflet noukeurig deur voordat jy begin om Warfarin 5 Biotech te neem
- Hou hierdie pamflet. Jy mag dit dalk weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- Warfarin 5 Biotech is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle skade aandoen, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie pamflet
1. Wat Warfarin 5 Biotech is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy Warfarin 5 Biotech neem
3. Hoe om Warfarin 5 Biotech te neem
4. Moontlike newe-effekte
5. Hoe om Warfarin 5 Biotech te bewaar
6. Inhoud van die pak en ander inligting

1. Wat Warfarin 5 Biotech is en waarvoor dit gebruik word
Warfarin 5 Biotech bevat die aktiewe bestanddeel warfarien wat behoort aan 'n groep medisyne wat antikoagulante genoem word. Dit word gebruik om die stollingsvermoë van die bloed te verminder en help dus om te verhoed dat skadelike klonte in die bloedvate vorm.
Warfarin 5 Biotech word gebruik om bloedklonte wat in die bene, longe, brein of hart vorm, te voorkom en te behandel.

2. Wat jy moet weet voordat jy Warfarin 5 Biotech neem
Moenie Warfarin 5 Biotech neem nie
- indien jy hipersensitief (allergies) is vir warfarien natrium of vir enige van die ander bestanddele van Warfarin 5 Biotech gelys in afdeling 6.1
- indien jy onlangs 'n beroerte gehad het wat veroorsaak is deur bloeding in die brein
- indien jy 'n bloedingsituasie het
- indien jy enige bloedingsversteuring of siekte het
- indien jy binne die afgelope 72 uur 'n operasie gehad het of binne die volgende 72 uur geopereer gaan word
- indien jy 'n maagseer of ander maagsiekte het wat jou inwendig laat bloei
- indien jy 'n ernstige wond het
- indien jy 'n prostetiese hartklep het
- indien jy 'n infeksie van die hartkleppe het
- indien jou nier- of lewerfunksie verswak is
- indien jy hoë bloeddruk het
- indien jy 'n aneurisme gehad het (bloedaar of slagaar wat 'n sak gevorm het of gebars het)
- indien jy inflammasie (swelling) van die perikardium het, wat die vloeistofgevulde sak is wat jou hart omring (perikarditis)
- indien jy 'n abnormale hoeveelheid vloeistof tussen die hart en perikardium het (perikardiale perfusie)
- indien jy 'n operasie gehad het of gaan ondergaan wat jou oë, brein, rug of senuwees of enige ander groot operasies behels
- indien jy 'n baba in die laaste 48 ure gehad het
- indien jy ernstige artritis (ontsteking van die gewrigte) het wat vyf of meer gewrigte op dieselfde tyd aantas
- indien jy 'n Vitamien C tekort het
- indien jy die moontlikheid het om jou baba te verloor (dreigende aborsie)
- indien jy jonger as 18 jarige ouderdom is, omdat die veiligheid nie vasgestel is nie
- indien jy ander medisyne neem wat jou risiko vir bloeding verhoog
- indien jy ander medisyne neem om die blokkering van 'n bloed vat deur 'n bloedklont te behandel en te voorkom
- indien jy swanger is of swanger mag raak of jou baba borsvoed.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met Warfarin 5 Biotech
- indien jy 'n genetiese versteuring het genaamd proteïen C-tekort wat jou geneig maak tot bloedklonte (trombofilie);
- jy moenie jou behandeling met Warfarin 5 Biotech skielik staak nie. Jou dokter sal geleidelik jou dosis verminder oor die tydperk van drie tot vier weke;
- indien jy 'n vitamien K tekort het;
- medisyne soos Warfarin 5 Biotech, wat teen vitamien K werk, kan jou in gevaar stel vir swakker bene (verhoogde risiko van frakture). Jy het ekstra aandag nodig om hierdie probleem te vermy;
- indien jy aan dieettekorte ly, op antibiotikabehandeling is, aan vaskulêre siektes, diabetes ly of allergiese afwykings het;
- indien jy onlangs 'n iskemiese beroerte gehad het (veroorsaak deur blokkasie van bloedvate in die brein);
- indien jy 'n infeksie van die hartvoering gehad het (bakteriële endokarditis);
- indien jy voorheen gastroïntestinale bloeding gehad het;
- indien jy 'n hoër risiko van bloeding het, byvoorbeeld as jy ouer as 65 jaar is of onstabiel op jou voete is en meer geneig is om te val en jouself te beseer;
- baie hoë bloeddruk wat nie deur medisyne beheer word nie;
- probleme met bloedsirkulasie na die brein (serebrovaskulêre siekte);
- indien jy ernstige hartsiekte, lewer- of nierprobleme het;
- indien jy bloedarmoede het (lae hemoglobien wat uiterste moegheid, asemnood, swak weerstand teen infeksie veroorsaak);
- indien jy 'n gewas het of kanker het;
- indien jy trauma gehad het, 'n onlangse wond of besering gehad het;
- indien jy enige anti-plaatjie medisyne (soos klopidrogel, aspirien) gebruik, want dit kan die risiko van bloeding verhoog;
- indien jy die toestand kalsifilakse het, waar kalsium in die bloedvate van die vet en vel opbou;
- indien jy 'n ooraktiewe skildklier het;
- indien jy 'n pynlike en langdurige ereksie ervaar wat priapisme genoem word. Hierdie probleem blyk te wees gekoppel aan 'n gebrek aan proteïen C, en dit gebeur dikwels saam met 'n ander probleem genoem warfarien-geïnduseerde vel nekrose;
- indien jy 'n pynlike plek op die vel ervaar, wat aanvanklik rooi kan lyk of bloei. Later kan dit blase vorm en swart word van weefseldood. Mense met 'n gebrek aan proteïen C-vlakke blyk die hoogste risiko te hê;
- wees versigtig indien jy "nat" ouderdomverwante oogsiekte het wat jou sentrale visie kan vervaag en Warfarin 5 Biotech neem omdat dit jou in jou oog kan laat bloei en tot sigverlies kan lei.

Gereelde bloedtoetse:
Jy sal gereeld bloedtoetse hê om te sien hoe lank dit jou bloed neem om te stol. Hierdie bloedtoetse is baie belangrik om seker te maak jy neem die regte dosis. Bloedtoetse sal meer gereeld wees as jy jou dosis warfarien verander het, as jy begin of opgehou het om ander medisyne te neem, of lewer- of nierprobleme het.

Warfarin 5 Biotech kan beïnvloed word deur:
'n Aantal dinge beïnvloed bloedstolling en kan dus jou Warfarin 5 Biotech-behandeling beïnvloed. Dit is belangrik om die advies hieronder te volg:
Die volgende verhoog die effek van Warfarin 5 Biotech
- Gewigsverlies
- Skielike siekte soos verkoue of afgeloop gevoel
- Ophou rook, soek dus mediese advies voor jy ophou rook
- Bosbessiesap en bosbessieprodukte (en moontlik pomelosap)
- Groot volumes alkohol

Die volgende verminder die effek van Warfarin 5 Biotech
- Gewigstoename
- Maagongesteldheid, diarree
- Siek wees (braking)

Hou jou gesondheidsorgverskaffers ingelig:
Dra jou antikoagulasie-rekordkaart te ALLE tye by jou. Vertel altyd vir enige dokters, chirurge, verpleegsters, tandartse of aptekers waarheen jy gaan dat jy Warfarien neem. Jy moes ook 'n boekie ontvang het wat meer inligting oor Warfarien insluit saam met 'n lys van simptome wat dadelik deur jou dokter nagegaan moet word.

Chirurgiese operasies:
Vertel jou dokter dat jy Warfarin 5 Biotech neem.
As gevolg van die risiko van bloeding, sal jou dokter dalk jou dosis moet verlaag voor 'n operasie of verwydering van tande.
Jy moet ophou om Warfarin 5 Biotech 3 tot 5 dae voor en na die operasie te neem waar daar 'n risiko van ernstige bloeding is. Maak seker jy vertel jou dokter of tandarts dat jy Warfarin 5 Biotech neem. Afhangende van die rede waarom jy warfarien gebruik, moet Warfarin 5 Biotech dalk deur 'n ander medisyne (heparien) vervang word.

Kinders en adollesente
Warfarin 5 Biotech moet nie aan kinders 18 jaar en jonger gegee word nie, aangesien die veiligheid en doeltreffendheid nie vasgestel is nie.

Ander medisyne en Warfarin 5 Biotech
Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem.
(Dit sluit alle komplementêre of tradisionele medisyne in.)
Vertel jou dokter indien jy enige van die volgende medisyne neem:
Moenie Warfarin 5 Biotech neem nie en vertel jou dokter as jy:
- Fibrinolitiese medisyne neem om bloedklonte te behandel of te voorkom, soos alteplase, reteplase, tenekteplase, streptokinase en urokinase
- St John's wort (Hypericum perforatum) 'n kruiemiddel vir depressie.

Raadpleeg eers jou dokter voordat jy hierdie medisyne neem:
- Clopidogrel (antiplaatjie medisyne om bloedklonte te voorkom of af te breek)
- nie-steroïdale anti-inflammatoriese middels (NSAIMs) vir pyn en inflammasie, insluitend aspirien, ibuprofen, selekoksib, diklofenak, indometasien, meloksikaam
- sulfinpirasoon (vir jig)
- trombieninhibeerders (vertraagde bloedstolling) soos bivalirudin, dabigatran
- dipiridamool (antiplaatjiemiddels om bloedklonte te voorkom of af te breek)
- heparien of medisyne wat heparien, bivalirudien, fondaparinuks, dabigatran, rivaroksaban, danaparoid, prostasiklien bevat (ander antikoagulante)
- Glikoproteïen IIb/IIIa reseptorantagoniste soos eptifibatied, tirofiban en absiksimab (teenplaatjiemiddels om bloedklonte te voorkom of af te breek)
- SSRI en SNRI antidepressante soos sitalopram, fluoksetien, paroksetien, venlafaksien
- glukosamien (vir osteoartritis)

Medisyne wat die effek van Warfarin 5 Biotech verhoog:
- verlengde, gereelde gebruik van parasetamol (vir pyn of inflammasie)
- antibiotika soos amoksisillien, levofloksasien en tetrasiklien
- allopurinol (vir jig)
- kapesitabien, erlotinib, tamoksifen (vir tipes kanker)
- disulfiram (vir alkoholafhanklikheid)
- ketokonasool, flukonasool, itrakonasool, mikonasool (vir swaminfeksies)
- omeprasool (vir maagsere)
- propafenoon, amiodaroon, kinidien (vir hartversteurings)
- metielfenidaat (vir aandagafleibaarheid)
- zafirlukast (vir asma)
- besafibraat, siprofibraat, fenofibraat, gemfibrosiel (om hoë bloedvette te verminder)
- statiene soos fluvastatien om cholesterol te verlaag (hierdie sluit nie pravastatien in nie)
- eritromisien, sulfametoksasool, metronidasool (vir bakteriële infeksies)
- orlistat (vir vetsug)
- Vitamien K (in vitamienaanvullings of in kabeljou lewer olie).

Medisyne wat die effek van Warfarin 5 Biotech verminder:
- barbiturate (sedeermiddels)
- primidoon, fenitoïen, karbamasepien (om epilepsie te behandel)
- griseofulvin (vir swaminfeksies)
- orale voorbehoeding (die "Pil")
- rifampisien (vir tuberkulose)
- azatioprien (vir inflammatoriese dermsiekte en rumatoïede artritis en om orgaanverwerping te voorkom)
- sukralfaat (vir maagsere)
- cholestiramien (om cholesterol te verlaag)
- vitamien K ('n toename in die hoeveelheid van jou vitamien K-inname kan die effek van Warfarin 5 Biotech verminder).

Medisyne wat verskillende effekte op Warfarin 5 Biotech het:
- kortikosteroïede (vir inflammasie en vele ander siektes)
- nevirapien, ritonavir (vir MIV infeksie).

Warfarin 5 Biotech met kos, drank en alkohol
Pasiënte moet mediese advies inwin voordat hulle enige groot veranderinge in dieet onderneem of voedselaanvullings gebruik terwyl hulle Warfarin 5 Biotech neem.
Moenie óf bosbessiesap óf pomelosap of produkte wat dit bevat drink terwyl jy Warfarin 5 Biotech neem nie.
Akute inname van 'n groot hoeveelheid alkohol kan die metabolisme van Warfarin 5 Biotech inhibeer en INV verhoog. Omgekeerd kan chroniese swaar alkoholinname die metabolisme van Warfarin 5 Biotech veroorsaak.

Swangerskap, borsvoeding en vrugbaarheid
As jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy Warfarin 5 Biotech ontvang.

Moenie Warfarin 5 Biotech neem as jy swanger is, swanger kan raak of 'n baba binne die afgelope 48 uur gehad het nie.
Vroue van vrugbare ouderdom wat Warfarin 5 Biotech neem, moet voorbehoedmiddels gebruik tydens hul behandeling met Warfarin 5 Biotech en vir ten minste 1 maand na die finale dosis Warfarin 5 Biotech.

Moenie jou baba borsvoed terwyl hy Warfarin 5 Biotech neem nie.

Bestuur en die gebruik van masjiene
Dit is nie altyd moontlik om te voorspel tot watter mate Warfarin 5 Biotech met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet verseker dat hulle nie by bogenoemde aktiwiteite betrokke raak voordat hulle bewus is van die mate waarin Warfarin 5 Biotech hulle affekteer nie.

Warfarin 5 Biotech bevat laktose
As jy deur jou dokter gesê is dat jy 'n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy hierdie medisyne gebruik.

Warfarin 5 Biotech bevat sukrose
As jy deur jou dokter gesê is dat jy 'n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy hierdie medisyne gebruik.

3. Hoe om Warfarin 5 Biotech te neem
Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem Warfarin 5 Biotech altyd presies soos jou dokter of apteker vir jou gesê het. Gaan praat met jou dokter of apteker as jy nie seker is nie.

Moet nooit meer of minder tablette neem as jou aanbeveelde dosis nie.
Jou dokter of gesondheidsorgverskaffer moet jou vordering met Warfarin 5 Biotech by gereelde besoeke nagaan.
'n Bloedtoets moet gereeld gedoen word om te sien hoe vinnig jou bloed stol. Hierdie toets word INV (internasionale genormaliseerde verhouding) toets genoem.

Volwassenes:
Die gewone aanvangsdosis Warfarin 5 Biotech is 5 mg een keer per dag. Dan kan jou dosis aangepas word, afhangende van jou toestand en die resultate van jou bloedtoetse.

Probeer om die Warfarin 5 Biotech elke dag op dieselfde tyd te neem.

Jou dokter sal jou vertel hoe lank jou behandeling met Warfarin 5 Biotech sal duur. Moenie die behandeling vroegtydig stop nie. As jy die indruk het dat die effek van Warfarin 5 Biotech te sterk of te swak is, vertel jou dokter of apteker.

Indien jy meer Warfarin 5 Biotech neem as wat jy moet
In die geval van 'n oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Simptome van die neem van te veel Warfarin 5 Biotech sluit in bloeding, swart teeragtige stoelgang, bloed in uriene, swaar bloeding of uitvloei van snye en wonde of buitengewoon swaar menstruele bloeding.

Geaktiveerde houtskool moet gebruik word as jy simptome het 1 uur nadat jy te veel (50 g vir volwassenes en 1 g/kg vir kinders) Warfarin 5 Biotech ingeneem het.

Indien jy vergeet om Warfarin 5 Biotech te neem
Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dossisse nie.

4. Moontlike newe-effekte
Warfarin 5 Biotech kan newe-effekte hê.
Nie alle newe-effekte wat vir Warfarin 5 Biotech aangemeld is word in hierdie pamflet bevat nie. Sou jou algemene gesondheid versleg of indien jy enige ongewensde effekte ervaar terwyl jy Warfarin 5 Biotech neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om Warfarin 5 Biotech te neem en vertel jou dokter onmiddelik of gaan na die naaste ongevalle-afdeling van jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat moeilike sluk of moeilike asemhaling mag veroorsaak,
- uitslag of jeuk,
- floute.

Hierdie is almal baie ernstige newe-effekte. Indien jy dit het mag jy dalk 'n ernstige reaksie op Warfarin 5 Biotech gehad het. Jy mag dringende mediese aandag of hospitalisasie benodig.

Vertel onmiddelik jou dokter of gaan na die ongevalle-afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:
- 'n aterie in die brein wat bars en in die brein veroorsaak (serebrale bloeding)
- Bloeding wat voorkom binne die skedel van die kop, maar buite die werklike breinweefsel (serebrale subdurale hematoom).
- ontsnapping van bloed uit 'n gebarste bloedvat (bloeding)
- hemotoraks (bloed versamel tussen jou borswand en jou longe).
- bloeding in die spysverteringskanaal, van die mond tot die rektum. Wanneer daar baie bloedverlies oor 'n kort tyd is, kan simptome braking van rooi bloed, braking van swart bloed, bloederige stoelgang of swart stoelgang insluit (Gastrointestinale bloeding, rektale bloeding, hematemese).
- erge boonste maagpyn ('n teken van inflammasie van die pankreas) (pankreatitis).
- die produksie van donker, taai ontlasting wat gedeeltelik verteerde bloed bevat, as gevolg van inwendige bloeding of die insluk van bloed (melaena).
- Skade aan jou lewer wat lei tot donker uriene (lewer disfunksie)
- 'n pynlike veluitslag. In seldsame gevalle kan warfarien ernstige veltoestande veroorsaak, insluitend een wat kalsifilakse genoem word, wat kan begin met 'n pynlike veluitslag, maar kan lei tot ander ernstige komplikasies. Hierdie nadelige reaksie kom meer gereeld voor by pasiënte met chroniese niersiekte.
- Indien jy 'n beensiekte het wat plaasvind wanneer die liggaam te veel been verloor, te min been maak, of albei. As gevolg hiervan word bene swak en kan dit breek as gevolg van 'n val of, in ernstige gevalle, van nies of geringe stamp (osteoporose)
- indien jy bloed in jou uriene het (hematurie)
- verlaging in die aantal rooibloedselle, bloed hemaglobien (gewys in bloedtoetse).

Hierdie is almal ernstige newe-effekte. Jy mag dalk dringende mediese aandag benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:
Minder gereelde newe-effekte:
- laer as normale aantal leukosiete (witbloedselle) in die bloed
- te veel granulosiete (sekere tipe witbloedselle) in die bloed
- verminderde bloedstolling (deur vitamien K sintese te inhibeer), mag ook die risiko vir bloeding verhoog
- diarree
- naarheid
- braking
- opgeblaasde gevoel
- verlies van aptyt
- maagpyn
- nierbeskadiging (wat lei tot swelling op verskillende plekke van die liggaam, abnormale hoeveelheid proteïene in die uriene of moeilike uitskeiding van uriene).

Newe-effekte met onbekende frekwensie
- koors
- lae aantal rooibloedselle (anemie/ bloedarmoede)
- bloeding van die neus (epistakse)
- vergeling van die vel en die wit van die oë (geelsug)
- veluitslag
- haarverlies
- 'n uitslag of pers kolle op die vel veroorsaak deur interne bloeding van klein bloedvate (purpura)
- pynlike velletsel gesien by pasiënte met matige tot ernstige nierprobleme
- vel rooiheid
- velnekrose (ook genoem warfarien- geïnduseerde velnekrose-toestand waarin vel- en weefseldood plaasvind)
- arm of been word ernstig beskadig en kan sterf aan probleme met die are in daardie ledemaat
- sere of wit kolle in jou mond of keel.

Indien jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief jou dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRa aanmeld deur die vorm **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn onder SAHPRA se publikasies gevind kan word: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van Hemawarien te verskaf.

5. Hoe om Warfarin 5 Biotech te bewaar
Bewaar alle medisyne buite bereik van kinders.
Bewaar teen of benede 25 °C.
Bewaar in die oorspronklike houer.
Moenie gebruik na die vervaldatum wat op die karton gedruk is nie.
Gee alle ongebruikte medisyne terug aan jou apteker.
Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting
Wat Warfarin 5 Biotech bevat
Die aktiewe stof is 5 mg warfarien natrium
Die ander bestanddele is laktosemonohidraat, sukrose, mieliestysel, gesuiwerde water, voorgegelatineerde stysel, magnesiumstearaat en eritrosien-aluminiummeer (E127).

Hoe Warfarin 5 Biotech lyk en die inhoud van die pak
Pienkkleurige, ronde, plat, afgeskuinsde, onbedekte tablette met breeklyn aan die een kant en ongedruk aan die ander kant.

Warfarin 5 Biotech word verpak in ondeursigtige stulpstroke. Elke stulpstrook bevat 10 of 14 tablette wat in 'n buitenste karton geplaas word wat 10 of 2 stulpstroke bevat.

Houer van die Sertifikaat van Registrasie
Biotech Laboratories (Edms) Bpk.
Grondvloer, Blok K Wes, Central Park,
16de Weg 400, Randjespark, Midrand, 1685
Suid-Afrika
Tel: +27 (0) 11 848 3050

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