

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ASPEN WARFARIN 5 mg tablets

Warfarin sodium clathrate

Contains sugar: Lactose monohydrate 130,6 mg

Read all of this leaflet carefully before you start taking ASPEN WARFARIN 5 mg

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

1. What ASPEN WARFARIN 5 mg is and what it is used for

ASPEN WARFARIN 5 mg belongs to a group of medicines called anticoagulants. This medicine decreases the clotting ability of the blood and therefore helps to prevent harmful clots from forming in the blood vessels.

ASPEN WARFARIN 5 mg is used in adults to treat and prevent blocking of a blood vessel by a blood clot, which has been transported from a distant area by the blood stream.

2. What you need to know before you take ASPEN WARFARIN 5 mg

Do not take ASPEN WARFARIN 5 mg:

- if you are hypersensitive (allergic) to warfarin or any of the other ingredients of ASPEN WARFARIN 5 mg (listed in section 6).
- if you recently had a stroke caused by bleeding in the brain.
- 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 loss of feeling in a large part of the body for a medical procedure (major regional block anaesthesia).
- if you have a peptic ulcer or other stomach disease that causes you to bleed internally.
- If you have a condition that involves bleeding from the airways or bladder or sex organs.
- if you have a severe wound.
- if you have 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 live in an area where you do not have access to laboratory facilities or you are not willing to do regular blood tests to see how fast your blood is clotting.
- if you have the possibility of losing your baby (threatened abortion).
- if you are younger than 18 years of age.
- if you are taking other medicines that increase your risk of bleeding (see Other medicines and ASPEN WARFARIN 5 mg).
- if you are taking other medicines to treat and prevent blocking of a blood vessel by a blood clot (see Other medicines at ASPEN WARFARIN 5 mg).
- if you are using over-the-counter miconazole oral gel (see Other medicines at ASPEN WARFARIN 5 mg).
- if you are pregnant or breastfeeding (see Pregnancy, breastfeeding and fertility).

Warnings and precautions

Take special care with ASPEN WARFARIN 5 mg:

- Tell any doctors, dentists and pharmacists you go to that you are taking ASPEN WARFARIN 5 mg.
- If you are using ASPEN WARFARIN 5 mg you should carry a medic alert bracelet or other form of identification to show that you are using ASPEN WARFARIN 5 mg.
- Never stop using ASPEN WARFARIN 5 mg abruptly. Your doctor will gradually reduce your dose if necessary.
- If you have a genetic disorder called protein C deficiency.
- If you are elderly (≥ 65 years).
- You may be at risk of developing a rare, serious disease that involves a buildup of calcium in the small blood vessels of the fat tissues and skin (calciphylaxis) when taking warfarin, as contained in ASPEN WARFARIN 5 mg.
- If you have a vitamin K deficiency. If you have been on ASPEN WARFARIN 5 mg for a long time, you may be at risk of osteoporosis (reduced bone density) and fractures (bone breaks).
- If you have an overactive or underactive thyroid gland.
- If you have a low body mass due to a lack of good nutrition.
- While you are taking ASPEN WARFARIN 5 mg it is very important that you avoid sports and activities that may cause you to be injured or bleed.
- If you experience a painful and prolonged erection (priapism).
- If you have a painful spot on your skin that is red and bleeding initially, but develops into a blister or a black sore, this is serious, speak to your doctor.
- If you have neovascular (wet) age-related macular degeneration you may get bleeding in the eye that may lead to loss of vision.

- If you have an infectious disease, disturbances of your gut flora, you are not able to absorb nutrients from food (sprue) or you are taking antibiotics.
- If you have a type of blood cancer (polycythaemia vera), inflammation of blood vessels, severe diabetes or allergies,
- Anticoagulation therapy after ischaemic stroke (blocked blood flow to the brain causing damage to the brain tissue) increases the risk of secondary bleeding in the brain. Your doctor may advise you to stop ASPEN WARFARIN 5 mg after the stroke for a period of time,
- If you or someone in your family has genetic variability of certain genes (CYP2C9 and VKORC1), this may affect your ASPEN WARFARIN 5 mg dose.

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.

ASPEN WARFARIN 5 mg may be affected by:

A number of things affect blood clotting and can therefore affect your ASPEN WARFARIN 5 mg treatment. It is important to follow the advice given below:

The following increases the effect of ASPEN WARFARIN 5 mg

- Weight loss
- Cranberry juice or cranberry products and possibly grapefruit juice
- Large amounts of alcohol
- Sudden illness, such as the flu or generally feeling unwell

- Stopping smoking

The following decreases the effect of ASPEN WARFARIN 5 mg

- Weight gain
- Vitamin K
- Foods such as liver, broccoli, Brussels sprouts and green leafy vegetables contain large amounts of vitamin K.
- Stomach upset, diarrhoea, being sick (vomiting)

What you should do

- Do not go on a weight reducing diet or change your eating habits without discussing it first with your doctor or healthcare provider. Keep your level of activity as close to normal as possible.
- Do not take vitamin K supplements.
- Do not make any major changes to your diet while taking ASPEN WARFARIN 5 mg.
- Don't drink cranberry or grapefruit juice or any products containing cranberry or grapefruit while taking ASPEN WARFARIN 5 mg.
- Only drink small amounts of alcohol while taking ASPEN WARFARIN 5 mg.
- If you feel unwell, tell your doctor or healthcare provider, as your dose may need to be changed.
- Contact your doctor or healthcare professional before you give up smoking.

Surgical operations:

Tell your doctor you are taking ASPEN WARFARIN 5 mg.

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 ASPEN WARFARIN 5 mg 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 ASPEN WARFARIN 5 mg. Depending on the reason you are using warfarin, ASPEN WARFARIN 5 mg may have to be replaced by another medicine (heparin).

Children and adolescents

ASPEN WARFARIN 5 mg should not be used in children under 18 years of age (see Do not take ASPEN WARFARIN 5 mg).

Other medicines and ASPEN WARFARIN 5 mg

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Many medicines can affect the way that ASPEN WARFARIN 5 mg works in your body, therefore it is very important that you tell your doctor, pharmacist or other healthcare provider of any medication.

Tell your doctor if you are taking any of the following:

Medicines that should not be used as they could affect bleeding:

- Alteplase, reteplase, streptokinase, tenecteplase, urokinase (fibrinolytic medicines to treat or prevent blood clots).
- Over-the-counter miconazole oral gel (used to treat thrush in your mouth).
- Disopyramide (treats heart dysrhythmia), phenytoin (anti-epileptic), quinidine (anti-malarial), oral contraceptives.

- Dipyridamole (used to prevent blood clots) and aspirin (anti-inflammatory or used to prevent blood clots).
- St John's wort (*Hypericum perforatum*) (a herbal remedy for depression).
- Vitamin K (in vitamin supplements or in cod liver oil, used to prevent blood loss).

Medicines that should be avoided or used with caution:

- Non-steroidal anti-inflammatory medicines (NSAIDs) for pain and inflammation including, ibuprofen, celecoxib, diclofenac, indomethacin, meloxicam.
- Clopidogrel, abciximab, dipyridamole, eptifibatide, tirofiban, bivalirudin, dabigatran, prostacyclin (antiplatelet medicines to prevent or break down blood clots).
- Heparin or medicines containing heparin, fondaparinux, dabigatran, rivaroxaban, (other anticoagulants).
- Glucosamine (for osteoarthritis).
- SSRI and SNRI anti-depressants such as citalopram, fluoxetine, paroxetine, venlafaxine.
- Certain medicines used for gout (sulfapyrazone).

Medicines that increase the effect of ASPEN WARFARIN 5 mg:

- Prolonged, regular use of paracetamol (for pain or fever).
- Vitamin E (fat-soluble vitamin).
- Allopurinol (for gout).
- Capecitabine, erlotinib, tamoxifen (for types of cancer).
- Disulfiram (for alcohol dependence).
- Ketoconazole, fluconazole, itraconazole (for fungal infections).
- Omeprazole (for stomach ulcers).
- Propafenone, amiodarone, quinidine (for heart disorders).

- Methylphenidate (for attention deficit disorder).
- Zafirlukast (for asthma).
- Bezafibrate, fenofibrate, clofibrate, gemfibrozil (to reduce high blood fats).
- Statins such as fluvastatin to lower cholesterol (but this does not include pravastatin).
- Antibiotics such as erythromycin, sulfamethoxazole, metronidazole, telithromycin, chloramphenicol, aminoglycosides, sulphonamides (for bacterial infections).
- Orlistat (for obesity).
- Cimetidine (used to treat heartburn).
- Thyroid hormones (used to treat thyroid disorders).
- Aspirin and other NSAIDs (non-steroidal anti-inflammatory drugs), including phenylbutazone and other pyrazolones.
- Hormonal treatments (danazol).
- Glucagon (used to treat low blood sugar).
- Tramadol, dextropropoxyphene (opioid pain medicine).
- Diazoxide (used to treat low blood pressure).
- Triclofos and chloral hydrate (used to treat insomnia).
- Sulphonylurea-type antidiabetic medicines (used to treat diabetes).
- Anabolic steroids (medicines used to build muscle mass).
- Sulphinpyrazone (used for blood clotting disorders).

Medicines that decrease the effect of ASPEN WARFARIN 5 mg:

- Barbiturates, glutethimide (sedatives).
- Primidone, phenytoin, carbamazepine (to treat epilepsy).
- Griseofulvin (for fungal infections).
- Oral contraceptives (to prevent pregnancy).

- Rifampicin (for tuberculosis (TB)).
- Azathioprine (for inflammatory bowel disease and rheumatoid arthritis and to prevent organ rejection).
- Sucralfate (for stomach ulcers).
- Cholestyramine (for lowering cholesterol).
- Glucocorticoids (used to treat inflammatory conditions).

Medicines that have varying effects on ASPEN WARFARIN 5 mg:

- Corticosteroids (for inflammation and many other diseases).
- Nevirapine, ritonavir (for HIV infection).

The following conditions could be a reason for delayed blood clotting:

- Cancer
- Collagen disease
- Heart failure
- Diarrhoea
- Fever
- Liver not functioning properly
- Liver infection
- Jaundice (yellowing of the skin due to a liver condition)
- Poor nutritional state.

The following conditions could be a reason for decrease in prothrombin time:

- Diabetes
- Oedema (fluid retention)

- Inherited resistance to ASPEN WARFARIN 5 mg
- High blood cholesterol levels
- Underactive thyroid.

Heparins and danaparoid (anticoagulants) may prolong the INR, therefore a sufficient time interval should be allowed after administration before performing the test.

Not all the medicines that may interact with ASPEN WARFARIN 5 mg are listed above.

ASPEN WARFARIN 5 mg with food, drink and alcohol

Certain foods can decrease the effect of ASPEN WARFARIN 5 mg (see Warnings and precautions). Certain drinks can increase the effects of ASPEN WARFARIN 5 mg (see Warnings and precautions). Alcohol can increase the effects of ASPEN WARFARIN 5 mg (see Warnings and precautions).

Avoid taking any food supplements whilst taking ASPEN WARFARIN 5 mg and advise your doctor if you are taking any.

Pregnancy, breastfeeding and fertility

You should not be treated with ASPEN WARFARIN 5 mg or any other warfarin medicine if you are pregnant or breastfeeding your baby. Warfarin, as contained in ASPEN WARFARIN 5 mg, can cause foetal birth defects.

If you are a female of childbearing potential, you must use effective contraception during treatment, and for at least 1 month after the final dose of ASPEN WARFARIN 5 mg.

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 taking this medicine (see Do not take ASPEN WARFARIN 5 mg).

Driving and using machines

ASPEN WARFARIN 5 mg is not expected to influence your ability to drive. However, you should not drive, use machinery or perform any tasks that require concentration until you are certain that ASPEN WARFARIN 5 mg does not adversely affect your ability to do so safely.

It is not always possible to predict to what extent ASPEN WARFARIN 5 mg may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ASPEN WARFARIN 5 mg affects you (see Possible side effects).

ASPEN WARFARIN 5 mg contains lactose monohydrate

which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take ASPEN WARFARIN 5 mg.

3. How to take ASPEN WARFARIN 5 mg

Do not share medicines prescribed for you with any other person.

Always take ASPEN WARFARIN 5 mg exactly as your doctor 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 ASPEN WARFARIN 5 mg 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.

The usual dose of ASPEN WARFARIN 5 mg is:

Adults: The usual starting dose is 5 mg once a day. Then, your dose may be adjusted, depending on your condition and results of your blood tests. Take your ASPEN WARFARIN 5 mg dose at the same time each day.

Your doctor will tell you how long your treatment with ASPEN WARFARIN 5 mg will last. Do not stop treatment early without instructions from your doctor. If you have the impression that the effect of ASPEN WARFARIN 5 mg is too strong or too weak, tell your doctor or pharmacist.

If you take more ASPEN WARFARIN 5 mg than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ASPEN WARFARIN 5 mg

If you miss a dose of this medicine, take it as soon as possible. Then continue with your regular dosing schedule.

If you do not remember until the next day, do not take the missed dose at all. Do not take a double dose to make up for any forgotten individual doses.

Continue to take the next tablet at the usual time. **Double dosing may cause bleeding. It is recommended that you keep a record of each dose as you take it, to avoid mistakes.**

4. Possible side effects

ASPEN WARFARIN 5 mg can have side effects.

Not all side effects reported for ASPEN WARFARIN 5 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ASPEN WARFARIN 5 mg, please consult your healthcare provider for advice.

If any of the following happens, stop taking ASPEN WARFARIN 5 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and 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 ASPEN WARFARIN 5 mg. 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:

- Bleeding from almost any organ of your body,
- Bleeding in the brain (cerebral haemorrhage), bleeding within the skull (intracranial haemorrhage), including a blood clot that occurs between the brain and the skull

(cerebral subdural haematoma), bleeding in the digestive tract (gastrointestinal haemorrhage),

- Unusual heavy bleeding from cuts or wounds,
- Unusual heavy or unexpected menstrual bleeding,
- Black tarry stools,
- Bleeding in your eye,
- Blood in your stools,
- Blood in vomit or vomit that looks like coffee grounds,
- Bleeding in the space in between the layers that line the lungs (haemothorax),
- Liver damage (hepatotoxicity), usually asymptomatic and seen on laboratory results,
- Skin tissue death (skin necrosis, also called warfarin-induced skin necrosis-condition in which skin and tissue death occurs),
- Fatigue, pale skin, fever, chills. (Red or white blood cell conditions such as anaemia, leukopenia, granulocytosis),
- Fat clots in the blood (lipid emboli, including systemic athero-emboli and cholesterol emboli),
- Pain in the upper abdomen (inflammation of the pancreas),
- A rare, serious disease that involves build-up of calcium in small blood vessels of fat tissues and skin (calciophylaxis). This can lead to gangrene of the limbs, sores, ulcers or white spots in the mouth or throat,
- Anticoagulant-related kidney damage (see Warnings and precautions),
- Kidney damage with resultant fluid retention and protein in urine, with difficult urination,
- Prolonged erection of the penis (priapism).

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:

- Fever,
- Diarrhoea, nausea, vomiting, bloated stomach or gas, loss of appetite, stomach cramps or pain,
- Skin rash, loss of hair, purple, red or brown patches on the skin (purpura), purple or blue toes, red swollen skin patches leading to bruises (ecchymosis), painful skin lesions (infarction), skin tissue death (necrosis), skin reactions,
- Weak bones (osteoporosis), increased risk of osteoporotic fracture due to vitamin K deficiency, patients on long-term ASPEN WARFARIN 5 mg treatment may be at increased risk,
- Blood in urine,
- Unexplained drop in red blood cells, decreased haemoglobin.

Side effects with an unknown frequency:

- Dark urine.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website: www.sahpra.org.za

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of ASPEN WARFARIN 5 mg.

5. How to store ASPEN WARFARIN 5 mg

Store at or below 25 °C in airtight containers.

Protect from light.

Keep in original packaging until required for use.

Do not store in bathroom.

Do not use after the expiry date printed on the label or carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What ASPEN WARFARIN 5 mg contains

The active substance is 5 mg of warfarin sodium as warfarin sodium clathrate.

The other ingredients are Dye P/B pink PB, Erythrosine Aluminium Lake, FD&C Blue Indigo Carmine Aluminium Lake, FD&C Yellow Sunset Yellow FCM Aluminium Lake, lactose monohydrate, magnesium stearate, sodium starch glycolate, starch (maize).

Contains sugar: Lactose monohydrate Contains sugar: 130,6 mg

What ASPEN WARFARIN 5 mg looks like and contents of the pack

ASPEN WARFARIN 5 mg is an 8,0 mm diameter, flat, pink speckled, circular, bevelled edged tablet with a break line on one side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

100 or 500 tablets are packed into a white polypropylene securitainer, together with a silica gel desiccant and a foam insert of polyurethane or cotton wool balls and sealed with a white low-density polyethylene (LDPE) closure.

100 tablets are packed into a white high-density polyethylene (HDPE) securitainer, together with a silica gel desiccant and a foam insert of polyurethane or cotton wool balls and sealed with a white low-density polyethylene (LDPE) tamper evident cap.

100 tablets are packed into a white high-density polyethylene (HDPE) securitainer, together with a silica gel desiccant and a foam insert of polyurethane or cotton wool balls and sealed with a white low-density polyethylene (LDPE) tamper evident handycap.

Not all packs and pack sizes are necessarily marketed.

**Holder of Certificate of Registration**

PHARMACARE LIMITED

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Woodlands Drive

Woodmead 2191

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Registration number

H/8.2/0742

Access to the corresponding Professional Information**SAHPRA Repository of Professional Information and Patient Information Leaflets:**

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Botswana: B9323045 S2

Namibia: NS2 05/8.2/0501

Zimbabwe: P.P.10 92/10.2/2609

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