Applicant/PHCR: Pharmacare Limited
Product name: ASPEN WARFARIN 5 mg
Dosage form and strength: Tablet,
Warfarin sodium clathrate 5 mg

MODULE 1
1.3.2
Date of Variation:
23 December 2021

1.3.2 APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

PROPRIETARY NAME AND DOSAGE FORM

ASPEN WARFARIN 5 mg

Tablets

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 or your pharmacist.
- 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 ASPEN WARFARIN 5 mg CONTAINS

Each ASPEN WARFARIN 5 mg tablet contains 5 mg warfarin sodium as warfarin sodium clathrate.

The other ingredients are:

Dye P/B pink PB, lactose monohydrate, magnesium stearate, sodium starch glycollate, starch (maize).

Contains sugar: Lactose monohydrate 130,375 mg

WHAT ASPEN WARFARIN 5 mg IS USED FOR

ASPEN WARFARIN 5 mg contains the active ingredient warfarin which decreases the clotting ability of blood and therefore helps to prevent harmful clots from forming in the blood vessels.

ASPEN WARFARIN 5 mg is used 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.

BEFORE YOU TAKE ASPEN WARFARIN 5 mg

Do not take ASPEN WARFARIN 5 mg

- If you are allergic (hypersensitive) to warfarin or to any inactive ingredients (see WHAT ASPEN WARFARIN 5 mg CONTAINS).
- 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 a peptic ulcer or other stomach disease that causes you to bleed internally.
- If you have a severe wound.
- 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.
- 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 using over-the counter miconazole oral gel.
- If you are pregnant or breastfeeding (see Pregnancy and breastfeeding).

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).
- If you have a Vitamin K deficiency.
- If you have an overactive 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.

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).

Pregnancy and breastfeeding

You should not be treated with ASPEN WARFARIN 5 mg or any other warfarin medicine if you are pregnant or breastfeeding your baby.

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking ASPEN WARFARIN 5 mg (see DO NOT TAKE ASPEN WARFARIN 5 mg).

Driving and using machinery

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.

Important information about some of the ingredients of ASPEN WARFARIN 5 mg tablets:

ASPEN WARFARIN 5 mg contains lactose 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.

Taking other medicines with ASPEN WARFARIN 5 mg

Always tell your healthcare provider if you are taking any other medicines (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.

Do not take ASPEN WARFARIN 5 mg until you have told your doctor if you are taking:

- Alteplase, reteplase, streptokinase, tenecteplase, urokinase (fibrinolytic medicines to treat or prevent blood clots).
- St. John's wort (*Hypericum perforatum*) (a herbal remedy for depression).

Check with your doctor first before taking these medicines:

- Non-steroidal anti-inflammatory medicines (NSAIDs) for pain and inflammation including aspirin, ibuprofen, celecoxib, diclofenac, indomethacin, meloxicam.
- Clopidogrel, abciximab, dipyridamole, eptifibatide, tirofiban (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.

Medicines that increase the effect of ASPEN WARFARIN 5 mg:

- Prolonged, regular use of paracetamol (for pain or fever).
- Antibiotics such as amoxicillin, levofloxacin and tetracycline.
- Vitamin K (in vitamin supplements or in cod liver oil).
- 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, 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).

Medicines that decrease the effect of ASPEN WARFARIN 5 mg:

- Barbiturates (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).

Medicines that have varying effects on ASPEN WARFARIN 5 mg:

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

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

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.

You should 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.

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.

If you take more ASPEN WARFARIN 5 mg than you should

In the event of an overdosage, 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.**

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 doctor, pharmacist or other 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, mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic 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 your gums when you brush your teeth,
- Blood in your urine,
- Nose bleeds,
- Unusual heavy bleeding from cuts or wounds,
- Unusual heavy or unexpected menstrual bleeding,
- Black tarry stools,
- Bleeding in your eye,
- Blood in your stools or urine,
- Blood in vomit or vomit that looks like coffee grounds,
- Fainting,
- Yellowing of the skin and eyes, also called jaundice,

- Skin necrosis (also called warfarin-induced skin necrosis-condition in which skin and tissue death occurs).

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

Tell your doctor if you notice any of the following:

- Sudden weakness,
- Diarrhoea,
- Vomiting,
- Nausea,
- Temporary loss of hair,
- Purple or blue toes,
- Dark urine,
- Skin rash, hives or itching of skin,
- Yellow eyes or skin,
- Painful or difficult urination.

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

STORAGE AND DISPOSING OF 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.

PRESENTATION

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.

IDENTIFICATION OF ASPEN WARFARIN 5 mg

8,0 mm diameter, flat, pink speckled, circular, bevelled edged tablet with a breakline on one side.

REGISTRATION NUMBER

H/8.2/0742

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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