1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

CANCARD 81 mg enteric coated tablets

Aspirin (acetyl salicylic acid)

Sugar free

Read all of this leaflet carefully before you start taking CANCARD

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

1. What CANCARD is and what it is used for

CANCARD contain aspirin, also known as acetylsalicylic acid, which in low doses belong to a group of medicines called anti-platelet medicines. Platelets are tiny cells in the blood that cause the blood to clot and are involved in blocking veins and arteries (thrombosis). When a blood clot occurs in an artery it stops the blood flowing and cuts off the oxygen supply. When this happens in the heart it can cause a heart attack or angina, and in the brain it can cause a stroke.

CANCARD is taken to reduce the risk of blood clots forming and thereby prevent further:

- heart attacks,
- strokes,
- heart and circulatory (cardiovascular) problems in patients who suffer from stable or unstable angina (a type of chest pain).

2. What you need to know before you take CANCARD

Do not take CANCARD

- If you are hypersensitive (allergic) to aspirin (acetyl salicylic acid) or any of the other ingredients of CANCARD (listed in section 6),
- if you have asthma that is worsened by taking aspirin,
- if you are allergic to other medicines similar to aspirin (salicylates) or non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs are often used for arthritis or pain,
- if your blood does not clot and you tend to bleed excessively,
- if you suffer from gout,
- if you have severe liver or kidney problems,
- if you are pregnant, or breastfeeding your baby (see section Pregnancy, breastfeeding and fertility),
- if you have problems with your heart (heart failure),

- if you have a history of tears, ulcers or bleeding in your stomach or intestines after taking NSAIDs or aspirin,
- if you currently have or have ever had an ulcer in your stomach or intestines or any other type of bleeding like a bleed in your brain,
- if you are taking a medicine called methotrexate (used to treat cancer or rheumatoid arthritis) in doses higher than 15 mg per week,
- if you have any scheduled surgical procedures.

Warnings and precautions

Take special care with CANCARD:

- CANCARD may cause Reye's syndrome when given to children. Reye's syndrome is a disease which affects the brain and liver and can be life-threatening. For this reason, CANCARD should not be given to children and adolescents,
- if you are asthmatic, CANCARD may induce allergic reactions such as skin eruptions, swelling, chest tightness or difficulty breathing (dyspnoea),
- CANCARD may cause you to bleed for longer than usual. Inform your doctor if you are planning to have an operation (even a minor one, such as tooth extraction) since you may be at risk of bleeding too much,
- if you suffer from indigestion (dyspepsia),
- if you have low levels of iron in your blood (anaemia),
- if you have high blood pressure (hypertension),
- if you are lacking water or fluids in your body (dehydrated),
- avoid CANCARD during your menstrual cycle as it may increase bleeding,
- if you suffer from any disease of the stomach such as swelling or inflammation of the colon (ulcerative colitis), bulging of your stomach upwards (hiatus hernia) or chronic heartburn and acid reflux (reflux disease),

- if you have serious skin reactions, including Drug Rash with Eosinophilia and Systemic Symptoms (DRESS). CANCARD should be discontinued immediately at the first appearance of any type of skin rash, fever, mucosal lesions, or any other sign of hypersensitivity. You should also contact your doctor as soon as possible.

Children and adolescents

CANCARD is not recommended for use in adolescents and children. CANCARD may cause a rare but serious condition called Reye's Syndrome in some children.

Other medicines and CANCARD

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

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

- Methotrexate: medicines for cancer or rheumatoid arthritis. CANCARD may lessen the removal of methotrexate from your body via the kidneys causing toxicity in your blood,
- uricosuric medicines (e.g. probenecid, sulphinpyrazone): medicines used to treat gout. CANCARD may decrease the effect of these medicines,
- anticoagulants (e.g. coumarin, heparin, warfarin): medicines used to thin the blood and prevent blood clots. CANCARD may increase the effect of these medicines and increase risk of bleeding,
- antiplatelets (e.g. clopidogrel and dipyramidole): medicines that stop cells in the blood from sticking together to form a clot. CANCARD may cause increase risk of gastrointestinal bleeding with these medicines due to a combined action of both,
- selective serotonin re-uptake inhibitors (SSRIs) (e.g. sertraline, paroxetine): medicines used to treat depression: CANCARD may cause increase risk of gastrointestinal bleeding with these medicines due to a combined action of both,

- antidiabetics (e.g. sulfonylureas): medicines used to treat diabetes. CANCARD may increase the blood sugar lowering effect of these medicines,
- digoxin: medicine used to treat heart conditions. CANCARD may affect the removal of this medicine from the body causing higher levels of it in the blood,
- lithium: medicine used to treat mental conditions. CANCARD may affect the removal of this medicine from the body causing higher levels of it in the blood,
- antihypertensives (e.g. diuretics, ACE-inhibitors): medicines used to treat high blood pressure. CANCARD may decrease the blood pressure lowering effect of these medicines and affect kidney function,
- carbonic anhydrase inhibitors (e.g. acetazolamide): may result in severe acidosis and increased central nervous system toxicity,
- corticosteroids and other NSAIDs (e.g. ibuprofen): medicines used to treat pain and inflammation. CANCARD may increase the risk of ulcerations and gastrointestinal bleeding due to combined action,
- metamizole: medicines used to decrease pain and fever. Metamizole may decrease the anti-blood clotting effect of CANCARD when taken together,
- ciclosporin, tacrolimus: medicines used to prevent organ rejection after a transplant. CANCARD use with these medicines may increase the risk of kidney toxicity so kidney function should be monitored,
- antacids: medicines used to treat indigestion. Some antacids may cause increased excretion of CANCARD from the body,
- phenytoin and valproic acid: medicines for treatment of epilepsy. CANCARD may increase the effect of these medicines.

CANCARD with food, drinks, and alcohol

Drinking alcohol may possibly increase the risk of bleeding in the stomach and intestines and should be avoided.

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 taking this medicine.

You should not take CANCARD if you are pregnant or breastfeeding.

CANCARD may cause kidney problems in your unborn baby, which can lead to low levels of amniotic fluid that surrounds the baby. This fluid provides a protective cushion and helps the unborn babies' lungs, digestive system, and muscles develop. Complications can occur with low levels of this fluid.

CANCARD may also cause bleeding complications resulting in prolonged or delayed labour.

CANCARD use in early pregnancy may increase the risk of miscarriage and also cardiac and abdominal wall abnormalities in the foetus.

Low quantities of CANCARD are excreted in breastmilk.

Even though there is no fertility data available women that are trying to fall pregnant should use CANCARD for the shortest time at the lowest dose.

Driving and using machines

CANCARD may cause dizziness. You should not drive, use machinery or perform any tasks that require concentration until you are certain that CANCARD does not affect your ability to do so safely.

It is not always possible to predict to what extent CANCARD 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 CANCARD affects you (see section 4).

3. How to take CANCARD

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

Always take CANCARD exactly as described in this leaflet or as your doctor, or pharmacist or nurse has have told you. Check with your doctor or pharmacist or nurse if you are not sure.

The usual dose of CANCARD is:

For inhibition of platelet aggregation: 1 to 3 tablets as directed by your doctor to be taken every day, preferably at the same time each day. CANCARD should be taken with water or fruit juice.

If you take more CANCARD than you should

After repeated large doses of CANCARD you may notice dizziness, nausea, vomiting, headache, sweating, mental confusion, ringing in the ear or deafness.

Severe overdose may cause fever, restlessness, fast breathing, low levels of carbon dioxide in the blood, and high levels of acid in the body.

Depression of the central nervous system may lead to coma, heart and circulatory system collapse, severe low blood sugar levels and lung failure.

In children drowsiness and high acid levels are common. The drop in blood sugar levels may be severe.

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

If you forget to take CANCARD

Do not take a double dose to make up for forgotten individual doses.

If you have missed a dose of CANCARD, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take several doses, contact your doctor without delay.

4. Possible side effects

CANCARD can have side effects.

Not all side effects reported for CANCARD are included in

this leaflet. Should your general health worsen or if you experience any untoward effects while taking CANCARD please consult your healthcare provider for advice.

If any of the following happens, stop taking CANCARD 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,
- reddening of the skin with blisters or peeling and may be associated with a high fever and joint pains. This could by erythema multiforme, Stevens-Johnson syndrome, Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) or Lyell's syndrome.

These are all very serious side effects. If you have them, you may have had a serious reaction to CANCARD. 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:

- Blood disorders which are usually detected in blood tests, but may be seen as pale skin, tiredness, fever, sore throat and mouth, small red spots on the skin, bruising or prolonged bleeding after injury. Blood disorders (such as thrombocytopaenia,

granulocytosis and anaemia) may be seen with symptoms of severe chills, mouth ulcers, headache, shortness of breath and dizziness,

- bleeding in the brain (intracranial haemorrhage),
- inflammation of the blood vessels which results in severe bleeding (haemorrhagic vasculitis),
- difficulty breathing (dyspnoea), asthma attacks,
- blood in stools (melaena), vomiting of blood (haematemesis),
- severe bleeding within the stomach and intestines (gastrointestinal haemorrhage),
- signs of liver failure such as yellowing of the eyes or skin (jaundice), abdominal pain or abnormal tiredness (hepatic insufficiency),
- signs of impaired kidney function such as a reduced amount of urine, swelling of your legs, ankles or feet, shortness of breath, abnormal tiredness, or fits (seizures).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Increased tendency for bleeding,
- nausea, indigestion, vomiting, peptic ulcers, gastrointestinal bleeding,
- loose stools (diarrhoea), passing wind (flatulence), difficulty passing stools (constipation), stomach pain, blood in the stool or vomiting of blood.

Less frequent side effects:

- Menstrual periods with abnormally heavy or prolonged bleeding (menorrhagia),
- runny nose (rhinitis), shortness of breath, difficulty breathing,
- increase in liver enzymes (determined by a blood test).

Side effects with an unknown frequency:

- Increased levels of uric acid in the blood (hyperuricaemia) – you may experience severe pain or stiffness in your joints,
- dizziness, headache, loss of balance (vertigo),
- reduced ability to hear, ringing in your ears (tinnitus),
- inflammation in the stomach (erosion),
- ulcers or tears in the stomach or intestines,
- nose bleeds, bleeding gums,
- high blood pressure,
- blisters on the skin or painful, red skin which may be accompanied by fever,
- impaired renal function, salt and water retention - you may notice change in the amount of urine you pass, swelling in your legs, ankles or feet.

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 Reactions Reporting Form", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of CANCARD.

5. How to store CANCARD

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 CANCARD contains

Each enteric-coated tablet contains 81 mg aspirin (acetyl salicylic acid).

The other ingredients are colloidal anhydrous silica, hypromellose (E464), macrogol (E1521), methacrylic acid - ethyl acrylate copolymer (1:1) dispersion 30 %, microcrystalline cellulose, pregelatinised starch, purified talc, stearic acid, titanium dioxide (E171), triethyl citrate.

What CANCARD looks like and contents of the pack

CANCARD is a white to off white enteric-coated, round, biconvex tablet, plain on both sides.

30, 50 or 100 tablets are packed in a white round high density polyethylene (HDPE) bottle with a white round opaque HDPE screw cap with induction seal, together with a silica gel desiccant or silica gel-molecular sieve dessicant, and leaflet.

10 tablets are packed in a clear rigid polyvinylchloride, polyethylene and polyvinylidene chloride film sealed with an aluminium foil backing. 3 or 10 blister strips are packed into an outer cardboard carton together with a leaflet.

10 tablets are packed in a cold forming foil made of oriented polyamide (OPA), aluminium and polyvinylchloride. 3 or 10 blister strips are packed into an outer cardboard carton together with a leaflet.

Holder of Certificate of Registration

PHARMACARE LIMITED

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Hotline: 0800 122 912

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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

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