PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

DISPRIN® CARDIOCARE 100 mg Tablets

Sugar free

Contains sweetener:

Saccharin 0,3 mg per tablet

Read all of this leaflet carefully before you start taking DISPRIN® CARDIOARE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- DISPRIN® CARDIOCARE 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 DISPRIN® CARDIOCARE is and what it is used for

2. What you need to know before you take DISPRIN® CARDIOCARE

3. How to take DISPRIN® CARDIOCARE

4. Possible side effects

5. How to store DISPRIN® CARDIOCARE

6. Contents of the pack and other information

1. What DISPRIN® CARDIOCARE is and what it is used for

DISPRIN® CARDIOCARE belong to a group of medicines which have analgesic (pain relieving), anti-pyretic (fever reducing) and anti-inflammatory (inflammation reducing) properties.

DISPRIN® CARDIOCARE tablets are used to reduce the risk of the disorders of the heart and blood vessels that may occur when a blood vessel is blocked by blood clots.

It works by helping to prevent blood clots from forming.

2. What you need to know before you take DISPRIN® CARDIOCARE

Do not take DISPRIN® CARDIOCARE tablets:

- If you are allergic to aspirin or to any of the other ingredients (listed in section 6) or to other pain-reducing medicines,
- If you have peptic ulcer or history of ulcers,
- If you have a blood or bleeding disorder,
- If you have a history of stomach bleeding related to previous use of NSAIDs (medicines against pain, fever, or inflammation) including DISPRIN® CARDIOCARE
- If you have kidney (Child-Pugh C) problems,
- If you have liver problems (eGFR<30 mL/minute),
- If you have heart problems (NYHA grade III or IV),
- If you have growths in the nose or the sinuses,
- If you are taking medicines that thin the blood (e.g. warfarin),
- If you are in the first or third trimester pregnant or during breast-feeding- DISPRIN® CARDIOCARE tablet should not be used while breast- feeding your baby,

- If you are under the age of 16 years due to the risk of Reye's syndrome (a serious condition that causes swelling in the liver and brain in children).
- If you are currently taking methotrexate (a medicine used to treat cancer and certain rheumatic disorders) at doses of 15 mg/week or more.

Warnings and precautions:

Take special care with DISPRIN® CARDIOCARE tablets:

- If you have a history of high blood pressure and/or heart failure as fluid retention and oedema have been reported in association with NSAIDs therapy like DISPRIN® CARDIOCARE.
- If you have a history of gastrointestinal disease e.g ulcerative colitis, Crohn’s disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia) – causing should be exercised as the condition may be exacerbated.
- If you have a history of ulcers, the risk of gastrointestinal bleeding or perforation is higher with increasing dosages and treatment should be commenced on the lowest dose available. In the case where gastrointestinal bleeding or ulceration occurs, treatment should be stopped.
- stomach problems

- above 65 years of age (the elderly)
- kidney problems
- if you are receiving medicines which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin.

In children and teenagers – aspirin products such as DISPRIN® CARDIOCARE tablet have been implicated in Reyes syndrome, a rare but serious illness that may follow a viral infection such as chickenpox or influenza. The medicine must not be used in children and teenagers.

- If you have asthma –asthmatic patients may be sensitive to aspirin and more likely to have an allergic reaction (i.e. skin rash, breathing problems) after treatment with aspirin.
- If you have heartburn, anaemia or if you are dehydrated – DISPRIN® CARDIOCARE tablets may make these conditions worse or increase the chance of side effects.
- If you have blood or urine tests done – DISPRIN® CARDIOCARE tablets may interfere with the results of some laboratory tests.
- If you are going to have surgery – DISPRIN® CARDIOCARE tablets should be withdrawn one week before surgery because of possibility of increasing bleeding after surgery.
- If you have systemic lupus erythematosus (SLE), this is a chronic inflammatory disease, which could increase the risk of meningitis (inflammation of the lining of the brain)
- If you are of child bearing age, due to the possibility of DISPRIN® CARDIOCARE impairing women fertility.
- If you have gout (a kind of arthritis).
- If you are an elderly person, due to the increased risk of side-effects**.**

The optimal dose of DISPRIN® CARDIOCARE tablets in humans to prevent clots is not known.

Do not use DISPRIN® CARDIOCARE to prevent blood clots unless directed by a doctor.

Do not use DISPRIN® CARDIOCARE if you have liver problems.

You need to discontinue DISPRIN® CARDIOCARE treatment and consult your doctor if these occur during treatment:

Drug reaction with eosinophilia and systemic symptoms (DRESS): a life-threatening reaction which may resemble a flu-like infection, other signs may include rash, facial swelling, abdominal pain and abdominal heartbeat.

Serious skin reactions including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis: these are indicated by severe skin peeling, painful blisters and starts by flu-like illness.

Children

There is an association between acetylsalicylic acid and Reyes's syndrome when given to children. Reye's syndrome is a very rare disease, which affects the brain and liver, and can be fatal. For this reason, aspirin should not be given to children aged under 16 years.

Other medicines and DISPRIN® CARDIOCARE:

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

DISPRIN® CARDIOCARE should NOT be used together with:

- Blood thinners (e.g. warfarin),
- Methotrexate,
- Some oral medicines used for diabetes mellitus,
- Sulphonamide antibacterial medicines,
- Ciclosporin (medicines used during transplantation),
- Tacrolimus (medicines used to suppress immune system),
- Varicella vaccine,
- Calcium channel blockers (medicine used in the treatment of hypertension),
- Sedatives such as barbiturates,

- Zidovudine (anti-viral agents),
- Metoclopramide and domperidone, (medicines used for nausea and vomiting),
- Valproate (medicine used to treat fits or seizures),
- Quinolones (broad-spectrum antibacterial medicines) and
- Mifepristone (medicine used to terminate pregnancy).

DISPRIN® CARDIOCARE tablets may enhance the activity of theses medicines.

- Non-steroidal anti- inflammatory medicines,
- Alcohol or cortisone- like medicines – DISPRIN® CARDIOCARE tablets may worsen effects of stomach irritation
- Medicines for gout such as probenecid and sulphinpyrazone -DISPRIN® CARDIOCARE tablets may lessen the effect of these medicines.
- Cardiac glycosides (medicines used to treat heart failure).

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of DISPRIN® CARDIOCARE tablets with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health professionals for advice.

DISPRIN® CARDIOCARE with food, drink and alcohol:

Take DISPRIN® CARDIOCARE after food to lessen the risk of stomach irritation. Do not drink alcohol while you take DISPRIN® CARDIOCARE as alcohol can increase stomach irritation, especially if you regularly take DISPRIN® CARDIOCARE**.**

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 health care provider for advice before taking this medicine

Pregnancy and Breastfeeding:

DISPRIN® CARDIOCARE tablets should not be used during the first and third trimesters of pregnancy and while breastfeeding your baby. DISPRIN® CARDIOCARE should be avoided during the second trimester.

If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist, or other healthcare professionals for advice.

Fertility:

The use of DISPRIN® CARDIOCARE may cause female infertility. This is reversible on withdrawal of treatment.

Driving and using machinery:

DISPRIN® CARDIOCARE tablets in recommended doses may cause dizziness and interfere with driving or the ability to operate tools or machines.

3. How to take DISPRIN® CARDIOCARE

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

Always take DISPRIN® CARDIOCARE exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults: 100 to 300 mg (1 to 3 tablets) taken every day, preferably at the same time each day.

DISPRIN® CARDIOCARE tablets can be dissolved on the tongue without water preferably after meals to reduce stomach irritation. Do not place the tablet directly on a tooth or on the gums as this may cause burn marks.

If you have the impression that the effect of DISPRIN® CARDIOCARE tablets is too strong or too weak, talk to your doctor or pharmacist.

If you take more DISPRIN® CARDIOCARE 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 an adult presents with overdosage symptoms within 1 hour of ingestion of more than 250 mg/kg of aspirin, give activated charcoal.

Some of the symptoms of overdose include dizziness, ringing in the ears, sweating, nausea, vomiting, dehydration, deafness, confusion, and breathing problems. In children, signs of serious overdose may develop rapidly.

Long-term use of high doses of this medicine may lead to bleeding problems, stomach problems or kidney problems.

Some medicines, such as sedatives, may mask breathing problems and worsen toxicity in the case of an overdose.

If you forget to take DISPRIN® CARDIOCARE tablets

If you miss a dose of this medicine, take it as soon as you remember. If it is nearly time for the next dose, skip the missed dose and go back to your normal dosing schedule. Do not take double dose to make up for the forgotten individual doses

Effects when treatment with DISPRIN® CARDIOCARE is stopped

Do not stop taking DISPRIN® CARDIOCARE for any reason without speaking to your doctor first.

4. Possible side effects

Like all medicines, DISPRIN® CARDIOCARE tablets can have side effects.

If any of the following minor side effects continue, are severe or bother you, speak to your doctor or pharmacist:

Not all side effects reported for DISPRIN® CARDIOCARE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist, or other healthcare professional for advice.

If any of the following happens, stop taking DISPRIN® CARDIOCARE and tell your doctor immediately or go to the casualty department at your nearest hospital:

Skin rash, hives or itching, shortness of breath, breathing problems swelling of the face, eyelids, or lips.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DISPRIN® CARDIOCARE. 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:

Stomach pain (mild), heartburn, indigestion, nausea and vomiting, stomach ulcers, unusual bleeding, heart condition, meningitis, difficulty in breathing, swelling and hypertension.

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

If any of the following side effects occur, speak to your doctor or pharmacist:

- Dizziness (with high doses), stomach pain, or bruising, vomiting blood, black stools, problems with passing urine, diarrhoea, constipation,
- Tightness of chest, and stuffy and runny nose

DRESS reaction (rash, facial swelling accompanied by abnormal heart rates)

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

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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 DISPRIN® CARDIOCARE

5. How to store: DISPRIN® CARDIOCARE

Store all medicines out of reach of children.

Store at or below 25 °C in a dry place

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 DISPRIN® CARDIOCARE contains

The active substance is: Aspirin 100,00 mg

The other ingredients are: Glycine, lemon flavour, maize starch, microcrystalline cellulose, purified talc and saccharin.

What DISPRIN® CARDIOCARE looks like and contents of the pack:

A white, matte, circular, flat tablet, with bevelled edges embossed on one side with a sword motif and having a lemon odour.

Packs of 30 tablets in foil

Holder of Certificate of Registration

Reckitt Benckiser Pharmaceuticals (Pty) Ltd

8 Jet Park Road

Elandsfontein

1601

This leaflet was last revised: TBA

Date on the registration certificate of DISPRIN® CARDIOCARE: 16 January 1997

Date of the most recently revised package insert as approved by council: 17 April 2024

Registration number

31/2.8/0071

Access to the corresponding Professional Information

To be made available electronically at: https://cpdcentre.co.za/rb-product-inserts/