ANNOTATED PROPOSED PROFESSIONAL INFORMATION

1.5.5 CLEAN PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

DISPRIN EXTRA STRENGTH 500 mg Tablets

DISPRIN REGULAR STRENGTH 300 mg Tablets

Aspirin

Sugar free

Contain sweetener

DISPRIN EXTRA STRENGTH 500 mg contains saccharin 7,5 mg per tablet

DISPRIN REGULAR STRENGTH 300 mg contains saccharin 4,5 mg per tablet

Read all of this leaflet carefully because it contains important information for you

DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablet is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablet carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.

- Do not share DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablet with any other person
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days

What is in this leaflet

1. What DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablet is and what it is used for
2. What you need to know before you take DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablet
3. How to take DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablet
4. Possible side effects
5. How to store DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablet
6. Contents of the pack and other information

1. What DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablet is and what it is used for

DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets

have analgesic, antipyretic and anti-inflammatory action. Disprin Regular Strength 300 mg and Disprin Extra Strength 500 mg are indicated for the relief of mild to moderate pain, and fever.

2. What you need to know before you take DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablet

Do not take DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets to your child:

- If you or your child is hypersensitive (allergic) to aspirin or to any of the other ingredients of DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg (listed in section 6)
- If you or your child is hypersensitive to other non-steroidal anti-inflammatory drugs.
- If you or your child has 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 or your child has history of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.
- If you suffer from heartburn, anaemia or if you or your child is dehydrated. DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg or your child has tablets may make these conditions worse or increase the chance of side effects.
- If you or your child has active or a history of peptic ulceration.

- If you or your child is receiving oral anticoagulant therapy such as warfarin.
- If you or your child has haemophilia.
- If you or your child has severe liver disease.
- If you or your child has severe kidney disease.
- If you or your child has heart failure
- If your child is aged under 16 years
- If you are pregnant or breastfeeding your baby.
- If you have blood or urine tests done - DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets may interfere with the results of some laboratory tests.
- If you are going to have surgery - DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets should be withdrawn one week before surgery because of the possibility of increasing bleeding after surgery.

Warnings and precautions

DO NOT USE CONTINUOUSLY FOR MORE THAN 10 DAYS WITHOUT CONSULTING YOUR DOCTOR.

Talk to your health care provider before taking DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg if any of the following applies to you or your child:

- You suffer from stomach problems
- You are above 65 years of age (the elderly).

- You have Systemic Lupus Erythematosus (SLE) (an inflammatory disease caused when the immune system attacks its own tissues) and mixed connective tissue disease.
- You have, liver or kidney problems.
- You are receiving medicines which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin.
- You have a history of hypertension (high blood pressure) as fluid retention and oedema (swelling) have been reported.
- You have a history of bronchial asthma or allergic disease.
- You should stop taking DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets several days before surgery due to increased bleeding time.

You need to discontinue DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg treatment and consult your doctor if these problems 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 abnormal 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 Reye'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, asprin should not be given to children aged under 16 years.

Other medicines and DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets

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

DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets should NOT be used together with:

Corticosteroids: medicines used for severe allergies and skin problems.

Anti-platelet agents: used for blood clots, eg aspirin and clopidogrel

Antidepressants: used in the treatment of mood disorders

Calcium channel blockers: are used mainly in the management of chest pains, high blood pressure and irregular heartbeat.

Cardiac glycosides: medicines for heart problems such as heart failure and irregular heart rates, eg digoxin are used in to slow the heart rate in supraventricular arrhythmias, especially atrial fibrillation, and are also given in chronic heart failure.

Varicella vaccine: chicken pox vaccine

Antihypertensives (ACE inhibitors and Angiotensin II Antagonists) and diuretics: water tablets and other high blood pressure medicines.

Anti-coagulants: used for preventing or treating blood clots, eg warfarin

Other NSAIDs or other salicylates including cyclooxygenase-2 selective inhibitors: NSAIDs painkillers (eg ibuprofen and naproxen) including those used for arthritis.

Ciclosporin: medicines such as tacrolimus or ciclosporin, these are used for prevention or treatment of organ transplants.

Zidovudine: is used in the treatment of HIV infection and AIDS.

Metoclopramide & domperidone: used for nausea and/or vomiting disorders

Valproate: is used in the treatment of seizures (fits).

Uricosurics: used to treat gout

Quinoline antibiotics: Antibiotics for treating bacterial infections, e.g pneumonia and urinary infections).

Mifepristone: used to end pregnancy

Methotrexate: used in the treatment of cancer

Antidiabetics sulphonylureas: diabetes (high blood sugar) medicines like insulin

DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets with food, drink and alcohol

Take DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets after food to lessen the risk of stomach irritation. Do not drink alcohol while you take DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets as alcohol can increase stomach irritation, especially if you regularly take DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets.

Pregnancy, breastfeeding and fertility

DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets

should not be used during pregnancy and while breastfeeding your infant. 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.

Fertility

The use of DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg may cause infertility.

Driving and using machines

DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets in recommended doses may cause dizziness, interfere with driving or the ability to operate tools or machines.

Important information about DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets

The optimal dose of DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets in humans to prevent blood clots is not known. Do not use this medicine to prevent blood clots unless directed by a doctor.

3. How to take DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets

Do not share medicines prescribed for you with any other person. Always take DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

Disprin Regular Strength 300 mg

Adults:1-3 tablets. Repeat 4 hourly if necessary but not more than 12 tablets during any 24hour period.

Children 16 years and over: 1-2 tablets not more than four times a day, to a maximum of 10 tablets in 24 hours.

Disprin Regular Strength 300 mg can be dissolved in water, or if preferred, on the tongue.

Disprin Extra Strength 500 mg

Adult: 1-2 tablets

Children 16 years and over: 1 tablet

Repeat 4 hourly if necessary but not more than 8 tablets during 24 hour period, but if symptoms persist consult your doctor. Do not use continuously for more than 10 days without consulting your doctor.

DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULARSTRENGTH 300 mg tablets can be dissolved on the tongue without water. Do not place the tablet directly on a tooth or on the gums as this may cause a burn mark. If you have the impression that the effect of DISPRIN EXTRA STRENGTH 500 mg/ DISPRIN REGULAR STRENGTH 300 mg tablets is

too strong or too weak, talk to your doctor or pharmacist.

If you take more DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Symptoms of overdose include dizziness, dehydration, ringing in the ears, sweating, nausea, vomiting, altered glucose metabolism, mental confusion and breathing problems. In children, signs of serious overdosage may develop rapidly. Long-term use of high doses of this medicine may lead to bleeding problems, stomach problems or kidney problems.

If you forget to take DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg 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 a double dose to make up for forgotten individual doses.

If you stop taking DISPRIN EXTRA STRENGTH 500 mg /DISPRIN REGULAR STRENGTH 300 mg tablets

Do not stop taking this medicine for any reason without speaking to your doctor first.

4. Possible side effects

DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets can have side effects. Not all side effects reported for DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DISPRIN REGULAR STRENGTH 300 mg / DISPRIN EXTRA STRENGTH 500 mg, please consult your doctor, pharmacist or other healthcare professional for advice. If any of the following happens, stop taking DISPRIN EXTRA STRENGTH 500 mg /

DISPRIN REGULAR STRENGTH 300 mg

- increased risk of bleeding.
- slow blood clotting.
- bone marrow failure.
- reduced number of blood cells.
- fever.
- skin rash.
- severe itching of the skin.
- swelling of the skin.
- DRESS reaction (rash, facial swelling accompanied by abnormal heart rates)

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DISPRIN REGULARSTRENGTH 300 mg / DISPRIN EXTRA STRENGTH 500 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:

Less frequent side effects:

- increased blood level of sodium
- fluid retention
- stiff neck, sensitivity to light, headache caused by inflammation (swelling and redness) of the linings of the brain
- heart failure
- excess of watery fluid collecting in the cavities or tissues of the body

- high blood pressure
- narrowing of the small airways of the lungs that can cause wheezing and shortness of breath
- asthma
- shortness of breath
- hay fever
- bleeding in the digestive tract
- disturbances in the digestive tract
- sore (ulcer) in the lining of the stomach
- dark sticky faeces containing partly digested blood
- vomiting of blood
- sore (ulcer) in the lining of the mouth.
- cell death causing the epidermis (outer layer) to separate from the dermis (inner layer)

- increase in blood uric acid

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 or 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 EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets.

5. How to store DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets

Store all medicines out of the 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).

Do not use after the expiry date stated on the label, blister pack and carton.

6. Contents of the pack and other information

What DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets contain

DISPRIN EXTRA STRENGTH 300 mg tablet

The active substance is Aspirin 300 mg

The other ingredients are anhydrous citric acid, calcium carbonate, maize starch, sodium lauryl sulphate, saccharin, purified talc.

DISPRIN EXTRA STRENGTH 500 mg tablet

The active substance is Aspirin 500 mg

The other ingredients are anhydrous citric acid, calcium carbonate, maize starch, sodium lauryl sulphate, saccharin, purified talc.

DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets contain saccharin.

What DISPRIN EXTRA STRENGTH 500 mg / DISPRIN REGULAR STRENGTH 300 mg tablets looks like and contents of the pack

DISPRIN REGULAR STRENGTH 300 mg

A flat, white tablet, 12,7 mm in diameter, with bevelled edges. The name “Disprin” and sword is imprinted on one side and the other side is plain. It effervesces in water.

In packs of 12, 24, 48 and 96 tablets packed in aluminium foil.

For hospital use - bottles of 1 000 tablets.

For State use only – pouches of 14 tablets packed in aluminium foil.

DISPRIN EXTRA STRENGTH 500 MG

A flat, white tablet, 14 mm in diameter, with bevelled edges. A “D” and a sword motif are imprinted on one side and the other side is plain. It effervesces in water. ln packs of 2, 12, 24, 48 and 72 tablets packed in aluminium foil.

Holder of Certificate of Registration

Reckitt Benckiser Pharmaceuticals (Pty) Ltd

8 Jet Park Road

Elandsfontein 1601

This leaflet was last revised in

1. Date on the registration certificate of DISPRIN EXTRA STRENGTH: 20/10/1980

2. Date on the registration certificate of DISPRIN REGULAR STRENGTH: 26/04/1984

3. Date of the most recently revised package insert as approved by council: 27/05/2021

Registration number

DISPRIN REGULAR STRENGTH 300 mg: B/2.7/570

DISPRIN EXTRA STRENGTH 500 mg: M/2.7/292

Access to the corresponding Professional Information

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

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