1.5.5.3 CLEAN PROPOSED PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

DISPRIN REGULAR STRENTH 300 mg Tablets

DISPRIN EXTRA STRENTH 500 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

DlSPRIN REGULAR STRENGTH 300 mg: Aspirin 300 mg

DlSPRIN EXTRA STRENGTH 500 mg: Aspirin 500 mg

Sugar free

Contain sweetener:

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

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

3. PHARMACEUTICAL FORM

Tablets

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.

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.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:

DISPRIN REGULAR STRENGTH 300 mg and DISPRIN EXTRA STRENGTH 500 mg are indicated for the relief of mild to moderate pain, and fever.

4.2 Posology and method of administration

Posology

Use the lowest effective dose for the shortest possible duration of treatment.

DISPRIN REGULAR STRENGTH 300 mg:

Adults: 1- 3 tablets.

Repeat 4 hourly if necessary but not more than 12 tablets during any 24- hour 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 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, a doctor should be consulted. If symptoms persist for more than 10 days, a doctor should be consulted.

Method of administration

For oral administration

DISPRIN REGULAR STRENGTH 300 mg can be dissolved in water, or if preferred, on the tongue.

4.3 Contraindications:

- Hypersensitivity to acetylsalicylic acid or to any of the excipients in the product.
- Hypersensitivity to other non-steroidal anti-inflammatory drugs.
- Nasal polyps associated with asthma (high risk of severe sensitivity reactions).
- History of gastrointestinal perforation, ulceration or bleeding (PUBs) related to previous NSAIDs, including DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg. Patients with active or a history of recurrent gastrointestinal ulcer/haemorrhage/perforations. Patients with active or a history of peptic ulceration.
- Patients receiving oral anticoagulant therapy.
- Haemophilia.
- Severe hepatic impairment.
- Severe renal impairment.
- Heart failure.

- Children aged under 16 years due to a possible risk of Reye's syndrome, unless specifically indicated.
- Pregnancy and lactation (see section 4.6)
- Combination with methotrexate at doses of 15 mg/week or more

4.4 Special warnings and precautions for use

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

ASPIRIN has been implicated in Reye's syndrome, a rare but serious illness in children and teenagers with chickenpox and influenza. A doctor should be consulted before aspirin is used in such patients. Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

Gastrointestinal effects:

DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg should be given with caution to patients with a history of gastrointestinal disease (e.g. ulcerative colitis, Crohn's disease, hiatus hernia, gastrooesophageal reflux disease, angiodysplasia) as their condition may be exacerbated. (see section 4.3) Gastrointestinal bleeding, ulceration or perforation which can be fatal, has been reported with all NSAIDs including DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg at any time during treatment, with or without warning symptoms or a previous history of serious GI events. The risk of gastrointestinal perforation, ulceration or bleeding (PUBs) is higher with increasing doses of DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation and in the elderly. These patients should commence treatment on the lowest dose available.

Patients with a history of GI toxicity, particularly the elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment. DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg decreases platelet adhesiveness and increases bleeding time. Caution should be advised in patients receiving concomitant medicines which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin (see section 4.3), selective serotonin-reuptake inhibitors or anti-platelet medicines such as clopidogrel and ticlopidine. When gastrointestinal bleeding or ulceration occurs in patients receiving DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg, treatment with DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg should be stopped immediately.

SLE and mixed connective tissue disease:

Systemic lupus erythematosus and mixed connective tissue disease, due to increased risk of aseptic meningitis.

Dermatological effects:

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis may occur. DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Paediatric Use:

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, acetylsalicylic acid should not be given to children aged under 16 years unless specifically indicated (e.g. for Kawasaki’s disease).

Cardiovascular effects:

Caution is required in patients with a history of hypertension as fluid retention, and oedema have been reported in association with DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg therapy. In view of the DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients. Caution is required in patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking).

Respiratory effects:

Bronchospasm, skin eruptions, paroxysmal bronchospasm and dyspnoea may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease.

Hepatic:

Caution is advised in patients with hepatic impairment.

Elderly:

The elderly have an increased frequency of adverse reactions to NSAIDs including DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg especially gastrointestinal perforation, ulceration and bleeding (PUBs) which may be fatal.

Impaired female fertility:

May cause impairment of female fertility.

Patients with gout:

The product should not be given to patients with gout, as serum urate may be increased and acute gout may be, unless recommended by a healthcare professional.

Laboratory tests:

DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg can interfere with thyroid function tests. DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg may produce falsely increased results for blood creatinine, urate and urea. Falsely decreased results may be obtained for blood thyroxine and urate (>4 g/day aspirin) and for urinary 5- HIAA (with nitrosoonaphthol method). Urinary VMA (HMMA) levels may be falsely increased or decreased depending on the method of analysis. Urinary glucose oxidase: Aspirin may cause a false negative test in the presence of glycosuria. DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg should be administered with caution to patients with dyspepsia, anaemia and when the patient is dehydrated.

Surgical procedures:

DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg should be stopped several days before scheduled surgical procedures due to increased bleeding time.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS):

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) has been reported in patients taking NSAIDs such as DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg. Some of these events have been fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling. Other clinical manifestations may include hepatitis, nephritis, haematological abnormalities, myocarditis, or myositis. Sometimes symptoms of DRESS may resemble an acute viral infection. Eosinophilia is often present. Because this disorder is variable in its presentation, other organ systems not noted here may be involved. It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present

even though rash is not evident. If such signs or symptoms are present, discontinue DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg and evaluate the patient immediately.

4.5 Interaction with other medicines and other forms of interaction

Corticosteroids:

Increased risk of gastrointestinal perforation, ulceration or bleeding (PUBs).

Anti-platelet agents:

Increased risk of bleeding, including gastrointestinal bleeding.

Selective serotonin reuptake inhibitors (SSRIs):

Increased risk of gastrointestinal bleeding.

Calcium channel blockers:

Reduced hypotensive effects, increased anti- platelet effects which may result in prolonged bleeding time.

Digoxin:

NSAIDs including DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg may exacerbate cardiac failure, reduce GFR and increase plasma digoxin levels.

Varicella vaccine:

Avoid use of DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg in varicella vaccine recipients due to a possible association with Reye's syndrome.

Antihypertensives (ACE inhibitors and Angiotensin II Antagonists and renin antagonists such as aliskiren) and diuretics:

NSAIDs may reduce the effect of diuretics and decrease the blood pressure lowering effect of antihypertensive medicines. In patients with compromised renal function and in dehydrated patients or elderly patients the co-administration of an ACE inhibitor or Angiotensin II antagonist and DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg may result in further deterioration of renal function including acute renal failure. These interactions should be considered in patients taking DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg concomitantly with ACE inhibitors or angiotensin II antagonists. Therefore, the combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy, and periodically thereafter. Diuretics can increase the risk of nephrotoxicity of DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg.

Anti-coagulants:

DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg may enhance the effects of anti-coagulants, such as warfarin.

Ibuprofen:

Experimental data suggest that ibuprofen may inhibit the effect of DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg on platelet aggregation when they are dosed concomitantly.

Other NSAIDs or other salicylates including cyclooxygenase-2 selective Inhibitors:

NSAIDs:

use of DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg and NSAIDs concomitantly can result in an increase in side effects.

Ciclosporin:

Increased risk of nephrotoxicity with DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg.

Tacrolimus:

Possible increased risk of nephrotoxicity when DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg is given with tacrolimus.

Zidovudine:

Increased risk of haematological toxicity when DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg is given with zidovudine.

Metoclopramide & domperidone:

May increase the rate of absorption of DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg.

Valproate:

DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg may increase valproate levels resulting in valproate toxicity.

Quinolone antibiotics:

Animal data indicate that DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg can increase the risk of convulsions associated with quinolone antibiotics. Patients taking DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg and quinolones may have an increased risk of developing convulsions.

Uricosurics:

Acetylsalicylic acid inhibits the effects of uricosurics.

Mifepristone:

DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg can reduce the effect of mifepristone.

Methotrexate:

Decreased elimination of methotrexate and increased methotrexate side effects.

Laboratory investigations:

DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg may interfere with some laboratory tests used to measure urine glucose.

Barbiturates and other sedatives

May mask the respiratory symptoms of DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg and have been reported to enhance its toxicity. Prolonged use of high doses may lead to anaemia, blood dyscrasias, gastro-intestinal haemorrhage, peptic ulceration and renal papillary necrosis.

Alcohol

Increased damage to gastro-intestinal mucosa and prolonged bleeding time due to additive effects of DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg and alcohol.

4.6 Fertility, pregnancy and lactation

DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg is contraindicated in pregnancy and lactation (see section 4.3).

Pregnancy

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies show an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor such as DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg in early pregnancy. DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg is teratogenic in animals.

During the third trimester of pregnancy, DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg may expose the foetus to:

- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
- renal dysfunction, which may progress to renal failure with oligo- hydroamniosis; the mother and the neonate, at the end of pregnancy, to:
- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
- inhibition of uterine contractions resulting in delayed or prolonged labour.

Regular use of NSAIDs such as DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg during the third trimester of pregnancy, may result in premature closure of the foetal ductus arteriosus in *utero*, and possibly, in persistent pulmonary hypertension of the new-born. The onset of labour may be delayed and its duration increased.

Lactation

Use of the DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg is contraindicated in women breastfeeding their infants. DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg given in breastfeeding mothers may pose a risk of Reye's syndrome in nursing infants.

Fertility

Medicines such as DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg which inhibit cyclo-oxygenase /prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible on withdrawal of treatment.

4.7 Effects on ability to drive and use machines

DISPRIN REGULAR STRENGTH 300 mg/ DISPRIN EXTRA STRENGTH 500 mg have no or negligible influence on ability to drive and use machines.

4.8 Undesirable effects:

System Organ Class	Frequency	Adverse Events
Blood and Lymphatic System Disorders	Less frequent	Hypoprothrombinaemia, thrombocytopenia, aplastic anaemia, agranulocytosis, pancytopenia

Immune System Disorders	Less frequent	Pyrexia, urticaria, pruritus, angioedema
Metabolism and Nutrition Disorders	Less frequent	Sodium retention, fluid retention
Nervous System Disorders	Less frequent	Aseptic meningitis, Headache, dizziness.
Cardiac Disorders	Less frequent	Cardiac failure, oedema
Vascular Disorders	Less frequent	Hypertension
Respiratory, Thoracic and Mediastinal Disorders	Less frequent	Bronchospasm, asthma, dyspnoea, rhinitis
Gastrointestinal Disorders	Less frequent	Gastrointestinal haemorrhage, gastrointestinal disturbances, peptic ulcer, melaena, haematemesis, mouth ulceration
Hepatobiliary Disorders	Frequency unknown	Transient hepatic impairment with increase in liver transaminases
Skin and Subcutaneous Tissue Disorders	Less frequent	Stevens-Johnson syndrome, toxic epidermal necrolysis, rash
	Frequency unknown	Drug Reaction with

		Eosinophilia and Systemic Symptoms (DRESS) (see section 4.4)
Renal and Urinary Disorders	Less frequent	Blood uric acid increased
Investigations	Less frequent	Bleeding time prolonged, platelet adhesiveness decreased

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions 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.

4.9 Overdose

Salicylate poisoning is usually associated with plasma concentrations >350 mg/L (2,5 mmol/L). Most deaths in adults occur in patients whose concentrations exceed 700mg/L (5,1 mmol/L). Single doses less than 100 mg/kg are unlikely to cause serious poisoning.

Symptoms

These include dizziness, tinnitus, dehydration, vertigo, deafness, warm extremities with bounding pulses, increased respiratory rate and depth, sweating, nausea, vomiting, altered glucose metabolism, mental confusion, hyper-ventilation, respiratory alkalosis, metabolic

acidosis, ketosis, and fluid and electrolyte losses. Some degree of acid-base disturbance is present in most cases. Uncommon features include haematemesis, hyperpyrexia, hypoglycaemia, hypokalaemia, thrombocytopenia, increased INR/PTR, intravascular coagulation, renal failure and non-cardiac pulmonary oedema. Central nervous system features including confusion, disorientation, coma and convulsions may occur and are more common in children than in adults. In children, serious signs of overdosage may develop rapidly.

Management

Treatment is symptomatic and supportive: the serum salicylate levels should be closely monitored and forced alkaline diuresis instituted if appropriate. Restoration of fluid, electrolyte and acid balance, dialysis and supportive therapy may be required. Adults presenting within one hour of ingestion of more than 250 mg/kg should be given activated charcoal. Elimination is increased by urinary alkalinisation. The urine pH should be monitored. Correct metabolic acidosis with intravenous 8,4% sodium bicarbonate (first check serum potassium). Forced diuresis should not be used since it does not enhance salicylic excretion and may cause pulmonary oedema. Haemodialysis is the treatment of choice for severe poisoning and should be considered in patients with plasma salicylate concentrations > 700 mg/L (5,1 mmol/L) or lower concentrations associated with severe clinical or metabolic features. Patients under ten years or over 70 have increased risk of salicylate toxicity and may require dialysis at an earlier stage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacological classification:

A 2.7 Antipyretic or antipyretic and anti-inflammatory analgesics.

Pharmacotherapeutic group: Other analgesics and antipyretics: ATC Code: N02BA01

Aspirin has analgesic, antipyretic and anti-inflammatory actions. Aspirin inhibits the biosynthesis of prostaglandins. Aspirin inhibits the cyclo-oxygenase enzyme involved in conversion of phospholipids to prostaglandins and its effects on the body are believed to result primarily from prevention of prostaglandin production. These effects include peripheral analgesia, fever reduction, reduction in inflammation and irreversible inhibition of platelet aggregation. Experimental data suggest that

NSAIDs may inhibit the effect of aspirin on platelet aggregation when they are dosed concomitantly.

5.2 Pharmacokinetic Properties

Aspirin is rapidly absorbed from the stomach and upper gastrointestinal tract. It is subject to first-pass metabolism with an overall bioavailability of around 70 %. Metabolism is by conversion to salicylic acid and then by further conversion to other metabolites. These are excreted by the kidneys in both free and conjugated form. The plasma half-life of acetylsalicylic acid is around 15-20 minutes and that of salicylic acid is 2-3 hours.

5.3 Preclinical safety data

The preclinical safety profile of acetylsalicylic acid is well documented.

In animal studies, salicylates caused kidney damage at high dosages but no other organic lesions. Acetylsalicylic acid has been extensively studied in vitro and in vivo for mutagenicity; no relevant evidence of a mutagenic potential was found. The same applies to carcinogenicity studies.

Salicylates have exhibited teratogenic effects in animal studies and a number of different species. Implantation disorders, embryotoxic and fetotoxic effects and impairment of learning ability in the offspring after prenatal exposure have been described.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

DISPRIN REGULAR STRENGTH 300 mg:

Calcium Carbonate

Anhydrous Citric Acid

Maize Starch

Sodium Lauryl Sulphate

Saccharin (sweetener)

Purified Talc.

DISPRIN EXTRA STRENGTH 500 mg:

Calcium Carbonate

Anhydrous Citric Acid

Maize Starch

Sodium Lauryl Sulphate

Saccharin (sweetener)

Purified Talc

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 25 °C in a dry place.

6.5 Nature and contents of container

DISPRIN REGULAR STRENGTH 300 mg:

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:

In packs of 2, 12, 24, 48 and 72 tablets packed in aluminium foil.

6.6 Special precautions for disposal and other handling

No special requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION

Reckitt Benckiser Pharmaceuticals (Pty) Ltd

8 Jet Park Road

Elandsfontein 1601

8. REGISTRATION NUMBER:

DISPRIN REGULAR STRENGTH 300 mg: B/2.7/570

DISPRIN EXTRA STRENGTH 500 mg: M/2.7/292

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1. Date on the registration certificate of DISPRIN EXTRA STRENGTH 500 mg: 20/10/1980

2. Date on the registration certificate of DISPRIN REGULAR STRENGTH 300 mg:

   26/04/1984

10. DATE OF REVISION OF THE TEXT

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

Namibia: 90/2.7/001388 NS0

Zimbabwe: L77/2.1/900 HR

2.1 Analgesics and Antipyretics (single ingredient product)