SCHEDULING STATUS **S2**

PROPRIETARY NAME (AND DOSAGE FORM):

SOLUSPIRIN CV (Aspirin Soluble 100 mg Tablets)

COMPOSITION: Each tablet contains: Aspirin 100 mg

Inactive ingredients: calcium carbonate, maize starch, anhydrous citric acid, purified talc, sodium saccharin, sodium lauryl sulphate, lemon flavour. Sugar-free.

PHARMACOLOGICAL CLASSIFICATION: A8 Medicines acting on the blood and haemopoietic system.

PHARMACOLOGICAL ACTION: Aspirin has analgesic, anti-inflammatory and antipyretic actions. It inhibits platelet aggregation by inactivation of platelet cyclo-oxygenase, the enzyme that produces the cyclic endoperoxide precursor of thromboxane A_2.

INDICATIONS: Indications related to inhibition of platelet aggregation: To reduce the risk of myocardial infarction in patients with unstable angina or in patients who have had a previous myocardial infarction. To reduce the risk of recurrent transient ischaemic attacks or stroke in men who have had transient ischaemia of the brain due to fibrin platelet emboli. To reduce the risk of graft occlusion following aorta coronary by-pass surgery.

CONTRA-INDICATIONS: Patients with a history of gastro-intestinal bleeding or perforation (PUBs) related to previous NSAIDs. Patients with active or a history of recurrent ulcer/ haemorrhage/ perforations. Patients with haemophilia. Intolerance (hypersensitivity) to aspirin. Severe renal or hepatic impairment. Heart failure. Patients receiving oral anti-coagulant therapy.

WARNINGS: The optimal dose for inhibition of platelet aggregation in humans is not known. Do not use **SOLUSPIRIN CV** for indications related to the inhibition of platelet aggregation unless directed by a 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. Caution is required in patients with a history of hypertension and/ or heart failure as fluid retention and oedema have been reported in association with **SOLUSPIRIN CV** therapy. Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs, especially gastro-intestinal bleeding and perforation (PUBs) which may be fatal. The risk of gastro-intestinal bleeding or perforation (PUBs) is higher with increasing doses of **SOLUSPIRIN CV**, in patients with a history of ulcers, and the elderly. When gastro-intestinal bleeding or ulceration occurs in patients receiving **SOLUSPIRIN CV**, treatment with **SOLUSPIRIN CV** should be stopped. **SOLUSPIRIN CV** should be given with caution to patients with a history of gastro-intestinal disease (e.g. ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia) as the condition may be exacerbated. Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported. **SOLUSPIRIN CV** should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

INTERACTIONS: Aspirin may enhance the activity of anticoagulants such as warfarin, oral antidiabetic preparations, methotrexate and sulphonamides. Aspirin diminishes the effects of anti-gout preparations such as probenecid and sulphinpyrazone. Barbiturates and other sedatives may mask the respiratory symptoms of aspirin overdosage and have been reported to enhance its toxicity. NSAIDs: use of two or more NSAIDs or aspirin concomitantly, could result in an increase in side effects. Corticosteroids: increased risk of gastro-intestinal ulceration or bleeding (PUBs). Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs): increased risk of gastro-intestinal bleeding.

PREGNANCY AND LACTATION: Aspirin should not be taken during the first and third trimesters of pregnancy and during lactation. Regular use of non-steroidal anti-inflammatory medicines 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.

DOSAGE AND DIRECTIONS FOR USE:

Adults: 100 to 300 mg (1 to 3 tablets) to be taken every day, preferably at the same time each day. **SOLUSPIRIN CV** tablets can be dissolved in half a glass of water before administration or may be dispersed on the tongue without water.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Side effects:

Blood and the lymphatic system disorders: The following side effects have been reported and frequencies are unknown: Aspirin increases the bleeding time and decreases platelet adhesiveness. It may cause thrombocytopenia.

Cardiac disorders: Oedema, hypertension and cardiac failure.

Gastrointestinal disorders: Frequent: Peptic ulcers, perforation or gastro-intestinal bleeding, sometimes fatal. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease, gastritis.

Skin and subcutaneous tissue disorders: Bullous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis.

Special precautions: Some persons, especially asthmatics, exhibit notable sensitivity to aspirin, which may include urticaria and other skin eruptions, angioedema, rhinitis, paroxysmal bronchospasm and dyspnoea. Aspirin should be administered with caution to dehydrated patients and in the presence of uncontrolled hypertension. Caution is necessary when renal or hepatic function is impaired. Aspirin should be discontinued one week before scheduled surgical procedures. In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients. Prolonged use of high doses may lead to anaemia, blood dyscrasias, gastro-intestinal haemorrhage, peptic ulceration and renal papillary necrosis.

Effects on ability to drive and use machines: None known.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT: Mild chronic salicylate intoxication usually occurs only after repeated administration of large doses. Symptoms include dizziness, tinnitus, deafness, sweating, nausea, vomiting, headache and mental confusion. Symptoms of acute or more severe intoxication following overdosage include hyperventilation, fever, restlessness, ketosis, respiratory alkalosis and metabolic acidosis. Depression of the central nervous system may lead to coma; cardiovascular collapse and respiratory failure may occur. In children drowsiness and metabolic acidosis commonly occur; hypoglycaemia may be severe. In cases of overdosage consult a doctor immediately.

In acute overdosage by mouth the stomach should be emptied by lavage. Fluid and electrolyte management is the mainstay of treatment with the immediate aim being correction of acidosis, hyperpyrexia, hypokalaemia and dehydration. Activated charcoal may be given by mouth to prevent absorption of any salicylate remaining in the stomach. Alkaline diuresis, haemodialysis or haemoperfusion are effective methods of removing salicylate from the plasma.

IDENTIFICATION: A flat, round, beveled-edge, white tablet, with a heart-shape on one side.

PRESENTATION: In silver-coloured aluminium foil packs of 30 tablets.

STORAGE INSTRUCTIONS: Store at or below 25 ^{o}C in a dry place. Foil packs must be kept in the carton until required for use. KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER: 43/8/0830

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Resmed Healthcare, 71 Rochdale Road, Springfield Park, Durban, 4051.

DATE OF PUBLICATION OF THIS PACKAGE INSERT: 18/02/2016

SKEDULERINGSTATUS **S2**

EIENDOMSNAAM (EN DOSEERVORM):

SOLUSPIRIN CV (Oplosbare Aspirien 100 mg Tablette)

SAMESTELLING: Elke tablet bevat: Aspirien 100 mg

Onaktiewe bestanddele: kalsiumkarbonaat, mieliestysel, watervry sitroensuur, gesuiwerde talk, natriumsakkarien, natriumlourielsulfaat, suurlemoen geur. Suiker-vry.

FARMAKOLOGIESE KLASSIFIKASIE: A 8 Middels met uitwerking op bloed en hemopoïetiese stelsel.

FARMAKOLOGIESE WERKING: Aspirien het analgetiese, anti-inflammatoriese en antipiretiese werkings. Dit inhibeer plaatjieklomping deur die onaktivering van plaatjiesiklo-oksigenase, die ensiem wat die sikliese endoperoksied voorloper van tromboksaan A_2 produseer.

INDIKASIES: Indikasies verwant aan inhibeering van plaatjieklomping: Om die risiko van miokardiale infarksie by pasiënte met onstabiele angina of by pasiënte wat 'n vorige miokardiale infarksie gehad het te verminder. Om die risiko van herhaalde isgemiese aanvalle van verbygaande aard of beroerte by mans wat isgemie van verbygaande aard van die brein as gevolg van fibrienplaatjieembolieë gehad het, te verminder.Om die risiko van weefseloorplantingsokklusie na aortakoronêre omleidingschirurgie te verminder.

KONTRA-INDIKASIES: Pasiënte met 'n geskiedenis van gastro-intestinale bloeding of perforasie verwant aan vorige NSAIDs. Pasiënte met aktiewe of 'n geskiedenis van herhalende ulkus/bloeding/perforasies. Pasiënte met hemofilie. Onverdraagsaamheid (hipersensitiwiteit) vir aspirien. Ernstige renale of hepatiese belemmering. Hartversaking. Pasiënte wat antistolmiddelterapie ontvang.

WAARSKUWINGS: Die optimale dosis vir inhibering van plaatjieverklomping in die mens is nie bekend nie. Moenie **SOLUSPIRIN CV** gebruik vir indikasies verwant aan die inhibering van plaatjieklomping tensy voorgeskryf deur 'n dokter. Aspirien hou verband met Reye se sindroom,'n skaars maar ernstige siekte by kinders en tienderjariges met waterpokkies en griep. 'n Dokter moet geraadpleeg word voordat aspirien by sulke pasiënte gebruik word.

Omsigtigheid word benodig by pasiënte met 'n geskiedenis van hipertensie en/of hartversaking want vloeistofretensie en edeem is in verband met **SOLUSPIRIN CV** terapie aangemeld. Bejaardes: Bejaardes het 'n verhoogde frekwensie van negatiewe reaksies op NSAIDs, veral gastro-intestinale bloeding en perforasie wat dodelik kan wees. Die risiko van gastro-intestinale bloeding of perforasie word hoër met toenemende dosisse van **SOLUSPIRIN CV** by pasiënte met 'n geskiedenis van ulkusse, en bejaardes. Wanneer gastro-intestinale bloeding of ulserasie voorkom in pasiënte wat **SOLUSPIRIN CV** ontvang, moet behandeling met **SOLUSPIRIN CV** gestop word. **SOLUSPIRIN CV** moet met omsigtigheid aan pasiënte met 'n geskiedenis van gastro-intestinale siektes gegee word (bv. ulseratiewe kolitis, Crohn se siekte, diafragmabreuk, gastro-esofageale reflukssiekte, angiodisplasie) omdat die toestand vererger kan word. Ernstige vel reaksies, sommige van hulle noodlottig, insluitend eksfoliatiewe dermatitis, Stevens-Johnson sindroom, en toksiese epidermale nekrolise is aangemeld. **SOLUSPIRIN CV** moet gestaak word by die eerste verskyning van veluitslag, slymvliesletsels, of enige ander teken van hipersensitiwiteit .

INTERAKSIES: Aspirien kan die aktiwiteit van teenstolmiddels soos warfarien, orale antidiabetiese preparate, metotrexaat en sulfoonamiede versterk. Aspirien verswak die uitwerking van jigpreparate soos probenesied en sulfinpirasoon. Barbiturate en ander kalmeermiddels kan die asemhalingsimptome van aspirien oordosering verbloem en daar is gerapporteer dat dit die toksisiteit van aspirien verhoog het. NSAIMs: gebruik van twee of meer NSAIMs of aspirien gelyktydig, kan tot 'n toename in newe-effekte lei. Kortikosteroïede : verhoogde risiko van gastro-intestinale ulserasie of bloeding. Anti-plaatjie agente en Selektiewe Serotonien Heropneem Inhibeerders (SSRIs) : 'n verhoogde risiko van gastro-intestinale bloeding.

SWANGERSKAP EN LAKTASIE: Aspirien moet nie gedurende die eerste of derde trimesters van swangerskap of gedurende laktasie geneem word nie. Gereelde gebruik van nie-steroïed anti - inflammatoriese middels tydens die derde trimester van swangerskap kan tot voortydige sluiting van die fetale ductus arteriosus in utero lei, en moontlik, in aanhoudende pulmonale hipertensie van die pasgebore. Die aanvang van kraam mag vertraag word en die duur daarvan mag verleng word.

DOSIS EN GEBRUIKSAANWYSINGS:

Volwassenes: 100 tot 300 mg (1 tot 3 tablette) moet daagliks geneem word, verkieslik op dieselfde tyd elke dag. **SOLUSPIRIN CV** tablette kan in 'n halwe glas water opgelos word voor toediening of kan sonder water op die tong opgelos word.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Newe-effekte:

Bloed en die limfatiese sisteem versteurings : Die volgende newe-effekte is aangemeld en frekwensie is onbekend : Aspirien verleng die bloedingstyd en verminder plaatjie klewerigheid. Dit kan trombositopenie veroorsaak .

Kardiale versteurings : Edeem, hoë bloeddruk en hartversaking .

Gastro-intestinale versteurings: Dikwels: Peptiese ulkus, perforasie of gastro-intestinale bloeding, soms noodlottig. Naarheid, braking, diarree, winderigheid, hardlywigheid, dispepsie, abdominale pyn, melena, hematemese, ulseratiewe stomatitis, verergering van kolitis en Crohn se siekte, gastritis.

Vel en subkutane weefsel versteurings : Bulleuse reaksies, insluitende Stevens-Johnson sindroom en toksiese epidermale nekrolise .

Spesiale voorsorgmaatreëls: Sommige persone, veral asmalyers, toon noemenswaardige gevoeligheid vir aspirien wat urtikarie en ander veluitslae, angioedeem, rinitis, paroksismale brongospasma en dispnee kan insluit.

Aspirien moet versigtig aan dihidreerde pasiënte toegedien word en in die teenwoordigheid van onbeheerde hipertensie. Versigtigheid is nodig wanneer nier- of lewerfunksie verswak is. Aspirien moet een week voor geskeduleerde chirurgie opgehou word. In die lig van die inherente potensiaal van die produk om vloeistof retensie te veroorsaak, kan hartversaking in sommige gedrang pasiënte ontketen.

Langdurige gebruik van hoë dosisse kan tot anemie, bloedsiektes, gastro-intestinale bloeding, peptiese ulkusvorming en renale papillêre nekrose lei.

Effek op vermoë om te bestuur en masjinerie te gebruik Geen bekend.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN:

Matige chroniese salisilaat vergiftiging voorkom gewoonlik net na herhaalde toediening van groot dosisse. Simptome sluit in duiseligheid, tinnitus, doofheid, sweet, naarheid vomering, hoofpyn en geestesverwarring. Simptome van akute of meer ernstige vergiftiging na oordosering sluit in hiperventilasie, koors, rusteloosheid, ketose, respiratoriese alkalose en metabolise asidose. Onderdrukking van die sentrale senuweestelsel mag tot koma lei; kardiovasculêre ineenstorting en asemhalingsversaking kan voorkom. By kinders gebeur lomerigheid en metabolise asidose meer gewoonlik; hipoglisemie kan ernstig wees. In gevalle van oordosering moet 'n geneesheer onmiddelik geraadpleeg word. In akute mondelike oordosering moet die maag geledig word deur maaguitspoeling. Behandeling van vloeistof en elektroliete is die fokus van behandeling waar die onmiddelike doelwit korreksie van asidose, hiperpireksie, hipokalemie en ontwatering is. Geaktiveerde houtskool mag by mond gegee word om die absorpsie van enige oorblywende salisilaat in die maag te voorkom. Alkaliese diurese, hemodialise of hemoperfusie word effektiewe metode om salisilaat van die plasma te verwyder.

IDENTIFIKASIE: 'n Plat, ronde, afgeskuinste, wit tablet, met a hart-vorm op een kant.

AANBIEDING: Verpakkings van 30 tablette in silwer-gekleurde aluminium foelie.

BERGINGSAANWYSINGS: Bêre teen of benede 25ºC op 'n droë plek. Foelie verpakkings van tablette moet in die karton gehou word tot nodig is vir gebruik. HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER: 43/8/0830

NAAM EN SAKEADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:

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