SCHEDULING STATUS: S3

PROPRIETY NAME (And Dosage Form):
NAPINFLAM 250 mg (Tablet)

COMPOSITION:
Per tablet:
250 mg Naproxen.
Contains sugar: Lactose 40 mg.

PHARMACOLOGICAL CLASSIFICATION:
A 3.1 Anti-rheumatics (Anti-inflammatory agents)

PHARMACOLOGICAL ACTION:
NAPINFLAM has anti-inflammatory, antipyretic and analgesic properties. It inhibits prostaglandin synthesis.

INDICATIONS:
NAPINFLAM is indicated for the treatment of rheumatoid arthritis, (including juvenile rheumatoid arthritis), osteoarthritis (degenerative arthritis), ankylosing spondylitis, acute gout, acute musculoskeletal disorders (such as sprains and strains, direct trauma, lumbosacral pain, cervical spondylitis, tenosynovitis, and fibrosis) and dysmenorrhoea.

CONTRAINDICATIONS:
Pregnancy. Active peptic ulceration. Heart failure.
History of gastrointestinal bleeding or perforation (PUBs) related to previous NSAIDs. Active or history of recurrent ulcer/haemorrhage/perforations.
Hypersensitivity to naproxen sodium formulations. Since the potential exists for cross-sensitivity reactions, NAPINFLAM should not be given to patients in whom aspirin or other non-steroidal anti-inflammatory/analgesic medicines induce urticaria, rhinitis or asthma.

WARNINGS:
Regular use of NSAIDs such as NAPINFLAM 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.
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 NAPINFLAM therapy.
Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs, especially gastrointestinal bleeding and perforation (PUBs) which may be fatal.
The risk of gastrointestinal bleeding or perforation (PUBs) is higher with increasing doses of NAPINFLAM, in patients with a history of ulcers, and the elderly.
When gastrointestinal bleeding or ulceration occurs in patients receiving NAPINFLAM treatment with NAPINFLAM should be stopped.
NAPINFLAM should be given with caution to patients with a history of gastrointestinal 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. NAPINFLAM should be discontinued at the first appearance of skin rash, mucosal lesion, or any other sign of hypersensitivity.

INTERACTIONS:
Serious interactions have been reported after the use of high-dose methotrexate with NAPINFLAM.
Probenecid given concurrently increases NAPINFLAM plasma levels and extends its half-life considerably.
NAPINFLAM can reduce the anti-hypertensive effect of propranolol and possibly other beta-blockers. The natriuretic effect of furosemide has been reported to be inhibited by NAPINFLAM. Inhibition of renal lithium clearance leading to increases in plasma lithium concentrations has been reported.
Use of two or more NSAIDs (Non-steroidal anti-inflammatory) concomitantly could result in an increase in side effects.
Corticosteroids: increase risk of gastrointestinal ulceration or bleeding (PUBs).
Anti-coagulants: NAPINFLAM may enhance the effects of anti-coagulants such as warfarin.
Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs):
Increased risk of gastrointestinal bleeding.

PREGNANCY AND LACTATION:
The use of NAPINFLAM should be avoided in patients who are breastfeeding.
Safety and efficacy has not been established in pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE
Use the lowest effective dose for the shortest possible duration of treatment.
Adults: For rheumatoid arthritis, osteoarthritis and ankylosing spondylitis, the starting dose and usual maintenance dose is in the range of 500 mg to 1000 mg per day taken in two doses at twelve hour intervals.
In the following cases a dose of 750 mg or 1 000 mg per day for the acute phase is recommended:
a) in patients reporting severe night time pain and/or morning stiffness;
b) in patients being switched to NAPINFLAM from a high dose of another antirheumatic compound and;
c) in osteoarthritis where pain is the predominant symptom

For the patient who requires 750 mg per day whose night-time pain and/or morning stiffness is most troublesome, 500 mg should be taken upon retiring and 250 mg upon awakening. For the patient, whose daytime pain and reduced mobility are most troublesome, 500 mg should be taken upon awakening and 250 mg upon retiring.
In acute gout, the recommended dosage is 750 mg at once, then 250 mg every eight hours until the attack has passed.
For the treatment of acute musculo-skeletal disorders, the recommended dosage is 250 mg twice or trice daily; most patients will require only 7 days treatment, but some patients may require up to 14 days treatment.
In dysmenorrhoea, the recommended regime is 500 mg initially, followed by 250 mg every six to eight hours.
Children: For juvenile arthritis in children over 5 years of age the usual dose is 10 mg per kg body-mass per day in two doses at twelve-hour intervals. NAPINFLAM is not recommended for use in other indications in children under sixteen years of age.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
Definition of frequencies: very common (1/10); common (1/100. < 1/10); uncommon (1/1000, < 1/100;) rare (1/10 000, < 1/1 000); very rare (< 1/10 000) including isolated reports.

Blood and lymphatic system disorders
Less frequent: Bruising.
Rare:
Thrombocytopenia, granulocytopenia, aplastic anaemia, haemolytic anaemia, oesinophilic pneumonitis, leucopenia.

Cardiac disorders
Less frequent: Increased sweating, pounding heartbeat.
Rare: Cardiac failure.
Frequency unknown: Hypertension, oedema.

Ear and labyrinth disorders
Frequent: Tinnitus.
Less frequent: Hearing impairment.

Eye disorders
Less frequent: Visual disturbances.

Gastrointestinal disorders
Frequent: Nausea, vomiting, constipation
Less frequent: Diarrhoea
Rare: Peptic ulcers, perforation or gastrointestinal bleeding, sometimes fatal. Abdominal pain, melaena, haematemesis, exacerbation of colitis and Crohn's disease.
Frequency unknown: Flatulence, gastritis, ulcerative stomatitis.

Hepatobiliary disorders
Rare: Jaundice or hepatitis.

General disorders and administration site conditions
Less frequent: Aphthous stomatitis.
Rare: Anaphylactic reactions, fever.
Very rare: Angitis, angioedema, bronchospasm.

Musculoskeletal disorders
Rare: Muscle cramps or pain. Nervous System disorders
Frequent: Headache, drowsiness, dizziness.
Less frequent: Vertigo, thirst.
Rare: Mental depression, confusion, unusual weakness, insomnia.
Very rare: Aseptic meningitis, peripheral neuropathy.
Frequency unknown: Cognitive dysfunction, inability to concentrate.

Renal and urinary disorders
Rare: Reversible renal failure, blood in urine, nephritic syndrome, nephritis, oedema, tubular necrosis.

Reproductive system and breast disorders
Rare: Menstrual bleeding, cystitis.

Respiratory, thoracic and mediastinal disorders
Frequent: Shortness of breath.

Skin and subcutaneous tissue disorders
Frequent: Skin rashes, urticaria.
Rare: Exfoliative dermatitis.
Very rare: Itching, erythema multiforme, photosensitivity reactions, bullous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis.

SPECIAL PRECAUTIONS:
NAPINFLAM should be given under close supervision to patients with a history of gastrointestinal disease. Due to the high plasma protein binding of NAPINFLAM patients simultaneously receiving hydantoins, anticoagulants or other highly protein-bound medicines should be observed for signs of potentiation or overdosage of these medicines. Patients who have exhibited aspirin hypersensitivity in the past (usually as the angio-oedema/asthma syndrome) may exhibit the same phenomenon of NAPINFLAM. Sporadic abnormalities in laboratory tests (e.g. Liver function tests) have occurred in patients on NAPINFLAM therapy. This effect should be kept in mind when bleeding times are determined. It is suggested that NAPINFLAM therapy be temporarily discontinued 48 hours before adrenal function tests are performed, because NAPINFLAM may interfere with some assays of urinary 5-hydroxy-indoleacetic acid.
In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

Use in patients with renal impairment:
As naproxen is eliminated to a large extent (95 %) by urinary excretion via glomerular filtration it should be used with great caution in patients with impaired renal function and the monitoring of serum creatinine and/or creatinine clearance is advised in these patients. NAPINFLAM is not recommended in patients having baseline clearance less than 20 ml per minute.
Certain patients, specifically those where renal blood flow is compromised, such as extracellular volume depletion, cirrhosis of the liver, sodium restriction, congestive heart failure and pre-existing renal disease, should have renal function assessed before and during NAPINFLAM therapy. Elderly patients in whom impaired renal function may be expected could also fall within this category. A reduction in daily dosage is recommended to avoid the possibility of excessive accumulation of Naproxen metabolites in these patients.

Use in patients with impaired liver function:
Chronic alcoholic liver disease and probably also other forms of cirrhosis reduce the total plasma concentration of naproxen, but the plasma concentration of unbound naproxen is increased. Caution is advised when using NAPINFLAM in patients with hepatic disease.

Use in elderly:
Although total plasma concentration of naproxen is unchanged, the unbound plasma fraction if naproxen is increased in the elderly.
Caution is advised and lower doses might be required.
Mild peripheral oedema has been observed in a few patients receiving NAPINFLAM. Although sodium retention has not been reported in metabolic studies, it is possible that patients with questionable or compromised cardiac function may be at a greater risk when taking NAPINFLAM.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Significant overdosage of the drug may be characterised by drowsiness, heartburn, indigestion, nausea and vomiting. Should a patient ingest a large amount of naproxen accidentally or purposefully, the stomach may be emptied, and the usual supportive measures employed.

IDENTIFICATION:
250 mg Tablets: Yellow, round, biconvex tablet.

PRESENTATION:
250 mg Tablets: Securitainers, containing 30, 250 and 500 tablets.

STORAGE INSTRUCTIONS:
Store below 25°C and protect from light.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:
250 mg Tablets: 28/3.1/0038

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
TRINITY PHARMA (PTY) LTD
3 Gwen Lane, 4th Floor, Sandton, 2031.
Contact No.: +27 (0)10 594 5610
PV Email Address: pv@trinitypharma.co.za

DATE OF PUBICATION OF THIS PACKAGE INSERT:
30 November 2007

TRINITY PHARMA

Tel: 010 594 5610. Email: PV@kahmagroup.co.za

SKEDULERINGSTATUS: S3

EIENDOMSNAAM (EN DOSEERVORM):
NAPINFLAM 250 (Tablet)

SAMESTELLING:
Per tablet: 250 mg Naprokseen
Bevat suiker: Laktose 40 mg

FARMAKOLOGIESE KLASSIFIKASIE:
A 3.1 Rumatiekmiddels (anti-inflammatoriese middels)

FARMAKOLOGIESE WERKING:
NAPINFLAM het anti-inflammatoriese, koorswerende en analgetiese eienskappe. Dit inhibeer prostaglandiensintese.

INDIKASIES:
NAPINFLAM word aangedui vir die behandeling van rumato·iede artritis (insluitende rumatoïede artritis by jeugdiges), osteoartritis (degeneratiewe artritis), ankiloserende spondilitis, akute jig, akute skeletspierongesteldhede (soos verstuiting en verrekking, direkte rouma, lumbrosakrale pyn, servikale spondilitis, tenosinovitis, en fibrose) en dismenoree.

KONTRA-INDIKASIES:
Swangerskap. Aktiewe peptiese ulserering. Hartversaking.
Geskiedenis van gastrointestinale bloeding of perforasie (PUBs) verwant aan vorige NSAIMs. Aktiewe of geskiedenis van herhalende ulkus/hemoragie/perforasies.
Hipersensitiwiteit tot naprokseennatrium formulerings.
Daar is 'n potensiaal vir kruissensitiwiteitsreaksies,en NAPINFLAM moet daarom nie aan pasïente, by wie aspirien of ander nie-steroide anti-inflammatoriese/analgetiese medisynes urtikarie, rinitis of asma veroorsaak, toegedien word nie.

WAARSKUWINGS:
Gereelde gebruik van NSAIMs soos NAPINFLAM gedurende die derde trimester van swangerskap kan premature sluiting van die feta le ductus arteriosus in utero, en moontlik volgehoue pulmonere hipertensie van die pasgeborene tot gevolg he. Die aanvang van kraam kan vertraag word en die tydperk verleng. Versigtigheid is nodig by pasïente met 'n geskiedenis van hipertensie en/of hartversaking omdat vogretensie en edeem gerapporteer is in assossiasie met NAPINFLAM behandeling.
Bejaardes: by bejaardes is daar 'n verhoogde voorkoms van ongunstige effekte met NSAIMs, veral gastroïintestinale bleeding en perforasie (PUBs) wat noodlottig kan wees. Die risiko van gastroïntestinale bleeding of perforasie (PUBs) is hoer met verhoging in dosering van NAPINFLAM, by pasïente met 'n geskiedenis van ulkusse, en by bejaardes. Wanneer gastro'fntestinale bleeding of ulserasie voorkom by pasïente wat NAPINFLAM ontvang , moet behandeling met NAPINFLAM gestaak word. NAPINFLAM moet versigtig toegedien word by pasïente met 'n geskiedenis van gastroïntestinale siekte (bv ulseratiewe kolitis, Crohn se siekte, hiatus hernia, gastroesofageale refluks, angiodisplasie) omdat die toestand erger kan word. Ernstige velreaksies, sommige daarvan noodlottig, insl uitende eksfoliatiewe dermatitis, Stevens-Johnson se sindroom, en toksiese epidermale nekrolise is gerapporteer. NAPINFLAM moet gestaak word by die eerste voorkoms van veluitslag, mukosale letsel, of enige ander teken van hipersensitiwiteit.

INTERAKSIES:
Ernstige interaksies is gerapporteer na die gebruik van hoe-dosis metotreksaat met NAPINFLAM.
Probenesied toegedien saam met NAPINFLAM verhoog plasmavlakke en verleng die half-leefltyd aansienlik.
NAPINFLAM kan die antihipertensiewe effek van propranolol en moontlik ander beta-blokkeerders verminder. Dit is gerapporteer dat die natriuretiese effek van furosemied geïnhibeer kan word deur NAPINFLAM.
Dit is gerapporteer dat inhibisie van renale litium opruiming 'n toename in plasmalitiumkonsentrasies tot gevolg het. Gebruik van twee of meer NSAIMs (Nie-steroïed anti inflammatoriese middels) saam kan 'n verhoging in newe-effekte tot gevolg hê.
Kortikosteroïede: Verhoogde risiko van gastroïntestinale ulserasie of bleeding (PUBs).
Antikoagulante: NAPINFLAM kan die effekte van antikoagulante soos warfarien verhoog.
Antiplaatjie-middels en selektiewe serotonien heropname inhibeerders (SSRIs): Verhoogde risiko van gastroïntestinale bloeding.

SWANGERSKAP EN LAKTASIE:
Die gebruik van NAPINFLAM moet vermy word by pasïente wat borsvoed.
Veiligheid en effektiwiteit is nog nie vasgestel tydens swangerskap en laktasie nie.

DOSIS EN GEBRUIKSAANWYSINGS:
Gebruik die laagste effektiewe dosis vir die kortste moontlike tydperk van behandeling .
Volwassenes: Vir rumatoïede artritis, osteoartritis en ankiloserende spondilitis is die aanvangsdosis en gewone instandhoudingsdosis 500 mg tot 1000 mg per dag in twee twaalfuurlikse doserings.
In die volgende gevalle word, gedurende die akute fase, 'n dosis van 750 mg tot 1000 mg per dag aanbeveel:
a) by pasïente wat aan ernstige nagpyn en/of oggendstyfheid ly;
b) by pasïente wat van 'n ander hoe-dosis rumatiekmiddel oorgeskakel word na NAPINFLAM en;
c) by osteoartrose waar pyn die oorheersende simptoom is.

Vir pasïente wat 750 mg per dag nodig het en waar nagpyn en/of oggendstyfheid lastig is, moet 500 mg geneem word in die aand voor slapenstyd en 250 mg in die oggend. Vir pasïente wat gedurende die dag probleme het met pyn en verminderde beweeglikheid; moet 500 mg geneem word in die oggend en 250 mg in die aand met slapenstyd. By akute jig word aanbeveel dat 750 mg onmiddellik geneem word en daarna 250 mg elke agt uur totdat die aanval verby is. Vir die behandeling van akute spier-skeletale aandoenings word 250 mg twee tot drie maal per dag aanbeveel. Meeste pas'ïente het net behandeling vir 7 dae nodig, maar sommige pasïente mag behandeling vir 14 dae nodig he. By dismenoree word aanbeveel dat 500 mg aanvanklik toegedien word, gevolg deur 250 mg elke ses tot agt uur.
Kinders: Vir j uveniele artritis by kinders ouer as 5 jaar, is die gewone dosis 10 mg per kg liggaammassa per dag in twee twaalfuurlikse doserings. NAPINFLAM word nie aanbeveel vir enige ander indikasies by kinders jonger as 16 jaar nie.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Definisies van frekwensies: baie algemeen (≥1/10); algemeen (≥1/100, < 1/10); ongewoon (≥ 1/1 000, < 1/100); raar (≥ 1/10 000, < 1/1 000); baie raar (< 1/10 000) insluitende geïsoleerde verslae.

Bloed en limfatiese sisteem ongesteldhede
Minder dikwels: Kneusing.
Raar: Trombositopenie, granulositopenie, aplastiese anemie, hemolitiese anemie, esinofiliese pneumonitis, leukopenie.

Kardiale ongesteldhede
Minder dikwels: Verhoogde sweet, hartkloppings.
Raar: Hartversaking.
Frekwensie onbekend: Hipertensie, edeem.

Oor en labirint ongesteldhede
Dikwels: Tinnitus.
Minder dikwels: Gehoorbelemmering.

Oog ongesteldhede
Minder dikwels: Visuele versteurings.

Gastroïntestinale ongesteldhede
Dikwels: Naarheid, braking, hardlywigheid.
Minder dikwels: Diaree.
Raar: Peptiese ulkusse, perforasie of gastroïntestinale bloeding, soms noodlottig. Abdominale pyn, melaena, hematemese, opvlamming van kolitis en Crohn se siekte.
Frekwensie onbekend: Winderigheid, gastritis, ulseratiewe stomatitis.

Hepatobiliere ongesteldhede
Raar: Geelsug of hepatitis.

Algemene ongesteldhede en toestande by die plek van toediening
Minder dikwels: Afteuse stomatitis.
Raar: Anafilaktiese reaksies, koors.
Baie raar: Angitis, angio-edeem, brongospasma.

Muskuloskeletale ongesteldhede
Raar: Spierkrampe of pyn.

Senustelsel ongesteldhede
Dikwels: Hoofpyn, slaperigheid, duiseligheid.
Minder dikwels: Vertigo, dors.
Raar: Geestesdepressie,verwarring,ongewone swakheid, insomnie.
Baie raar: Aseptiese meningitis, perifere neuropatie.
Frekwensie onbekend: Kognitiewe disfunksie, onvermoe om te konsentreer.

Renale en urinere ongesteldhede
Raar: Omkeerbare nierversaking, bleed in uriene, nefritiese sindroom, nefritis, edeem, tubulere nekrose.

Reproduktiewe stelsel en borsongesteldhede
Raar: Menstruele bleeding, sistitis.

Respiratories, torakaal en mediastinale ongesteldhede
Dikwels: Asem tekort.

Vel en subkutaneuse weefselongesteldhede
Dikwels: Veluitslag, urtikarie.
Raar: Eksfoliatiewe dermatitis.
Baie raar: Jeuk, erythema multiforme, fotosensitiwiteitsreaksies, bulleuse reaksies, insluitende Stevens-Johnson se sindroom en toksiese epidermale nekrolise.

SPESIALE VOORSORGMAATREËLS:
NAPINFLAM moet onder noukeurige toesig toegedien word aan pasïente met 'n geskiedenis van gastrorntestinale siekte. Weens die hoe plasma-proteïenbinding van NAPINFLAM moet pasïente wat hidantorene, antikoagulante of ander hoogs proteïen-gebonde medisynes terselfdertyd ontvang, noukeuring gemonitor word vir tekens van potensiering of oordosering van hierdie medisynes. Pasïente wat hipersensitiwiteit in die verlede getoon het met aspirien (gewoonlik as die angio-edeem/asma sindroom) kan dieselfde fenomenoon met NAPINFLAM toon. Sporadiese abnormaliteite in laboratoriumtoetse (bv lewerfunksietoetse) het voorgekom by pasïente op NAPINFLAM terapie. Hierdie effek moet in gedagte gehou word wanneer bloedingstye bepaal word. Dit word voorgestel dat NAPINFLAM-terapie tydelik gestaak word 48 uur voor adrenale funksie toetse gedoen word, omdat NAPINFLAM sommige van die urien-5-hidroksie-indoolasynsuur bepalings kan beïnvloed. Weens die produk se inherente potensiaal om vogretensie te veroorsaak, kan hartversaking gepresipiteer word by sommige gekompromiseerde pasïente.

Gebruik by pasïente met nierbelemmering:
Aangesien naprokseen hoofsaaklik (95 %) in die uriene deur glomerulere filtrasie uitgeskei word, moet dit met groot versigtigheid gebruik word by pasïente met nierbelemmering en word daar aanbeveel dat of serum-kreatinien en/of kreatinien opruiming by hierdie pasïente gemonitor word. NAPINFLAM word nie aanbeveel by pasïente waar die opruiming minder as 20 ml per minuut is nie. Sommige pasïente, veral die pasïente waar nierbloedvloei belemmer is, soos in die geval van verminderde ekstrasellulere volume, sirrose van die lewer, natriumretensie, kongestiewe hartversaking en bestaande niersiektes, se nierfunksies moet voor en gedurende NAPINFLAM behandeling bepaal word. Bejaarde pasïente by wie belemmerde nierfunksie vermoed word, val ook in hierdie kategorie. 'n Vermindering in die daaglikse dosis word by hierdie pasïente aanbeveel om 'n moontlike uitermatige opeenhoping van naprokseenmetabolie. te te voorkom.

Gebruik by pasïente met lewerbelemmering:
Chroniese alkoholiese leweraandoenings en waarskynlik ook ander vorme van sirrose verminder die totale bloedkonsentrasie van naprokseen, maar die bloedkonsentrasie van ongebonde naprokseen word verhoog. Versigtigheid word aanbeveel wanneer NAPINFLAM by pasïente met lewersiektes gebruik word.

Gebruik by bejaardes:
Alhoewel die totale plasmakonsentrasie van naprokseen onveranderd is, is die ongebonde plasma fraksie van naprokseen verhoog, by bejaarde pasïente. Versigtigheid word aanbeveel en laer dosering kan nodig wees. Ligte perifere edeem is waargeneem in 'n paar pasïente wat NAPINFLAM ontvang. Alhoewel natriumretensie nie gerapporteer is in metaboliese studies nie, is dit moontlik dat pasïente met twyfelagtige of verswakte kardiale funksie 'n groter risiko loop wanneer hulle NAPINFLAM neem.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Betekenisvolle oordosering van die middel word gekenmerk deur lomerigheid, sooibrand, slegte spysvertering, naarheid en braking. Indien 'n pasient 'n groat hoeveelheid naprokseen toevallig of doelbewus inneem, moet die maag geledig en die nodige ondersteunende maatreels toegepas word.

IDENTIFIKASIE:
250 mg Tablette: Geel, ronde, bikonvekse tablette.

AANBIEDING:
250 mg Tablette: Verpakkings van 30, 250, en 500 tablette in securitainers

BERGINGSAANWYSINGS:
Berg benede 25 °C en beskerm teen lig.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMERS:
250 mg Tablette: 28/3.1/0038

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:
TRINITY PHARMA (EDMS.) BPK
3 Gwen Lane, 4de vloer, Sandton, 2031.
Kontaknommer: +27 (0)10 594 5610
PV E-posadres: pv@trinitypharma.co.za

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TRINITY PHARMA

Tel: 010 594 5610. Email: PV@kahmagroup.co.za