SCHEDULING STATUS: S2

PROPRIETARY NAME (AND DOSAGE FORM):
DICLOFENAC 50 mg CLICKS (TABLET)

COMPOSITION:
Each enteric-coated tablet contains 50 mg diclofenac sodium.

List of Excipients:
Maize starch, calcium sulphate dihydrate, sodium starch glycolate, docusate sodium, magnesium stearate, HPMC (Hydroxy propyl methyl cellulose) E-5, polyethylene glycol 600, acryl EZE yellow (93A82339).

Sugar free tablets

PHARMACOLOGICAL CLASSIFICATION:
A 3.1 Antirheumatics (anti-inflammatory agents)

PHARMACOLOGICAL ACTION:

Diclofenac sodium is a non-steroidal compound, a phenylacetic acid derivative, with analgesic, antipyretic and anti-inflammatory effects. Diclofenac sodium inhibits the biosynthesis and release of prostaglandins, which are known to be implicated in the pathogenesis of inflammation, pain and fever. **DICLOFENAC 50 mg CLICKS** tablets are enteric-coated so that absorption occurs in the gastrointestinal tract to give peak plasma concentrations approximately 2 hours after ingestion. There is at least 99 % binding to plasma proteins and excretion of metabolites is mainly in the urine.

INDICATIONS:
For the treatment of fever, dysmenorrhoea, mild to moderate pain, post-operative and post-traumatic inflammation and swelling; as well as for the emergency treatment of acute gout attacks.

CONTRAINDICATIONS:
Diclofenac sodium is contraindicated in patients with known hypersensitivity to diclofenac and in patients who respond to aspirin and aspirin-type drugs with sensitivity reactions like asthma, acute rhinitis and urticaria. Diclofenac sodium is absolutely contraindicated in patients with peptic ulceration or a history of such ulceration, and should be used with caution in patients with renal or hepatic insufficiency.

WARNINGS AND SPECIAL PRECAUTIONS:
Gastrointestinal bleeding or ulceration / perforation can occur at any time with or without symptoms. They generally have more serious consequences in the elderly. Strict accuracy of diagnosis and close medical surveillance are imperative in patients with symptoms indicative of gastrointestinal ulceration, ulcerative colitis and Crohn's disease, in patients suffering from impaired hepatic function, pre-existing dyshaematopoiesis or disorders of blood coagulation.

Blood counts and monitoring of hepatic and renal function are advised during prolonged therapy with **DICLOFENAC 50 mg CLICKS** as blood dyscrasias have been reported. **DICLOFENAC 50 mg CLICKS** should be given with care to patients with bleeding disorders, cardiovascular disease, and in those who are receiving coumarin anticoagulants. Patients who are sensitive to aspirin generally should not be given **DICLOFENAC 50 mg CLICKS** .

Serious interactions have been reported after concomitant use of methotrexate and diclofenac. Allergic reactions, including anaphylactic reactions, including hypotension, vasculitis and pneumonitis, can occur without previous exposure to diclofenac.

INTERACTIONS:
Serious interactions have been reported after the use of high dose methotrexate with diclofenac.
Blood concentrations of lithium are increased when **DICLOFENAC 50 mg CLICKS** is administered concomitantly.

PREGNANCY AND LACTATION:
The safe use of **DICLOFENAC 50 mg CLICKS** in pregnancy has not been demonstrated.
Regular use of NSAID's 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 newborn. The onset of labour may be delayed and its duration increased.

DOSAGE AND DIRECTIONS FOR USE:
Usual adult dose:
Dosage for mild to moderate pain and inflammation is a maximum daily dose of 75 mg for a maximum treatment period of 5 days. That is, 25 mg tablets three times daily after meals.
Dosage for an acute gout attack is a maximum daily dose of 150 mg for a maximum treatment period of 3 days. That is 50 mg tablets three times daily after meals.

DICLOFENAC 50 mg CLICKS is not recommended for use in children as safety and efficacy have not been established.

SIDE EFFECTS:
In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

Blood and the lymphatic system disorders
Less frequent: Thrombocytopenia, leucopenia, haemolytic anaemia, aplastic anaemia, agranulocytosis

Nervous system disorders
Frequent: Headache, dizziness, vertigo, nervousness
Less frequent: Drowsiness

Eye disorders
Less frequent: Disturbance of vision, blurred vision, diplopia

Ear and labyrinth disorders
Less frequent: Impaired hearing, tinnitus, taste alteration disorders

Cardiac disorders
Less frequent: Palpitations, chest pain, hypertension, congestive heart failure

Gastrointestinal disorders:
Frequent: Epigastric pain and other gastrointestinal disorders such as nausea, diarrhea, vomiting, abdominal cramps, dyspepsia, flatulence and anorexia
Less frequent: Gastric or intestinal ulceration with associated bleeding.
Aphthous stomatitis, glossitis, oesophageal lesions, diaphragm-like intestinal structures, lower gut disorders such as non-specific haemorrhagic colitis and exacerbation of ulcerative colitis or Crohn's disease, constipation, pancreatitis

Hepato-biliary disorders
Frequent: Elevation of serum aminotransferase values (SGOT, SGPT)
Less frequent: Hepatitis with or without jaundice, fulminant hepatitis.

Skin and subcutaneous tissue disorders
Frequent: Rashes and skin eruptions
Less frequent: Urticaria, pruritus, bullous eruptions, eczema, erythema multiforme, Stevens-Johnson syndrome, Lyell's syndrome (acute toxic epidermolysis), erythrodermia (exfoliative dermatitis), loss of hair, photosensitivity reactions, and purpura, including allergic purpura.

Renal and urinary disorders
Less frequent: Oedema, acute renal failure, urinary abnormalities such as haematuria and proteinuria, intestinal nephritis, nephrotic syndrome, papillary necrosis, nephropathy with long term use.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
See **"SIDE-EFFECTS AND SPECIAL PRECAUTIONS"**.
Treatment is symptomatic and supportive.

IDENTIFICATION:
Tan coloured, round, enteric-coated.

PRESENTATION:
9 tablets in white polypropylene securitainers with LDPE (low density polyethylene) closures and PVC film / printed aluminium foil blister packs.

STORAGE INSTRUCTIONS:
Store at or below 25 °C. Protect from light and moisture.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
U/3.1/182

NAME AND ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Adcock Ingram Limited
1 New Road, Erand Gardens, Midrand, 1685
Private Bag X69, Bryanston, 2021
www.adcock.com
Marketed by: Unicorn Pharmaceuticals (Pty) Ltd

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
February 1990 (December 2020)

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SKEDULERINGSTATUS: S2

EIENDOMSNAAM (EN DOSEERVORM):

DICLOFENAC 50 mg CLICKS (TABLET)

SAMESTELLING:
Elke enteriesbedekte tablet bevat 50 mg natriumdiklofenak.

Lys van bymiddels:
Mieliestysel, kalsiumsulfaatdihidraat, natriumstyselglikolaat, natriumdokusaat, magnesiumstearaat, HPMC (hidoksiepropielmetielsellulose) E-5, poliëtileenglikol 600, kleurstof ` acryl EZE yellow (93A82339)'.
Suikervrye tablette.

FARMAKOLOGIESE KLASSIFIKASIE:
A 3.1 Rumatiekmiddels (antiïnflammatoriese middels)

FARMAKOLOGIESE WERKING:
Natriumdiklofenak is 'n nie-steroïedverbinding, 'n fenielasynsuurderivaat met pynstillende, koorswerende en antiïnflammatoriese werkings. Natriumdiklofenak onderdruk die biosintese en die prostaglandienvrystelling wat by die patogenese van inflammasie, pyn en koors betrokke is. **DICLOFENAC 50 mg CLICKS** tablette is enteriesbedek sodat die absorbering in die maagdermkanaal kan plaasvind en kruinplasmakonsentrasies ongeveer 2 uur na inname bereik kan word. Binding aan die plasmaproteïene is ten minste 99 % en die metaboliete word hoofsaaklik in die urien uitgeskei.

INDIKASIES:
Vir die behandeling van koors, dismenoree, ligte tot matige pyn, na-operatiewe en na-troumatiese inflammasie en swelling; asook vir die noodbehandeling van akute jigaanvalle.

KONTRA-INDIKASIES:
Natriumdiklofenak word teenaangedui in pasiënte met bekende hipersensitiwiteit teenoor diklofenak en in pasiënte wat op aspirien en aspirien-tipe geneesmiddels reageer het met oorgevoeligheidsreaksies soos asma, akute rinitis en urtikaria. Natriumdiklofenak is absoluut teenaangedui in pasiënte met peptiese ulkusse of 'n geskiedenis van sodanige ulserering, en moet met omsigtigheid gebruik word deur pasiënte met nier- of lewerontoereikendheid.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
Gastroïntestinale bloeding of ulserering/perforasie kan enige tyd voorkom met of sonder simptome. Dit het gewoonlik erger gevolge in bejaarde pasiënte. Streng akkuraatheid in diagnose en noukeurige mediese toesig is noodsaaklik in pasiënte met simptome wat dui op gastroïntestinale ulserering, ulseratiewe kolitis en Crohn's siekte, in pasiënte met belemmerde lewerfunksie, voorafbestaande dis-hematopoiëse of bloedstollingversteurings.

Bloedtellings en monitering van lewer -en nierfunksies word aangeraai in die geval van verlengde behandeling met **DICLOFENAC 50 mg CLICKS**, aangesien bloeddiskrasieë aangemeld is. **DICLOFENAC 50 mg CLICKS** moet met omsigtigheid gegee word aan pasiënte met bloedingsaandoenings, kardiovaskulêre siekte, en aan pasiënte wat kumarienteenstollingsmiddels ontvang. Pasiënte wat sensitief is teenoor aspirien moet oor die algemeen nie **DICLOFENAC 50 mg CLICKS** gebruik nie.

Ernstige interaksies is aangemeld na die meegaande gebruik van metotreksaat en diklofenak. Allergiese reaksies, insluitend anafilaktiese reaksies, insluitend hipotensie, vaskulitis en pneumonitis, kan voorkom sonder vorige blootstelling aan diklofenak.

INTERAKSIES:
Ernstige interaksies is aangemeld na die gebruik van hoë dosisse metotreksaat saam met diklofenak.
Bloedvlakke van litium sal styg as dit saam met **DICLOFENAC 50 mg CLICKS** gebruik word.

SWANGERSKAP EN LAKTASIE:
Die veilige gebruik van **DICLOFENAC 50 mg CLICKS** tydens swangerskap is nie gedemonstreer nie.
Gereelde gebruik van NSAIM's gedurende die derde trimester van swangerskap kan lei tot voortydige sluiting van die fetale ductus arteriosus (tussenslagaarbuis) *in utero*, en moontlik tot volgehoue pulmonale hipertensie van die pasgeborene. Die intrede van kraam mag vertraag word en die duur daarvan mag verleng word.

DOSIS EN GEBRUIKSAANWYSINGS:
Gewone dosis vir volwassenes:
Dosis vir ligte tot matige pyn en inflammasie is 'n maksimum daaglikse dosis van 75 mg vir 'n maksimum behandelingstydperk van 5 dae. Dit is, 25 mg tablette drie keer per dag na etes.
Dosis vir akute jigaanvalle is 'n maksimum daaglikse dosis van 150 mg vir 'n maksimum behandelingstydperk van 3 dae. Dit is, 50 mg tablette drie keer per dag na etes.
DICLOFENAC 50 mg CLICKS word nie aanbeveel vir gebruik by kinders nie, aangesien veiligheid en doeltreffendheid nie vasgestel is nie.

NEWE-EFFEKTE:
In die lig van die produk se inherente potensiaal om vloeistofretensie te veroorsaak, kan hartversaking ontketen word in sommige pasiënte wat geneig is tot hartprobleme.

Bloed en limfstelselaandoenings
Minder dikwels: Trombositopenie, leukopenie, hemolitiese anemie, aplastiese anemie, agranulositose.

Senuweestelselaandoenings
Dikwels: Hoofpyn, duiseligheid, draaiduiseling, senuweeagtigheid.
Minder dikwels: Slaperigheid.

Oogaandoenings:
Minder dikwels: Sigversteurings, dowwe sig, diplopie.

Oor en labirintaandoenings
Minder dikwels: Aangetaste gehoor, tinnitus, smaakveranderingaandoenings.

Kardiale aandoenings
Minder dikwels: Hartkloppings, borskaspyn, hipertensie, kongestiewe hartversaking.

Gastroïntestinale aandoenings
Dikwels: Epigastriese pyn en ander gastroïntestinale aandoenings soos naarheid, diaree, braking, buikkrampe, slegte spysvertering, winderigheid en anoreksie.
Minder dikwels: Gastriese of intestinale ulserering met meegaande bloeding.
Afteuse stomatitis, glossitis, esofageale letsels, diafragma-agtige intestinale strukture, laebuik aandoenings soos nie-spesifieke hemoragiese kolitis en verergering van ulseratiewe kolitis, of van Crohn-siekte, hardlywigheid, pankreatitis.

Hepato-bilière aandoenings
Dikwels: Verhoging van serumaminotransferase waardes (SGOT, SGPT)
Minder dikwels: Hepatitis met of sonder geelsug, fulminante hepatitis.

Vel- en subkutaneweefselaandoenings
Dikwels: Veluitslae en velerupsies.
Minder dikwels: Urtikaria, pruritus, bulleuse erupsies, ekseem, veelvuldige eriteem, Stevens-Johnson- sindroom, Lyell-sindroom (akute toksiese epidermolise), eritrodermie (eksfoliatiewe dermatitis), haarverlies, fotosensitiwiteitsreaksies, en purpura, insluitend allergiese purpura.

Renale en urinêre aandoenings
Minder dikwels: Edeem, akute nierversaking, urinêre abnormaliteite soos hematurie en proteïenurie, intestinale nefritis, nefrotiese sindroom, papillêre nekrose, nefropatie met langtermyn gebruik.

BEKENDE SIMPTOME VAN 'N OORDOSIS EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN:
Sien **"NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS"**.
Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:
Taankleurige, ronde, enteries-bedek.

AANBIEDING:
9 tablette in wit polipropileensecuritainers met LDPE (laedigtheidpoliëtileen) doppe en PVC film/ gedrukte aluminiumfoelie stulpverpakkings.

BERGINGSAANWYSINGS:
Bêre teen of benede 25 °C. Beskerm teen lig en vog.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
U/3.1/182

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:
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