PACKAGE INSERT

SCHEDULING STATUS: **S3**

PROPRIETARY NAME: (and dosage form):

TRIO-DICLOFENAC (Injection)

COMPOSITION:

Each ampule contain Diclofenac Sodium 75 mg/3 ml

Benzyl Alcohol 4 % m/v as preservative, and contains sodium metabisulphite

PHARMACOLOGICAL CLASSIFICATION:

A3.1 Anti-Rheumatics (anti-inflammatory agents)

PHARMACOLOGICAL ACTION:

Diclofenac sodium is a non-steroidal compound with analgesic, anti-inflammatory, anti-rheumatic and antipyretic properties. Diclofenac sodium is eliminated principally by metabolism and subsequent urinary and biliary excretion of glucuronide and sulphate conjugates of the metabolities. The principle metabolite in man is the 4-hydroxy derivative of diclofenac sodium. The amount excreted in urine accounts for 20 – 30 % of the dose and that in bile of 10 to 20 %. The mean terminal elimination half-life is 1,2 to 1,8 hours

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INDICATIONS:

For use as initial therapy for inflammatory and degenerative rheumatic disease, as well as for painful conditions due to inflammation of non-rheumatic origin and acute attacks of gout.

CONTRA-INDICATIONS:

Diclofenac sodium is contra-indicated in patients with a history of gastro-intestinal bleeding or peptic ulceration, or severe hepatic or renal impairment. It is further contra-indicated in aspirin-sensitive patients, and in patients sensitive to any of the ingredients. Safety in pregnancy has not been established.

WARNINGS:

Serious interactions have been reported after the use of high dose methotrexate with diclofenac.

DOSAGE AND DIRECTIONS FOR USE:

Not to be given by intravenous injection, 75 mg by deep intragluteal injection once daily, or twice a day in severe or hospitalised cases. Each injection must be given at a different site. Each injection should be separated by an interval of a few hours. Parenteral administration should not be given more than a few days; if necessary the treatment can be continued with oral therapy.

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SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Gastro-intestinal disorders, including epigastric pain, eructation, nausea and vomiting may occur. Peptic ulceration and gastro-intestinal bleeding have been reported.

Other side effects include vertigo, headache, skin rashes, pruritus, tinnitus, depression, drowsiness, nervousness, insomnia, irritability, agitation, minor hearing disorders, oedema, palpitations, blurred vision and other ocular reactions.

Hypersensitivity reactions, abnormalities of liver function tests, impairment of renal function, agranulocytosis and thrombocytopenia have been observed. It is advisable to perform blood counts in patients undergoing prolonged treatment.

Diclofenac should be given with care to patients with cardiovascular disease, bleeding disorders, in those who are receiving coumarin anti-coagulants and in patients with impaired hepatic or renal function. In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

Acute allergic reactions have been reported. Because of the possibility of cross-sensitivity due to structural relationships which exist among non-steroidal anti-inflammatory medicines, acute allergic reactions may be more likely to occur in patients who have exhibited allergic reactions to these compounds.

Plasma concentrations are significantly decreased by the concomitant administration of therapeutic doses of aspirin. When given together with preparations containing lithium or digoxin, diclofenac sodium may raise their plasma concentrations. Concomitant administration of glucocorticoids or other non-steroidal anti-inflammatory agents may aggravate gastro-intestinal side effects. Concurrent administration with two or more non-steroidal anti-inflammatory agents may promote the occurrence of side effects.

Should be used with caution in patients with asthma or bronchoconstriction. Use carefully in elderly patients. Decreased platelet aggregation with increased bleeding time may occur. The half-life of probenecid may be increased. Use with care together with other protein-bound medicines e.g. tolbutamide and coumarin.

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KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Refer to “Side Effects and Special Precautions”. Treatment is symptomatic and supportive.

IDENTIFICATION:

TRIO-DICLOFENAC Injection: 3 ml clear/amber glass ampoules.

PRESENTATION:

TRIO-DICLOFENAC Injection: 50 x 3 ml clear/amber glass ampoules in a polystyrene box.

STORAGE INSTRUCTIONS:

Protect ampoules from heat and light.

Store in a cool place below 25 °C. Do not refrigerate ampules.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

Y/3.1/122

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NAME AND BUSINESS ADDRESS OF THE APPLICANT:

Innovata Pharmaceuticals (Pty) LTD

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2091

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

19 August 1991

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VOUBILJET

SKEDULERINGSTATUS: **S3**

EIENDOMSNAAM (en doseervorm):

TRIO-DICLOFENAC (Inspuiting)

SAMESTELLING:

Elke ampule bevat Natriumdiklofenak 75 mg/3 ml

Bensielalkohol 4 % m/v as preserveermiddel en bevat natriummetabisulfiet

FARMAKOLOGIESE KLASSIFIKASIE:

A 3.1 Rumatiekmiddels (anti-inflammatoriese middels)

FARMAKOLOGIESE WERKING:

Natriumdiklofenak is Diclofenac sodium is ’n nie-steroïedal verbinding met pynstillende, anti-inflammatoriese, anti-rumatiese en koorswerende eienskappe. Natriumdiklofenak word hoofsaaklik deur metabolisering en daaropvolgende uriene – en galuitskeiding van glukuronied- en sulfaatkonjugate van die metaboliete geëlimineer. Die hoofmetaboliet by die mens is die 4-hidroksiderivaat van natriumdiklofenak. Die hoeveelheid uitgeskei in die urine is 20 tot 30 % van die dosis en dié in gal is 10 tot 20 %. Die gemiddelde terminale halfleeftyd is 1,2 to 1,8 uur.

INDIKASIES:

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Vir gebruik as aanvangsterapie vir inflammatoriese en degeneratiewe rumatiese siektes, sowel as vir pynlike toestande veroorsaak deur inflammasie van nie-rumatiese oorsprong, en akute jigaanvalle.

KONTRA-INDIKASIES:

Natriumdiklofenak word teenaangedui by pasiënte met 'n geskiedenis van aktiewe gastroïntestinale bloeding of peptiese verswering en ernstige lewer- of nierverswakkink. Dit word verder teenaangedui by pasiënte wat sensitief is vir aspirien en by pasiënte wat sensitief is vir enige van die bestanddele.

Veiligheid gedurende swangerskap is nog nie vasgestel nie.

WAARSKUWINGS:

Ernstige interaksie is al gerapporteer na die gebruik van 'n hoë dosis metotrekstaat met diklofenak.

DOSIS EN GEBRUIKSAANWYSINGS:

Dit moet nie binneaars toegedien word nie. 75 mg per dag intraglutetaal ingespuit of 2 keer per dag by ernstige of gehospitaliseerde gevalle. Elke inspuiting moet op 'n ander plek toegedien word. Elke inspuiting moet gevolg word deur 'n tussenpose van 'n paar uur. Parenterale toediening moet nie langer as 'n paar dae duur nie. Behandeling kan deur mondelikse toediening voortgesit word, as dit nodig is.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

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Gastroïntestinale versteurings wat epigastriese pyn, eruktasie, naarheid en vomering insluit, kan voorkom. Peptiese ulserering, en gastroïntestinale bloeding is all aangemeld.

Ander newe-effekte sluit duiseligheid, hoofpyn, veluitslae, pruritus, tinnitus, depressie, slaperigheid, senuweeagtigheid, slaaploosheid, prikkelbaarheid, opgewondenheid, geringe gehoorversteurings, edeem, palpitasies, belemmerde sig en ander okulêre reaksies in.

Hipersensitiwiteitsreaksies, abnormaliteite van lewerfunksietoetse, nierontoereikendheid, agranulositose, en trombositopenie is al opgemerk. Dit is raadsaam om bloedtellings uit te voer by pasiënte wat langdurige behandeling ontvang.

Natriumdiklofenak moet sorgvuldig gebruik word by pasiënte met kardiovaskulêre siekte, bloedingsversteurings, by pasiënte wat kumarienteenstolmiddels ontvang, asook pasiënte met belemmerde lewer- of nierfunksie. Weens die produk se inherente potensiaal om vloeistofretensie te veroorsaak, kan hartversaking voorkom by sommige pasiënte.

Akute allergiese reaksies is al aangemeld. Omdat die moontlikheid van kruissensitiwiteit te wyte aan strukturele verwantskappe by nie-steroïedale anti-inflammatoriese middels bestaan, kom akute allergiese reaksies meer dikwels voor by pasiënte wat reeds allergiese reaksies op die middels getoon het. Plasmakonsentrasies word merkbaar verminder deur die gelyktydige toediening van terapeutiese dosisse van aspirien. Wanneer litium- of digoksienbevattende middels saam met natriumdiklofenak toegedien word, kan dit die plasmakonsentrasies van eersgenoemde middels verhoog. Gelyktydige toediening van glukokortikoïede of ander nie-steroïedale anti-inflammatoriese middels, kan gastroïntestinale newe-effekte vererger.

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Gelyktydige toediening van twee of meer nie-steroïedale anti-inflammatoriese middels kan die voorkoms van newe-effekte bevorder.

Dit moet versigtig gebruik word by pasiënte met asma of brongokonstriksie. Gebruik versigtig by bejaarde pasiënte. Verminderde plaatjieklomping met verlengde bloeityd kan voorkom.

Die halfleeftyd van probenesied kan verhoog word. Gebruik versigtig met ander proteienegebonde medisyne, b.v. tolbutamied en kumarien.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN BEHANDELING DAARVAN:

Sien newe-effekte en spesiale voorsorgmaatreël. Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

TRIO-DICLOFENAC Injection: 3 ml bruin/helder glas ampoule.

AANBIEDING:

TRIO-DICLOFENAC Injection: 50 x 3 ml bruin/helder glas ampoules verpak in ’n houer.

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BERGINGSAANWYSINGS:

Beskerm ampulle teen hitte en lig.

Bewaar op ’n koel plek op of benede 25 °C.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

Y/3.1/122

NAAM EN BESIGHEIDSADRES VAN DIE APPLIKANT:

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