SmPC (Summary of Product Characteristics)

1. NAME OF THE MEDICINAL PRODUCT

Product Name: **INDOKRIS CAPSULES**

Generic Name: **Indomethacin Capsules BP 25mg**

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Indomethacin BP----------25mg.

Excipients----------q.s.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Creamish -Yellow hard gelatin capsules Size "2" with 'INDOKRIS' printed on Cap and '25mg' printed on the body

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Indomethacin is indicated in treatment of pain & moderate to severe inflammation in rheumatic disease and other acute musculoskeletal disorders; acute gout; dysmenorrhoea; premature labour. In children it is used in relief of pain & inflammation in rheumatic diseases including juvenile idiopathic arthritis & is also useful in neonatal complication such as transient impairment of renal function & premature closure of ductus arteriosus.

4.2 Posology and method of administration

Adult: Rheumatic disease 50-200mg daily in divided dose. Acute gout 150-200mg daily in divided doses, Dysmenorrhoea up to 75mg daily. The capsule must be taken with food to minimize gastric distress. The total daily dose should not exceed 200mg per day.

Child: 1 month-18 years: 0.5-1 mg/kg twice daily: Higher doses may be used under specialist supervision.

Method of administration: Oral

4.3 Contraindications

Indomethacin is contra-indicated in allergic disorder in patients with a history of hypersensitivity to aspirin or any other NSAID—which includes those in whom attacks of asthma, angioedema, urticaria or rhinitis have been precipitated by aspirin or any other (NSAID), during pregnancy and breast-feeding, and in coagulation defects.

4.4 Special warnings and precautions for use

It should be used with caution in the elderly (risk of serious side effects and fatalities. Cautions are also required in patients with connective tissue disorders, Crohn's disease or ulcerative colitis. Cautions should be taken in epilepsy, parkinsonism, psychiatric disturbances; during prolonged therapy ophthalmic and blood examinations particularly advisable. Dizziness produced by Indomethacin may affect performance of skilled (e.g. Driving). Indomethacin should be cautiously used in infants with PDA and oliguria. Hepatic impairment: It should be used with caution in patients with hepatic impairment; there is an increased risk of gastro-intestinal bleeding and fluid retention. It should be avoided in severe liver disease.

Renal impairment: It should be avoided in if possible or use with caution in patients with renal impairment; the lowest effective dose should be used for the shortest possible duration, and renal function should be monitored. Sodium and water retention may be occur and renal function may deteriorate, possibly leading to renal failure; deterioration in renal function has also been reported after topical use.

CSM Advice (gastro-intestinal side-effects): All NSAIDs are associated with serious gastro-intestinal toxicity; the risk is higher in the elderly. Evidence on the relative safety of 7 non-selective NSAIDs indicates differences in the risks of serious upper gastrointestinal side-effects. Indomethacin is associated with intermediate risk of gastrointestinal toxicity. The CSM also contra-indicates non-selective NSAIDs in patients with a history of peptic ulceration.

4.5 Interaction with other medicinal products and other forms of interaction

It increases the risk of renal impairment when given with ACE Inhibitors, angiotensin-II receptor antagonist. NSAIDS antagonise hypotensive effect of ACE Inhibitors, angiotensin-II receptor antagonist, adrenergic neurone blockers, alpha-blockers, betablocker, Ca channel blocker, clonidine, diazoxide, methyldopa, moxonidine, nitrates, hydralazine, monoxidil & sodium nitroprusside. Avoid concomitant use of NSAIDS with NSAIDS as it increase the side effect, & also with anticoagulants & diuretics. Possible severe drowsiness when Indomethacin given with Haloperidol; effects of Desmopressin enhanced by Indomethacin. It reduces excretion

of Methotrexate. It possibly increases the plasma concentration of cardiac glycosides and amikacin & gentamicin in neonates, Increased risk of nephrotoxicity & bleeding when given with anticoagulants, clopidogrel, iloprost & penicillamine.

4.6 Fertility Pregnancy and lactation

Avoid use of Indomethacin during pregnancy or avoiding them unless the potential benefits outweigh the risk. Indomethacin should be avoided during the third trimester because is associated with a risk of closure of fetal ductus arteriosus in utero and possibly persistent pulmonary hypertension of the newborn. In addition, the onset of labour may be delayed and its duration may be increased. Indomethacin can appear in breast milk in very low concentrations. It should be used with caution during breast-feeding.

4.7 Effects on ability to drive and use machines

Not Known

4.8 Undesirable effects

Gastro-intestinal discomfort, nausea, diarrhoea, and occasionally bleeding and ulceration occur. Blood disorders have also occurred. Fluid retention may occur; blood pressure may be raised. Renal failure may be provoked by Indomethacin, especially in patients with renal impairment.

4.9 Overdose

Overdose symptoms of Indomethacin includes headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding, rarely diarrhoea. In cases of significant poisoning acute renal failure and liver damage are possible. Patients should be treated symptomatically as required. Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially life-threatening overdose.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Non-steroidal Anti-Inflammatory Drug ATC Code: M01AB01 Mechanism of action: Indomethacin, shows analgesic and antipyretic activity, exerts its pharmacological effects by inhibiting the synthesis of prostaglandins involved in pain, fever, and inflammation. Indomethacin inhibits the catalytic activity of the COX enzymes, the enzymes responsible for catalyzing the rate-limiting step in prostaglandin

synthesis via the arachidonic acid pathway. Indomethacin is known to inhibit two well-characterized isoforms of COX, COX-1 and COX-2, with greater selectivity for COX-1.

5.2 Pharmacokinetic properties

Indomethacin is readily absorbed from the gastrointestinal tract; peak plasma concentrations are reached in about 0.5-2 hours after a dose. It is distributed into synovial fluid, CNS and placenta. It is metabolised in the liver primarily by demethylation and deacetylation, it also undergoes glucuronidation and enterohepatic circulation. Mainly excreted in the urine, approximately 60%, the pH of the urine can affect this amount. Lesser amounts in the faeces.

5.3 Preclinical safety data

Not Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch BP, Dicalcium Phosphate BP, Microcrystalline Cellulose Powder, Purified Talc BP, Purified Water BP, Magnesium Stearate BP & Colloidal Silicon Dioxide.

6.2 Incompatibilities

NA

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30 °C, protect from light and moisture.

KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container

10 Capsules PVC/ALU blister Pack & 10 Blister pack in a monocarton (10x10 Capsules)

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

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