

OLFEN™-50/100 RECTOCAPS™ ACINO SWITZERLAND

Composition:

Olfen™-50/100 Rectocaps™ active ingredient is diclofenac.

Each Olfen™-50 Rectocap™ rectal capsule contains 50 mg diclofenac sodium & Olfen™-100 Rectocap™ rectal capsule contains 100 mg diclofenac sodium.

Indications and dosage:

Olfen™-50/100 Rectocaps™ is a non-steroidal anti-inflammatory drug (NSAID), it inhibits prostaglandin biosynthesis. Olfen™-50/100 Rectocaps™ is indicated for

- (1) inflammatory & degenerative rheumatism
- (2) chronic polyarthritis
- (3) juvenile chronic polyarthritis
- (4) ankylosing spondylitis
- (5) osteoarthritis, including spondylarthrosis, painful cervical syndrome
- (6) extra-articular rheumatic disorders
- (7) painful inflammation & swelling after trauma and surgery
- (8) gynaecological pain and/or inflammation
- (9) migraine attacks
- (10) acute gout
- (11) adjuvant in acute, painful inflammatory throat, nose or ear infections.

Olfen™-50/100 Rectocaps™ is given, 2 - 3 individual doses/day before meals, to:

Adults at

- (i) 100 - 150 mg/day as initial dose in most cases,
- (ii) 75 - 100 mg/day for less severe cases & long-term treatment,
- (iii) 50 - 100 mg initially in primary dysmenorrhoea &, if required, increased over several menstrual cycles to maximally 200 mg/day;
- (iii) if symptoms most severe during night or in the morning, dose should be taken in the evening.

Olfen™-50/100 Rectocaps™ are not suitable for children aged under 14 years & Olfen™-100 Rectocaps™ are not suitable for adolescents.

Contraindications:

Hypersensitivity to diclofenac or to any of the excipi-

ents of Olfen™-50/100 Rectocaps™; history of allergic diseases (bronchospasm, acute rhinitis, nasal polyps, urticaria) after acetylsalicylic acid or other NSAID; active gastric &/or duodenal ulcer; gastrointestinal (GI) haemorrhage or perforation; bowel inflammation; severe liver insufficiency; severe renal insufficiency (creatinine clearance <30 ml/min); severe cardiac insufficiency (NYHA III-IV); postoperative pain treatment after coronary by-pass surgery or heart-lung machine use, proctitis, during 3rd trimester of pregnancy.

Precautions:

Use lowest effective dose for shortest possible duration; avoid concomitant use with systemic NSAIDs; risk of GI ulceration/bleeding/perforation, thrombotic cardiovascular/cerebrovascular complications, oedema, hypertension, serious skin/allergic reactions, liver enzymes increase, severe hepatic reactions, hepatitis, masking infection symptoms; at high doses (150 mg/day) & long-term treatment: increased risk of arterial thromboembolic events; caution with:

- (i) elderly
- (ii) clinically confirmed cases of coronary heart disease/cerebrovascular disease/peripheral arterial occlusive disease/hypertension/extracellular fluid deficit
- (iii) patients with major risk factors
- (iv) cases of impaired cardiac/renal/hepatic function
- (v) hepatic porphyria
- (vi) conditions predisposing to fluid retention
- (vii) cases at risk of hypovolaemia
- (viii) allergies/asthma/seasonal allergic rhinitis/chronic obstructive pulmonary disease/respiratory tract infections
- (ix) concomitant intake of diuretics/medications affecting renal function/ACE inhibitors/medications increasing ulceration/bleeding risk; discontinue use in cases of GI ulceration/bleeding, skin rash, mucosal lesions, other signs of hypersensitivity, abnormal/deteriorating liver function, signs/symptoms of liver disease;

Olfen™-50/100 Rectocaps™ contain lactose monohydrate & should not be taken by patients with galactose intolerance/severe lactase deficiency/glucose-galactose malabsorption.

Pregnancy / lactation:

Only use Olfen™-50/100 Rectocaps™ if absolutely necessary during 1st/2nd trimester; contraindicated in 3rd trimester; not recommended during breastfeeding or when attempting to conceive.

Undesirable effects:

Headache, dizziness, vertigo, nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence, anorexia, transaminases increased, rash, fluid retention, oedema, hypertension, gastritis, GI bleeding, haematemesis, bloody diarrhoea, melaena, GI ulcer, hypersensitivity reactions, local irritation.

Interactions:

Caution in patients receiving concomitant treatment of Olfen™-50/100 Rectocaps™ with the following medicines:

- (i) lithium,
- (ii) digoxin,
- (iii) diuretics,
- (iv) antihypertensives,
- (v) other NSAIDs/corticosteroids,
- (vi) anticoagulants/anti-platelet agents,
- (vii) selective serotonin reuptake inhibitors,
- (viii) antidiabetics,
- (ix) methotrexate,
- (x) ciclosporin,
- (xi) quinolone antibiotics.

Presentation:

Olfen™-50 Rectocaps™: packs of 10 rectal capsules;

Olfen™-100 Rectocaps™: packs of 5 rectal capsules; hospital packs.

Since indications, dosage forms and strengths may vary from country to country, please consult your local prescribing information. Full prescribing information, details and literature references are available on request.

Latest update of information: January 2010.