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CIN NO: U24231GJ1992PLC018237

CLOTAFEN - SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

CLOTAFEN

Diclofenac Potassium Tablets USP

2. Qualitative and quantitative composition

Each film coated tablet contains: 50 mg of diclofenac potassium

Sr. No.	Ingredients	Spec.	Label Claim	Qty./Tablet (mg)	%w/w	Function
Mixing						
1.	Diclofenac Potassium	USP	50.00	50.00	25.61	Active
2.	Microcrystalline Cellulose Grade 102	BP	---	112.000	57.04	Diluent
3.	Sodium Starch Glycollate	BP	---	6.000	3.06	Super Disintegrant
4.	Cros Povidone	BP	---	10.000	5.1	Disintegrant
5.	Colloidal Silicon Dioxide	BP	---	3.500	1.79	Disintegrant
6.	Purified Talc	BP	---	5.000	2.55	Lubricant
7	Magnesium Stearate	BP		3.500	1.79	Lubricant
Total weight of uncoated tablet				**190.00**		
Film Coating						
9.	Isopropyl Alcohol***	BP	---	40.000	---	Coating Solvent
10.	Dichloromethane***	BP	---	74.000	---	Coating Solvent
11.	Col. Instacoat Universal (Brown) – A05D00722	IH	---	6.000	3.06	Coating Agent
Total weight of coated tablet				**196.00**	**100.00**	

3. Pharmaceutical form

Film coated tablet

4. Clinical particulars

4.1 Therapeutic indications

Rheumatoid arthritis

Osteoarthrosis

Low back pain

Migraine attacks

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Acute musculo-skeletal disorders and trauma such as periarthritis (especially frozen shoulder), tendinitis, tenosynovitis, bursitis, sprains, strains and dislocations; relief of pain in fractures

Ankylosing spondylitis

Acute gout

Control of pain and inflammation in orthopaedic, dental and other minor surgery

Pyrophosphate arthropathy and associated disorders

4.2 Posology and method of administration

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

For oral administration

The tablets should be swallowed whole with liquid, preferably before meals, and must not be chewed or divided.

Adults

The recommended daily dose is 100-150mg in two or three divided doses. For milder cases, 75-100 mg daily in two or three divided doses is usually sufficient.

In migraine an initial dose of 50 mg should be taken at the first signs of an impending attack. In cases where relief 2 hours after the first dose is not sufficient, a further dose of 50 mg may be taken. If needed, further doses of 50 mg may be taken at intervals of 4-6 hours, not exceeding a total dose of 200 mg per day.

Special populations

Paediatrics

For children over 14 years of age, the recommended daily dose is 75-100 mg in two or three divided doses. CLOTAFEN tablets are not recommended for children under 14 years of age.

The use of Diclofenac Potassium 50 mg tablets in migraine attacks has not been established in children.

Elderly

Although the pharmacokinetics of CLOTAFEN tablets are not impaired to any clinically relevant extent in elderly patients, nonsteroidal anti-inflammatory drugs should be used with particular caution in such patients who generally are more prone to adverse reactions. In particular it is recommended that the lowest effective dosage be used in frail elderly patients or those with a low body weight (see also precautions) and the patient should be monitored for GI bleeding during NSAID therapy.

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Cardiovascular and significant cardiovascular risk factors

CLOTAFEN is contraindicated in patients with established congestive heart failure (NYHA II-IV), ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease (see section 4.3 Contraindications).

Patients with congestive heart failure (NYHA-I) or significant risk factors for cardiovascular disease should be treated with diclofenac only after careful consideration. Since cardiovascular risks with diclofenac may increase with dose and duration of exposure, the lowest effective daily dose should be used and for the shortest duration possible.

Renal impairment

CLOTAFEN Tablets are contraindicated in patients with renal failure.

No specific studies have been carried out in patients with renal impairment, therefore, no specific dose adjustment recommendations can be made. Caution is advised when administering CLOTAFEN Tablets to patients with mild to moderate renal impairment.

4.3 Contraindications

Hypersensitivity to the active substance or any of the excipients.

Active, gastric or intestinal ulcer, bleeding or perforation.

History of gastrointestinal bleeding or perforation, relating to previous NSAID therapy

Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding)

Last trimester of pregnancy

Hepatic failure

Renal failure

Established congestive heart failure (NYHA II-IV), ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease.

Like other non-steroidal anti-inflammatory drugs (NSAIDs), diclofenac is also contraindicated in patients in whom attacks of asthma, angioedema, urticaria or acute rhinitis are precipitated by ibuprofen, acetylsalicylic acid or other non-steroidal anti-inflammatory drugs.

4.4 Special warnings and precautions for use

General

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

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The concomitant use of CLOTAFEN with systemic NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided due to the absence of any evidence demonstrating synergistic benefits and the potential for additive undesirable effects.

Caution is indicated in the elderly on basic medical grounds. In particular, it is recommended that the lowest effective dose be used in frail elderly patients or those with a low body weight.

As with other non-steroidal anti-inflammatory drugs including diclofenac, allergic reactions, including anaphylactic/anaphylactoid reactions, can also occur without earlier exposure to the drug. Hypersensitivity reactions can also progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction. Presenting symptoms of such reactions can include chest pain occurring in association with an allergic reaction to diclofenac.

Like other NSAIDs, diclofenac may mask the signs and symptoms of the infection due to its pharmacodynamic properties.

Gastrointestinal effects:

Gastrointestinal bleeding (haematemesis, melaena) ulceration or perforation which can be fatal has been reported with all NSAIDs including diclofenac and may occur at any time during treatment, with or without warning symptoms or a previous history of serious GI events. They generally have more serious consequences in the elderly. If gastrointestinal bleeding or ulceration occurs in patients receiving diclofenac, the drug should be withdrawn.

As with all NSAIDs, including diclofenac, close medical surveillance is imperative and particular caution should be excised when prescribing diclofenac in patients with symptoms indicative of gastrointestinal disorders, or with a history suggestive of gastric or intestinal ulceration, bleeding or perforation. The risk of GI bleeding, ulceration or perforation is higher with increasing NSAIDs doses including diclofenac, and in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation.

The elderly have increased frequency of adverse reactions to NSAIDs especially gastro intestinal bleeding and perforation which may be fatal.

To reduce the risk of GI toxicity in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation, and in the elderly, the treatment should be initiated and maintained at the lowest effective dose.

Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant use of medicinal products containing low dose acetylsalicylic acid (ASA/aspirin or medicinal products likely to increase

gastrointestinal risk. Patients with a history of GI toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially GI bleeding).

Caution is recommended in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as systemic corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors (SSRIs) or anti-platelet agents such as acetylsalicylic acid.

Close medical surveillance and caution should be exercised in patients with ulcerative colitis, or with Crohn's disease as these conditions may be exacerbated.

NSAIDs, including diclofenac, may be associated with increased risk of gastro-intestinal anastomotic leak. Close medical surveillance and caution are recommended when using diclofenac after gastro-intestinal surgery.

Hepatic effects:

Close medical surveillance is required when prescribing CLOTAFEN to patients with impairment of hepatic function as their condition may be exacerbated.

As with other NSAIDs, including diclofenac, values of one or more liver enzymes may increase. During prolonged treatment with Diclofenac, regular monitoring of hepatic function is indicated as a precautionary measure.

If abnormal liver function tests persist or worsen, clinical signs or symptoms consistent with liver disease develop or if other manifestations occur (eosinophilia, rash), CLOTAFEN should be discontinued.

Hepatitis may occur with diclofenac without prodromal symptoms.

Caution is called for when using diclofenac in patients with hepatic porphyria, since it may trigger an attack.

Renal effects:

As fluid retention and oedema have been reported in association with NSAIDs therapy, including diclofenac, particular caution is called for in patients with impaired cardiac or renal function, history of hypertension, the elderly, patients receiving concomitant treatment with diuretics or medicinal products that can significantly impact renal function, and those patients with substantial extracellular volume depletion from any cause, e.g. before or after major surgery. Monitoring of renal function is recommended as a precautionary measure when using diclofenac in such cases. Discontinuation therapy is usually followed by recovery to the pre-treatment state.

Skin effects: