



T2005-31

**Cataflam<sup>®</sup>**  
***diclofenac potassium immediate-release tablets***

***Tablets of 50 mg      Rx only***

***Prescribing Information***

**Cardiovascular Risk**

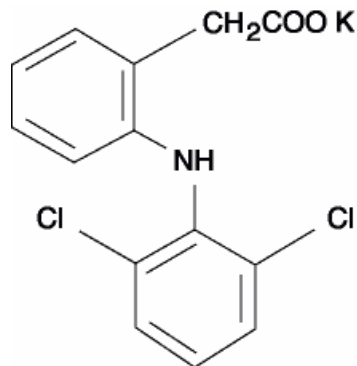
- NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk (See **WARNINGS**).
- Cataflam<sup>®</sup> is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery (see **WARNINGS**).

**Gastrointestinal Risk**

- NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events (See **WARNINGS**).

**DESCRIPTION**

Cataflam<sup>®</sup> (diclofenac potassium immediate-release tablets), is a benzeneacetic acid derivative. Cataflam is available as immediate-release Tablets of 50 mg (light brown) for oral administration. The chemical name is 2-[(2,6-dichlorophenyl)amino] benzeneacetic acid, monopotassium salt. The molecular weight is 334.25. Its molecular formula is C<sub>14</sub>H<sub>10</sub>Cl<sub>2</sub>NKO<sub>2</sub>, and it has the following structural formula



The inactive ingredients in Cataflam include: calcium phosphate, colloidal silicon dioxide, iron oxides, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, maize starch, sucrose, talc, titanium dioxide.

## CLINICAL PHARMACOLOGY

### *Pharmacodynamics*

Cataflam<sup>®</sup> (diclofenac potassium immediate-release tablets) is a nonsteroidal anti-inflammatory drug (NSAID) that exhibits anti-inflammatory, analgesic, and antipyretic activities in animal models. The mechanism of action of Cataflam, like that of other NSAIDs, is not completely understood but may be related to prostaglandin synthetase inhibition.

### *Pharmacokinetics*

#### *Absorption*

Diclofenac is 100% absorbed after oral administration compared to IV administration as measured by urine recovery. However, due to first-pass metabolism, only about 50% of the absorbed dose is systemically available (see Table 1). In some fasting volunteers, measurable plasma levels are observed within 10 minutes of dosing with Cataflam. Peak plasma levels are achieved approximately 1 hour in fasting normal volunteers, with a range of .33 to 2 hours. Food has no significant effect on the extent of diclofenac absorption. However, there is usually a delay in the onset of absorption and a reduction in peak plasma levels of approximately 30%.

**Table 1. Pharmacokinetic Parameters for Diclofenac**

PK Parameter	Normal Healthy Adults (20-52 yrs.)	
	Mean	Coefficient of Variation (%)
Absolute Bioavailability (%) [N = 7]	55	40
T <sub>max</sub> (hr) [N = 65]	1.0	76
Oral Clearance (CL/F; mL/min) [N = 61]	622	21
Renal Clearance (% unchanged drug in urine) [N = 7]	<1	—

Apparent Volume of Distribution (V/F; L/kg) [N = 61]	1.3	33
Terminal Half-life (hr) [N = 48]	1.9	29

## ***Distribution***

The apparent volume of distribution (V/F) of diclofenac potassium is 1.3 L/kg.

Diclofenac is more than 99% bound to human serum proteins, primarily to albumin. Serum protein binding is constant over the concentration range (0.15-105 µg/mL) achieved with recommended doses.

Diclofenac diffuses into and out of the synovial fluid. Diffusion into the joint occurs when plasma levels are higher than those in the synovial fluid, after which the process reverses and synovial fluid levels are higher than plasma levels. It is not known whether diffusion into the joint plays a role in the effectiveness of diclofenac.

## ***Metabolism***

Five diclofenac metabolites have been identified in human plasma and urine. The metabolites include 4'-hydroxy-, 5-hydroxy-, 3'-hydroxy-, 4',5-dihydroxy- and 3'-hydroxy-4'-methoxy diclofenac. In patients with renal dysfunction, peak concentrations of metabolites 4'-hydroxy- and 5-hydroxy-diclofenac were approximately 50% and 4% of the parent compound after single oral dosing compared to 27% and 1% in normal healthy subjects. However, diclofenac metabolites undergo further glucuronidation and sulfation followed by biliary excretion.

One diclofenac metabolite 4'-hydroxy-diclofenac has very weak pharmacologic activity.

## ***Excretion***

Diclofenac is eliminated through metabolism and subsequent urinary and biliary excretion of the glucuronide and the sulfate conjugates of the metabolites. Little or no free unchanged diclofenac is excreted in the urine. Approximately 65% of the dose is excreted in the urine and approximately 35% in the bile as conjugates of unchanged diclofenac plus metabolites. Because renal elimination is not a significant pathway of elimination for unchanged diclofenac, dosing adjustment in patients with mild to moderate renal dysfunction is not necessary. The terminal half-life of unchanged diclofenac is approximately 2 hours.

## ***Special Populations***

***Pediatric:*** The pharmacokinetics of Cataflam has not been investigated in pediatric patients.

***Race:*** Pharmacokinetics differences due to race have not been identified.

***Hepatic Insufficiency:*** Hepatic metabolism accounts for almost 100% of Cataflam elimination, so patients with hepatic disease may require reduced doses of Cataflam compared to patients with normal hepatic function.

***Renal Insufficiency:*** Diclofenac pharmacokinetics has been investigated in subjects with renal insufficiency. No differences in the pharmacokinetics of diclofenac have been detected in studies of patients with renal impairment. In patients with renal impairment (inulin clearance 60-90, 30-60, and

<30 mL/min; N=6 in each group), AUC values and elimination rate were comparable to those in healthy subjects.

## INDICATIONS AND USAGE

Carefully consider the potential benefits and risks of Cataflam<sup>®</sup> and other treatment options before deciding to use Cataflam<sup>®</sup>. Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals (see **WARNINGS**).

Cataflam<sup>®</sup> (diclofenac potassium immediate-release tablets) is indicated:

- For treatment of primary dysmenorrhea
- For relief of mild to moderate pain
- For relief of the signs and symptoms of osteoarthritis
- For relief of the signs and symptoms of rheumatoid arthritis

## CONTRAINDICATIONS

Cataflam<sup>®</sup> (diclofenac potassium immediate-release tablets) is contraindicated in patients with known hypersensitivity to diclofenac. Cataflam should not be given to patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients (see **WARNINGS, Anaphylactoid Reactions, and PRECAUTIONS, Preexisting Asthma**).

Cataflam<sup>®</sup> is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery (see **WARNINGS**).

## WARNINGS

### CARDIOVASCULAR EFFECTS

#### Cardiovascular Thrombotic Events

Clinical trials of several COX-2 selective and nonselective NSAIDs of up to three years duration have shown an increased risk of serious cardiovascular (CV) thrombotic events, myocardial infarction, and stroke, which can be fatal. All NSAIDs, both COX-2 selective and nonselective, may have a similar risk. Patients with known CV disease or risk factors for CV disease may be at greater risk. To minimize the potential risk for an adverse CV event in patients treated with an NSAID, the lowest effective dose should be used for the shortest duration possible. Physicians and patients should remain alert for the development of such events, even in the absence of previous CV symptoms. Patients should be informed about the signs and/or symptoms of serious CV events and the steps to take if they occur.

There is no consistent evidence that concurrent use of aspirin mitigates the increased risk of serious CV thrombotic events associated with NSAID use. The concurrent use of aspirin and an NSAID does increase the risk of serious GI events (see **GI WARNINGS**).

Two large, controlled, clinical trials of a COX-2 selective NSAID for the treatment of pain in the first 10-14 days following CABG surgery found an increased incidence of myocardial infarction and stroke (see **CONTRAINDICATIONS**).

#### Hypertension

NSAIDs, including Cataflam, ~~including TRADENAME~~ can lead to onset of new hypertension or worsening of pre-existing hypertension, either of which may contribute to the increased incidence of CV events. Patients taking thiazides or loop diuretics may have impaired response to these therapies when taking NSAIDs. NSAIDs, including Cataflam<sup>®</sup>, should be used with caution in patients with hypertension. Blood pressure (BP) should be monitored closely during the initiation of NSAID treatment and throughout the course of therapy

### **Congestive Heart Failure and Edema**

Fluid retention and edema have been observed in some patients taking NSAIDs. Cataflam<sup>®</sup> should be used with caution in patients with fluid retention or heart failure.

### ***Gastrointestinal Effects - Risk of Ulceration, Bleeding, and Perforation:***

NSAIDs, including Cataflam, can cause serious gastrointestinal (GI) adverse events including inflammation, bleeding, ulceration, and perforation of the stomach, small intestine, or large intestine, which can be fatal. These serious adverse events can occur at any time, with or without warning symptoms, in patients treated with NSAIDs. Only one in five patients, who develop a serious upper GI adverse event on NSAID therapy, is symptomatic. Upper GI ulcers, gross bleeding, or perforation caused by NSAIDs occur in approximately 1% of patients treated for 3-6 months, and in about 2-4% of patients treated for one year. These trends continue with longer duration of use, increasing the likelihood of developing a serious GI event at some time during the course of therapy. However, even short-term therapy is not without risk.

NSAIDs should be prescribed with extreme caution in those with a prior history of ulcer disease or gastrointestinal bleeding. Patients with a *prior history of peptic ulcer disease and/or gastrointestinal bleeding* who use NSAIDs have a greater than 10-fold increased risk for developing a GI bleed compared to patients with neither of these risk factors. Other factors that increase the risk for GI bleeding in patients treated with NSAIDs include concomitant use of oral corticosteroids or anticoagulants, longer duration of NSAID therapy, smoking, use of alcohol, older age, and poor general health status. Most spontaneous reports of fatal GI events are in elderly or debilitated patients and therefore special care should be taken in treating this population.

**To minimize the potential risk for an adverse GI event in patients treated with an NSAID, the lowest effective dose should be used for the shortest possible duration.** Patients and physicians should remain alert for signs and symptoms of GI ulceration and bleeding during NSAID therapy and promptly initiate additional evaluation and treatment if a serious GI adverse event is suspected. This should include discontinuation of the NSAID until a serious GI adverse event is ruled out. For high risk patients, alternate therapies that do not involve NSAIDs should be considered.

### ***Renal Effects***

Caution should be used when initiating treatment with Cataflam in patients with considerable dehydration.

Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. Renal toxicity has also been seen in patients in whom renal prostaglandins have a compensatory role in the maintenance of renal perfusion. In these patients, administration of a nonsteroidal anti-inflammatory drug may cause a dose-dependent reduction in prostaglandin formation and, secondarily, in renal blood flow, which may precipitate overt renal decompensation. Patients at greatest risk of this reaction are those with impaired renal function, heart failure, liver dysfunction,

those taking diuretics and ACE inhibitors, and the elderly. Discontinuation of nonsteroidal anti-inflammatory drug therapy is usually followed by recovery to the pretreatment state.

### ***Advanced Renal Disease***

No information is available from controlled clinical studies regarding the use of Cataflam<sup>®</sup> in patients with advanced renal disease. Therefore, treatment with Cataflam<sup>®</sup> is not recommended in these patients with advanced renal disease. If Cataflam<sup>®</sup> therapy must be initiated, close monitoring of the patient's renal function is advisable.

### ***Anaphylactoid Reactions***

As with other NSAIDs, anaphylactoid reactions may occur in patients without known prior exposure to Cataflam<sup>®</sup> (diclofenac potassium immediate-release tablets). Cataflam should not be given to patients with the aspirin triad. This symptom complex typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal bronchospasm after taking aspirin or other NSAIDs. (See **CONTRAINDICATIONS and PRECAUTIONS, *Preexisting Asthma.***) Emergency help should be sought in cases where an anaphylactoid reaction occurs.

### ***Skin Reactions***

NSAIDs, including Cataflam<sup>®</sup>, can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. These serious events may occur without warning. Patients should be informed about the signs and symptoms of serious skin manifestations and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

### ***Pregnancy***

In late pregnancy, as with other NSAIDs, Cataflam should be avoided because it may cause premature closure of the ductus arteriosus.

## **PRECAUTIONS**

### ***General***

Cataflam<sup>®</sup> (diclofenac potassium immediate-release tablets) cannot be expected to substitute for corticosteroids or to treat corticosteroid insufficiency. Abrupt discontinuation of corticosteroids may lead to disease exacerbation. Patients on prolonged corticosteroid therapy should have their therapy tapered slowly if a decision is made to discontinue corticosteroids.

The pharmacological activity of Cataflam in reducing fever and inflammation may diminish the utility of these diagnostic signs in detecting complications of presumed noninfectious, painful conditions.

### ***Hepatic Effects***

Borderline elevations of one or more liver tests may occur in up to 15% of patients taking NSAIDs including Cataflam. These laboratory abnormalities may progress, may remain unchanged, or may be transient with continued therapy. Based on this experience, in patients on chronic treatment with Cataflam, periodic monitoring of transaminases is recommended (see **PRECAUTIONS, *Laboratory***

**Tests**). Notable elevations of ALT or AST (three or more times the upper limit of normal) have been reported in approximately 2%-4% of patients, including marked elevations (eight or more times the upper limit of normal) in about 1% of patients in clinical trials with diclofenac. In addition, rare cases of severe hepatic reactions, including jaundice and fatal fulminant hepatitis, liver necrosis and hepatic failure, some of them with fatal outcomes have been reported.

A patient with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver test has occurred, should be evaluated for evidence of the development of a more severe hepatic reaction while on therapy with Cataflam. If clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur (e.g., eosinophilia, rash, etc.), Cataflam should be discontinued.

### ***Hematological Effects***

Anemia is sometimes seen in patients receiving NSAIDs, including Cataflam. This may be due to fluid retention, GI loss, or an incompletely described effect upon erythropoiesis. Patients on long-term treatment with NSAIDs, including Cataflam, should have their hemoglobin or hematocrit checked if they exhibit any signs or symptoms of anemia.

NSAIDs inhibit platelet aggregation and have been shown to prolong bleeding time in some patients. Unlike aspirin, their effect on platelet function is quantitatively less, of shorter duration, and reversible. Patients receiving Cataflam who may be adversely affected by alterations in platelet function, such as those with coagulation disorders or patients receiving anticoagulants, should be carefully monitored.

### ***Preexisting Asthma***

Patients with asthma may have aspirin-sensitive asthma. The use of aspirin in patients with aspirin-sensitive asthma has been associated with severe bronchospasm which can be fatal. Since cross-reactivity, including bronchospasm, between aspirin and other nonsteroidal anti-inflammatory drugs has been reported in such aspirin-sensitive patients, Cataflam should not be administered to patients with this form of aspirin sensitivity and should be used with caution in all patients with preexisting asthma.

### ***Information for Patients***

**Patients should be informed of the following information before initiating therapy with an NSAID and periodically during the course of ongoing therapy. Patients should also be encouraged to read the NSAID Medication Guide that accompanies each prescription dispensed.**

1. Cataflam<sup>®</sup>, like other NSAIDs, may cause serious CV side effects, such as MI or stroke, which may result in hospitalization and even death. Although serious CV events can occur without warning symptoms, patients should be alert for the signs and symptoms of chest pain, shortness of breath, weakness, slurring of speech, and should ask for medical advice when observing any indicative sign or symptoms. Patients should be apprised of the importance of this follow-up (see **WARNINGS, CARDIOVASCULAR EFFECTS**).
2. Cataflam, like other NSAIDs, can cause GI discomfort and, rarely, more serious GI side effects, such as ulcers and bleeding, which may result in hospitalization and even death. Although serious GI tract ulcerations and bleeding can occur without warning symptoms, patients should be alert for the signs and symptoms of ulcerations and bleeding, and should ask for medical advice when observing any indicative sign or symptoms including epigastric pain, dyspepsia, melena, and hematemesis. Patients should be apprised of the importance of this

follow-up (see **WARNINGS, Gastrointestinal Effects: Risk of Ulceration, Bleeding, and Perforation**).

3. Cataflam<sup>®</sup>, like other NSAIDs, can cause serious skin side effects such as exfoliative dermatitis, SJS, and TEN, which may result in hospitalizations and even death. Although serious skin reactions may occur without warning, patients should be alert for the signs and symptoms of skin rash and blisters, fever, or other signs of hypersensitivity such as itching, and should ask for medical advice when observing any indicative signs or symptoms. Patients should be advised to stop the drug immediately if they develop any type of rash and contact their physicians as soon as possible.
4. Patients should promptly report signs or symptoms of unexplained weight gain or edema to their physicians.
5. Patients should be informed of the warning signs and symptoms of hepatotoxicity (e.g., nausea, fatigue, lethargy, pruritus, jaundice, right upper quadrant tenderness, and “flu-like” symptoms). If these occur, patients should be instructed to stop therapy and seek immediate medical therapy.
6. Patients should be informed of the signs of an anaphylactoid reaction (e.g., difficulty breathing, swelling of the face or throat). If these occur, patients should be instructed to seek immediate emergency help (see **WARNINGS**).
7. In late pregnancy, as with other NSAIDs, Cataflam should be avoided because it may cause premature closure of the ductus arteriosus.

## **Laboratory Tests**

Because serious GI tract ulcerations and bleeding can occur without warning symptoms, physicians should monitor for signs or symptoms of GI bleeding. In patients on long-term treatment with NSAIDs, including Cataflam<sup>®</sup>, the CBC and a chemistry profile (including transaminase levels) should be checked periodically. If clinical signs and symptoms consistent with liver or renal disease develop, systemic manifestations occur (e.g., eosinophilia, rash, etc.) or if abnormal liver tests persist or worsen, Cataflam should be discontinued.

## **Drug Interactions**

**Aspirin:** When Cataflam is administered with aspirin, its protein binding is reduced. The clinical significance of this interaction is not known; however, as with other NSAIDs, concomitant administration of diclofenac and aspirin is not generally recommended because of the potential of increased adverse effects.

**Methotrexate:** NSAIDs have been reported to competitively inhibit methotrexate accumulation in rabbit kidney slices. This may indicate that they could enhance the toxicity of methotrexate. Caution should be used when NSAIDs are administered concomitantly with methotrexate.

**Cyclosporine:** Cataflam, like other NSAIDs, may affect renal prostaglandins and increase the toxicity of certain drugs. Therefore, concomitant therapy with Cataflam may increase cyclosporine's



nephrotoxicity. Caution should be used when Cataflam is administered concomitantly with cyclosporine.

**ACE-inhibitors:** Reports suggest that NSAIDs may diminish the antihypertensive effect of ACE-inhibitors. This interaction should be given consideration in patients taking NSAIDs concomitantly with ACE-inhibitors.

**FurosemideDiuretics:** Clinical studies, as well as post-marketing observations, have shown that Cataflam can reduce the natriuretic effect of furosemide and thiazides in some patients. This response has been attributed to inhibition of renal prostaglandin synthesis. During concomitant therapy with NSAIDs, the patient should be observed closely for signs of renal failure (see PRECAUTIONS - Renal Effects), as well as to assure diuretic efficacy.

**Lithium:** NSAIDs have produced an elevation of plasma lithium levels and a reduction in renal lithium clearance. The mean minimum lithium concentration increased 15% and the renal clearance was decreased by approximately 20%. These effects have been attributed to inhibition of renal prostaglandin synthesis by the NSAID. Thus, when NSAIDs and lithium are administered concurrently, subjects should be observed carefully for signs of lithium toxicity.

**Warfarin:** The effects of warfarin and NSAIDs on GI bleeding are synergistic, such that users of both drugs together have a risk of serious GI bleeding higher than users of either drug alone.

## **Pregnancy**

**Teratogenic Effects:** Pregnancy Category C

Reproductive studies conducted in rats and rabbits have not demonstrated evidence of developmental abnormalities. However, animal reproduction studies are not always predictive of human response. There are no adequate and well-controlled studies in pregnant women. Cataflam should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Nonteratogenic Effects:** Because of the known effects of nonsteroidal anti-inflammatory drugs on the fetal cardiovascular system (closure of ductus arteriosus), use during pregnancy (particularly late pregnancy) should be avoided.

## **Labor and Delivery**

In rat studies with NSAIDs, as with other drugs known to inhibit prostaglandin synthesis, an increased incidence of dystocia, delayed parturition, and decreased pup survival occurred. The effects of Cataflam on labor and delivery in pregnant women are unknown.

## **Nursing Mothers**

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Cataflam, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

## **Pediatric Use**

Safety and effectiveness in pediatric patients have not been established.

## **Geriatric Use**

As with any NSAIDs, caution should be exercised in treating the elderly (65 years and older).

## **ADVERSE REACTIONS**

In 718 patients treated for shorter periods, i.e., 2 weeks or less, with Cataflam<sup>®</sup> (diclofenac potassium immediate-release tablets), adverse reactions were reported one-half to one-tenth as frequently as by patients treated for longer periods. In a 6-month, double-blind trial comparing Cataflam (N=196) versus Voltaren<sup>®</sup> (diclofenac sodium delayed-release tablets) (N=197) versus ibuprofen (N=197), adverse reactions were similar in nature and frequency.

In patients taking Cataflam or other NSAIDs, the most frequently reported adverse experiences occurring in approximately 1%-10% of patients are:

Gastrointestinal experiences including: abdominal pain, constipation, diarrhea, dyspepsia, flatulence, gross bleeding/perforation, heartburn, nausea, GI ulcers (gastric/duodenal) and vomiting.

Abnormal renal function, anemia, dizziness, edema, elevated liver enzymes, headaches, increased bleeding time, pruritus, rashes and tinnitus.

Additional adverse experiences reported occasionally include:

**Body as a Whole:** fever, infection, sepsis

**Cardiovascular System:** congestive heart failure, hypertension, tachycardia, syncope

**Digestive System:** dry mouth, esophagitis, gastric/peptic ulcers, gastritis, gastrointestinal bleeding, glossitis, hematemesis, hepatitis, jaundice

**Hemic and Lymphatic System:** ecchymosis, eosinophilia, leukopenia, melena, purpura, rectal bleeding, stomatitis, thrombocytopenia

**Metabolic and Nutritional:** weight changes

**Nervous System:** anxiety, asthenia, confusion, depression, dream abnormalities, drowsiness, insomnia, malaise, nervousness, paresthesia, somnolence, tremors, vertigo

**Respiratory System:** asthma, dyspnea

**Skin and Appendages:** alopecia, photosensitivity, sweating increased

**Special Senses:** blurred vision

**Urogenital System:** cystitis, dysuria, hematuria, interstitial nephritis, oliguria/polyuria, proteinuria, renal failure

Other adverse reactions, which occur rarely are:

**Body as a Whole:** anaphylactic reactions, appetite changes, death

**Cardiovascular System:** arrhythmia, hypotension, myocardial infarction, palpitations, vasculitis

**Digestive System:** colitis, eructation, liver failure, pancreatitis

**Hemic and Lymphatic System:** agranulocytosis, hemolytic anemia, aplastic anemia, lymphadenopathy, pancytopenia

**Metabolic and Nutritional:** hyperglycemia

**Nervous System:** convulsions, coma, hallucinations, meningitis

**Respiratory System:** respiratory depression, pneumonia

**Skin and Appendages:** angioedema, toxic epidermal necrolysis, erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, urticaria

**Special Senses:** conjunctivitis, hearing impairment.

## OVERDOSAGE

Symptoms following acute NSAID overdoses are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression and coma may occur, but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs, and may occur following an overdose.

Patients should be managed by symptomatic and supportive care following an NSAID overdose. There are no specific antidotes. Emesis and/or activated charcoal (60 to 100 g in adults, 1 to 2 g/kg in children) and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose (5 to 10 times the usual dose). Forced diuresis, alkalinization of urine, hemodialysis, or hemoperfusion may not be useful due to high protein binding.

## DOSAGE AND ADMINISTRATION

Carefully consider the potential benefits and risks of Cataflam<sup>®</sup> and other treatment options before deciding to use Cataflam<sup>®</sup>. Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals (see **WARNINGS**).

After observing the response to initial therapy with Cataflam<sup>®</sup> (diclofenac potassium immediate-release tablets), the dose and frequency should be adjusted to suit an individual patient's needs.

For treatment of pain or primary dysmenorrhea the recommended dosage is 50 mg t.i.d. With experience, physicians may find that in some patients an initial dose of 100 mg of Cataflam, followed by 50-mg doses, will provide better relief.

For the relief of osteoarthritis the recommended dosage is 100-150 mg/day in divided doses, 50 mg b.i.d. or t.i.d.

For the relief of rheumatoid arthritis the recommended dosage is 150-200 mg/day in divided doses, 50 mg t.i.d. or q.i.d.

Different formulations of diclofenac [Voltaren<sup>®</sup> (diclofenac sodium enteric-coated tablets); Voltaren<sup>®</sup>-XR (diclofenac sodium extended-release tablets); Cataflam<sup>®</sup> (diclofenac potassium immediate-release tablets)] are not necessarily bioequivalent even if the milligram strength is the same.

### HOW SUPPLIED

#### **Cataflam Immediate-Release Tablets**

**50 mg** – light brown, round, biconvex, sugar-coated tablets (imprinted Cataflam on one side and 50 on the other side in black ink)

Bottles of 100..... NDC 0078-0436-05

Do not store above 30°C (86°F).

Dispense in tight container (USP).

Manufactured by:  
Patheon Inc., Whitby Operations  
Ontario, Canada L1N 5Z5

Distributed by:  
Novartis Pharmaceuticals Corp.  
East Hanover, NJ 07936

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