

PAG	E	1/2	Paincid®	Tablets
			Flurbiprofen U.S.P. 100	
			mg Anti-Inflammatory & Analgesic	
			COMPOSITION:	
			Each film coated tablet contains: Flurbiprofen U.S.P. 100mg	
			CLINICAL PHARMACOLOGY:	
			Pharmacokinetics: Rubuprofen is a nonsteroidal anti-inflammatory drug that exhibits anti-inflammatory, analgesic, and antipyretic activities. The mechanism of action of furbiprofen, like that of other non-steroidal anti-inflammatory drugs, is not completely understood but may be related to prostaglandin synthetase inhibition. Absorption: The mean oral bioavailability of furbiprofen is 96% relative to an oral solution. Furbiprofen is rapidly and non-selectively absorbed, with peak plasma concentrations occurring at about 2 hours. Administration of furbiprofen with either food or antacids may alter the rate but not the extent of furbiprofen absorption. Ranitidine has been shown to have no effect on either the rate or extent of furbiprofen absorption. Distribution: The apparent volume of distribution of both R- and S-furbiprofen is approximately 0.12 L/Kg. Both furbiprofen enantiomers are more than 99% bound to plasma proteins, primarily albumin. Plasma protein binding is relatively constant for the typical average steady-state concentrations (<10 µg/mL) achieved with recommended doses. Metabolism: Several furbiprofen metabolites have been identified in human plasma and urine. These metabolites include 4-hydroxy-furbiprofen, 3,4-dihydroxy-furbiprofen, 3-hydroxy-4-methoxy-furbiprofen, their conjugates, and conjugated furbiprofen. Unlike other arylpropanoic acid derivatives (e.g. ibuprofen), metabolism of R-furbiprofen to S-furbiprofen is minimal. Furbiprofen does not induce enzymes that alter its metabolism. The total plasma clearance of unbound furbiprofen is not stereoselective, and clearance of furbiprofen is independent of dose when used within the therapeutic range. Excretion: Following the dose, less than 3% of furbiprofen is excreted unchanged in the urine, with about 70% of the dose eliminated in the urine as parent drug and metabolites. Because renal elimination is a pathway of elimination of furbiprofen metabolites, dosing adjustment in patients with moderate or severe renal dysfunction may be necessary to avoid accumulation of furbiprofen metabolites. The mean terminal disposition half-lives ($t_{1/2}$) of R- and S-furbiprofen are similar, about 4.7 and 5.7 hours respectively. There is little accumulation of furbiprofen following multiple doses.	
			INDICATIONS: Paincid is indicated for the acute or long-term treatment of the signs and symptoms of rheumatoid arthritis and osteoarthritis. It is prepared in musculoskeletal and joint disorders such as ankylosing spondylitis, low back pain, and osteoarthritis of the knee and hip.	
Manufacture	Schazoo Zaka (Pvt)			
Jawala, 20-Km Lahore-Jaranwala Road,	Distr: Sheikhupura, Pakistan.			
Edited by	R&D OFFICE	R&D MANAGER	Q.C. MANAGER	QA. MANAGER

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DOSAGE & ADMINISTRATION:

ADULTS: The maximum recommended daily dosage of Paincid is 200mg taken as one 100mg tablet twice a day. In patients with severe symptoms or disease of recent origin, or during acute exacerbations, the total daily dosage may be increased to 300mg taken as one 100mg tablet three times a day. Doses above 300mg per day are not recommended.

CHILDREN: The use of Paincid in children under 12 years of age is not recommended.

CONTRA-INDICATIONS:

Paincid tablets are contra-indicated in patients who are hypersensitive to any component of this medication. It should not be given to patients who have experienced asthma, urticaria or allergic type reactions after taking aspirin or the other nonsteroidal anti-inflammatory drugs.

WARNINGS:

Serious gastrointestinal toxicity such as bleeding, ulceration and perforation can occur at anytime with or without warning symptoms in patients treated chronically with nonsteroidal anti-inflammatory drugs. Although minor upper gastrointestinal (GI) problems such as dyspepsia are common usually developing early in therapy physicians should remain alert for ulceration and bleeding in patients treated chronically with nonsteroidal anti-inflammatory drugs even in the absence of previous gastrointestinal symptoms.

PRECAUTIONS:

Impaired Renal or Hepatic Function: As with other nonsteroidal anti-inflammatory drugs, flurbiprofen should be used with caution in patients with impaired renal or hepatic function or a history of kidney or liver disease. Caution should be used when initiating treatment with flurbiprofen in patients with considerable dehydration.

Liver Tests: Patients 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 flurbiprofen.

Anemia: Patients who have initial hemoglobin values of 10 g/dL or less and who are to receive long-term therapy should have hemoglobin values determined periodically.

Fluid Retention and Edema: Fluid Retention and Edema have been reported therefore flurbiprofen should be used with caution in patients with cardiac decompensation, or similar conditions.

Vision Changes: Blurred and diminished vision has been reported with the use of flurbiprofen and other non-steroidal anti-inflammatory drugs. Patients experiencing eye complaints should have ophthalmologic examinations.

Effect on Platelets and Coagulation: Flurbiprofen inhibits collagen-induced platelet aggregation. Prolongation of bleeding time by flurbiprofen has been demonstrated in humans after single and multiple oral doses. Patients who may be adversely affected by prolonged bleeding time should be carefully observed when flurbiprofen is administered.

PEDIATRIC USE:

Safety and effectiveness in pediatric patients have not been established.

DRUG INTERACTIONS:

Antacids: Administration of flurbiprofen under fasting condition or with antacid suspension yielded similar serum flurbiprofen profiles in young subjects. In geriatric subjects there was a reduction in the rate but not the extent of flurbiprofen absorption.

Anticoagulants: Flurbiprofen like other nonsteroidal anti-inflammatory drugs has been shown to affect bleeding

parameters in patients receiving anti-coagulants and serious clinical bleeding has been reported. The physician should be cautious when administering flurbiprofen to patients taking anticoagulants.

Aspirin: Concurrent administration of aspirin and flurbiprofen resulted in 50% lower serum flurbiprofen concentrations. This effect of aspirin (which also lowers serum concentrations of other nonsteroidal anti-inflammatory drugs given with it) has been demonstrated in patients with rheumatoid arthritis. Concurrent use of flurbiprofen and aspirin is therefore not recommended.

Beta-adrenergic Blocking Agents: The effect of flurbiprofen on blood pressure response to propranolol and atenolol was evaluated in men with mild uncomplicated hypertension. Flurbiprofen pretreatment attenuated the hypotensive effect of a single dose of propranolol but not atenolol. Flurbiprofen did not appear to affect the beta-blocker-mediated reduction in heart rate. Flurbiprofen did not affect the pharmacokinetic profile of either drug, and the mechanism underlying the interference with propranolol's hypotensive effect is unknown. Patients taking both flurbiprofen and a beta-blocker should be monitored to ensure that a satisfactory hypotensive effect is achieved.

Cimetidine, Ranitidine: Cimetidine or ranitidine did not affect flurbiprofen pharmacokinetics except a small (13%) but statistically significant increase in the area under the serum concentration curve of flurbiprofen resulted with cimetidine.

Digoxin: Studies of concomitant administration of flurbiprofen and digoxin to healthy men did not show a change in the steady state serum levels of either drug.

SIDE EFFECTS:

Paincid is generally well tolerated. The most common side effects are dyspepsia, heartburn, headache, skin rash, gastrointestinal ulceration and acute allergic reactions. Because of the possibility of cross-sensitivity due to structural relationships which exist among nonsteroidal anti-inflammatory medicines, acute allergic reactions may be more likely to occur in patients who have exhibited allergic reactions to these compounds.

Dizziness, nervousness and other central effects, hypersensitivity depression, drowsiness, nausea and vomiting, diarrhea, oedema and tinnitus may occur.

Approved by

OVERDOSE:

Symptoms following acute overdoses with nonsteroidal anti-inflammatory drugs are usually limited to lethargy, drowsiness,

Colour		Leaflet:
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