PACKAGE INSERT

SCHEDULING STATUS: Unscheduled.
PROPRIETARY NAME (AND DOSAGE FORM):

GULF ASPIRIN 300mg (TABLETS)

COMPOSITION:
300mg Aspirin per tablet

PHARMACOLOGICAL CLASSIFICATION:
A 2.7 Anti-pyretic or anti-pyretic and anti-inflammatory analgesics.

PHARMACOLOGICAL ACTION:
Gulf Aspirin 300mg has analgesic, anti-pyretic and anti-inflammatory actions. Aspirin inhibits the biosynthesis of prostaglandins.

INDICATIONS:
Gulf Aspirin 300mg is effective for the relief of pain of mild to moderate intensity. Gulf Aspirin 300mg is indicated in a wide variety of febrile conditions.

CONTRA-INDICATIONS:
Patients with peptic ulcer, haemophilia or intolerance (hypersensitivity) to aspirin, severe renal impairment and patients receiving oral anti-coagulant therapy, heart failure, history of gastrointestinal bleeding or perforation (PUBs) related to previous NSAIDs, active or history of recurrent ulcer/haemorrhage/perforations.

WARNINGS:
DO NOT USE CONTINUOUSLY FOR MORE THAN 10 DAYS WITHOUT CONSULTING YOUR DOCTOR. Aspirin has been implicated in Reye's syndrome, a rare but serious illness, in children and teenagers with chickenpox and influenza. A doctor should be consulted before aspirin is used in such patients. Caution is required in patients with a history of hypertension and/or heart failure as fluid retention and oedema have been reported in association with Gulf Aspirin 300mg therapy. The risk of gastrointestinal bleeding or perforation (PUBs) is higher with increasing doses of Gulf Aspirin 300mg, in patients with a history of ulcers, and the elderly. When gastrointestinal bleeding or ulceration occurs in patients receiving Gulf Aspirin 300mg, treatment with Gulf Aspirin 300mg should be stopped. Gulf Aspirin 300mg should be given with caution to patients with a history of gastrointestinal disease (e.g. ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia) as the condition may be exacerbated. Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported. Gulf Aspirin 300mg should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity. Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs, especially gastrointestinal bleeding and perforation (PUBs) which may be fatal.

INTERACTIONS:
NSAIDs: Use of two or more NSAIDs concomitantly could result in an increase in side-effects. Corticosteroids: Increased risk of gastrointestinal ulceration and bleeding (PUBs). Anti-Coagulants: Gulf Aspirin 300mg may enhance the effects of anti-coagulants such as warfarin. Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs): increased risk of gastrointestinal bleeding. Aspirin may enhance the activity of coumarin anti-coagulants and oral-diabetic preparations and sulphonamides. Aspirin diminishes the effects of anti-gout preparations such as probenecid and sulphinpyrazone. Barbiturates and other sedatives may mask the respiratory symptoms of aspirin overdosage and have been reported to enhance its toxicity.

PREGNANCY AND LACTATION:
The use of aspirin during the first and third trimesters of pregnancy is not advised.Regular use of non steroidal anti-inflammatory drugs during the third trimester of pregnancy, may result in premature closure of the foetal ductus arteriosus in utero, and possibly, in persistent pulmonary hypertension of the new-born. The onset of labour may be delayed and its duration increased.

DOSAGE AND DIRECTIONS FOR USE:

Children:	**Under 6 years:**	Consult your doctor.
	2-4 years:	1/2 a tablet not more than 4 times a day.
	4-6 years:	1/2 -1 tablet not more than 4 times a day.
	6-12 years:	1 tablet not more than 4 times a day.
Adults:		1-3 tablets. Repeat 4 hourly if necessary, but not more than 12 tablets to be taken during any 24-hour period.

If symptoms persist, consult your doctor. Not to be taken during the first and third trimesters of pregnancy except under the advice and supervision of a medical doctor. Excessive and prolonged use of this medicine may be dangerous. Use the lowest effective dose for the shortest possible duration of the treatment.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
The most commonly observed adverse events are gastrointestinal in nature: Peptic ulcers, perforation or gastrointestinal bleeding (sometimes fatal), nausea, vomiting diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease, gastritis. Bullous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis.Dizziness, oedema, hypertension and cardiac failure may occur in some cases. Some persons especially asthmatics, exhibit notable sensitivity to aspirin which may provoke various hypersensitivity reactions which may include skin eruptions paroxysmal bronchospasm and dyspnoea. It should be administered with caution to patients with impaired renal function, dyspepsia, anaemia and when the patient is dehydrated. Prolonged use of high does may lead to anaemia, blood dycrasias, gastrointestinal haemorrhage, peptic ulceration and renal papillary necrosis.

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT:
These include dizziness, tinnitus, sweating, nausea, vomiting, mental confusion, hyperventilation, respiratory alkalosis, metabolic acidosis, ketosis and depression of the central nervous system. In children serious signs of overdosage may develop rapidly. In cases of overdosage, consult a doctor immediately. Treatment is supportive and symptomatic; the serum salicylate levels should be closely monitored and forced alkaline diuresis instituted if appropriate.

IDENTIFICATION:
A round, flat, white tablet with bevelled edges.

PRESENTATION:
Packs of 100, 1000, and 5000 tablets.

STORAGE INSTRUCTIONS:
Store below 25ºC in a dry place.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
B 1646 (Act 101 of 1965).

NAME AND BUSINESS ADDRESS OF THE APPLICANT:
GULF DRUG COMPANY (PTY) LTD
22 BURNSIDE DRIVE
OLD MILL INDUSTRIAL PARK
MOUNT EDGECOMBE
4300

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
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