SCHEDULING STATUS:

S0

PROPRIETARY NAME AND DOSAGE FORM:

BAYER ASPIRIN® PLUS C EFFERVESCENT TABLETS

COMPOSITION:

Active ingredients: 400 mg acetylsalicylic acid and 240 mg ascorbic acid per tablet.
Inactive ingredients: Citric Acid anhydrous, Monosodium Citrate, Sodium Carbonate anhydrous, Sodium Hydrogen Carbonate.

PHARMACOLOGICAL CLASSIFICATION

A 2.8 Analgesic combinations.

PHARMACOLOGICAL ACTION

Acetylsalicylic acid has analgesic, anti-pyretic and anti-inflammatory actions.
Ascorbic acid has a positive influence on the function of normal T-lymphocytes. It activates T-cell mediated immune functions.

INDICATIONS:

For relief of mild to moderate pain and/ or fever associated with colds and flu.

CONTRAINDICATIONS

BAYER ASPIRIN PLUS C must not be used in the following cases:

- patients with gastric or duodenal ulcers, haemophilia, thrombocytopenia or other bleeding tendencies, or intolerance (hypersensitivity) to aspirin or other salicylates or ascorbic acid, severe renal impairment or patients receiving oral anti-coagulant therapy.
- a history of asthma induced by the administration of salicylates or substances with a similar action, notably non-steroidal anti-inflammatory drugs.
- heart failure.
- history of gastrointestinal perforation, ulceration or bleeding (PUBs) related to previous. NSAIDs, including BAYER ASPIRIN PLUS C.
- active or history of recurrent ulcer/haemorrhage/perforations.
- combination with methotrexate doses of 15 mg/ week or more (see interactions).
- last trimester of pregnancy (see pregnancy and lactation).

WARNINGS AND SPECIAL PRECAUTIONS

If symptoms persist consult your doctor. 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 chicken pox and influenza. A doctor should be consulted before use in such patients.

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.

At low doses, aspirin reduces the excretion of uric acid, and can trigger gout in patients who already tend to have a low uric acid excretion.

BAYER ASPIRIN PLUS C should be withdrawn one week before surgery because of the possibility of increasing the bleeding times.

Special Precautions

It should be administered with caution to patients with impaired renal function, in the presence of severe liver disease, in patients with a history of gastrointestinal disorders such as peptic ulcers, ulcerative colitis and Crohn's disease, dyspepsia, anaemia and when the patient is dehydrated.

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 BAYER ASPIRIN PLUS C therapy. In view of the BAYER ASPIRIN PLUS C inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

- Caution is required in patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking) and should only be treated with diclofenac after careful consideration.
- Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs including BAYER ASPIRIN PLUS C especially gastrointestinal perforation, ulceration and bleeding (PUBs) which may be fatal.
- The risk of gastrointestinal perforation, ulceration or bleeding (PUBs) is higher with increasing doses of BAYER ASPIRIN PLUS C in patients with a history of ulcers, and the elderly.

When gastrointestinal bleeding or ulceration occurs in patients receiving BAYER ASPIRIN PLUS C treatment with BAYER ASPIRIN PLUS C should be stopped.

- BAYER ASPIRIN PLUS C 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 necrolyis have been reported. BAYER ASPIRIN PLUS C should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.
- Regular use of NSAIDs such as BAYER ASPIRIN PLUS C 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 **[SEE PREGNANCY AND LACTATION].**

"In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients."

Prolonged use of high doses may lead to anaemia, blood dyscrasia, gastrointestinal haemorrhage and peptic ulceration.

This product contains sodium which may be harmful to people on a low sodium diet.

Interference with laboratory tests

Aspirin may produce falsely increased results for blood creatinine, urate (low dose aspirin) and urea. Falsely decreased results may be obtained for blood thyroxine and urate (>4g/ day aspirin) and for urinary 5-HIAA (with nitrosonapthol method). Urinary VMA (HMMA) levels may be falsely increased or decreased depending on the method of analysis.
Urinary glucose oxidase: Aspirin may cause a false negative test in the presence of glycosuria.

Effects on ability to drive and use machines

No effects on ability to drive and use machines have been observed.

INTERACTIONS

Concomitant therapy with other gastric irritants, such as non-steroidal anti-inflammatory agents may increase the risk of gastric irritation.
Aspirin may increase the risk of gastrointestinal perforation, ulceration or bleeding (PUBs) when taken simultaneously with corticosteroids or alcohol.
Aspirin may enhance the activity of digoxin, thrombolytics and other anti-platelet agents e.g. coumarin, heparin, ticlopidine; methotrexate, valproic acid, anti-diabetic preparation such as insulin and sulphonylureas.
Aspirin diminishes the effects of anti-gout preparations such as probenecid and benzbromarone.
Diuretics in combination with Aspirin at doses of 3g/day or more may result in decreased glomerular filtration via decreased renal prostaglandin synthesis.
Angiotensin converting enzyme inhibitors (ACE) taken in conjunction with doses of 3g per day or more of Aspirin may result in decreased glomerular filtration via inhibition of vasodilator prostaglandins.
Barbiturates and other sedatives may mask the respiratory symptoms of Aspirin overdosage and have been reported to enhance its toxicity.

PREGNANCY AND LACTATION

Pregnancy

Aspirin should not be taken during the first and third trimester of pregnancy.

Lactation

BAYER ASPIRIN PLUS C should not be taken by lactating women.

DOSAGE AND DIRECTIONS FOR USE

Do not remove from foil until immediately before use. The effervescent tablets should be dissolved completely in a glass of water before use.

Adults:

1 to 2 effervescent tablets. Repeat four hourly if necessary if necessary but not more than 8 tablets to be taken during any 24 hour period.

Children over 12 years of age:

1 effervescent tablet not more than four times a day, to a maximum of 4 tablets in 24 hours.

Use the lowest effective dose for the shortest possible duration of treatment.

SIDE EFFECTS

Table 1: The following side-effects have been reported and the frequencies are unknown	
Blood and lymphatic System disorders	Bleeding diathesis, blood dyscrasia, anaemia
Immune system disorders	Hypersensitivity to anti-inflammatory agents or allergens, allergic reactions (e.g. cutaneous reactions, itching, urticarial, angioedema), dizziness.
Ear and labyrinth disorders	Tinnitus.
Cardiac disorders	Oedema, hypertension and cardiac failure.
Respiratory, thoracic and mediastinal disorders	Asthmatics, chronic urticaria, chronic rhinitis, paroxysmal bronchospasm and dyspnoea.
Gastrointestinal disorders	Peptic ulcers, perforation or gastrointestinal bleeding, sometimes fatal. Gastric ulcers, irritation of the gastric mucosa, dyspepsia, nausea, vomiting, diarrhoea, flatulence, constipation, abdominal pain, erosion, ulceration stomatitis, haematemesis, melaena, exacerbation of colitis and Crohn's disease, gastritis.
Skin and subcutaneous tissue disorder	Skin eruptions, urticarial, angioedema. Bullous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis.
Renal and urinary disorders	Gout.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Aspirin: These include dizziness, tinnitus, sweating, nausea, vomiting, altered glucose metabolism, mental confusion, hyperventilation, respiratory alkalosis, metabolic acidosis, ketosis,

fluid and electrolyte losses. Depression of the central nervous system may lead coma, cardiovascular collapse and respiratory failure.
In children and in elderly patients serious signs of overdosage may develop rapidly. In cases of overdosage, consult a doctor immediately.
Gastric lavage, forced alkaline diuresis, restoration of fluid and acid balance, dialysis and supportive therapy may be required.
Ascorbic acid: Large doses my cause diarrhea and other gastrointestinal disturbances.

IDENTIFICATION

Round, white tablets marked with the 'BAYER' cross, which dissolve to form a clear, colourless.

PRESENTATION

Effervescent tablets in foil strips in packs of 2, 10 or 20.

STORAGE INSTRUCTIONS

Store below 25°C. Keep dry.
Do not remove tablet from foil until immediately prior to use.
Keep out of reach of children.

REGISTRATION NUMBER

31/2.8/0473.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Bayer (Pty) Ltd,
27 Wrench Road,
Isando,
1600.
1968/11192/07.

DATE OF PUBLICATION OF THIS PACKAGE INSERT

Date on the registration certificate: 21 January 2000
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