PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

BAYER ASPIRIN PLUS C EFFERVESCENT TABLETS

Read all of this leaflet carefully because it contains important information for you

BAYER ASPIRIN PLUS C is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use BAYER ASPIRIN PLUS C carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BAYER ASPIRIN PLUS C with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

1. WHAT BAYER ASPIRIN PLUS CONTAINS

The active substance is aspirin (acetylsalicylic acid) 400 mg and vitamin C 240 mg.
The other ingredients are citric acid, sodium bicarbonate, sodium carbonate and sodium citrate.

2. WHAT BAYER ASPIRIN PLUS C IS USED FOR

BAYER ASPIRIN PLUS C may be taken for the relief of mild to moderate pain and the relief from fever, including the relief of fever or chills associated with colds and flu.

3. BEFORE YOU USE BAYER ASPIRIN PLUS C

Do not use BAYER ASPIRIN PLUS C:

- if you are allergic to aspirin or vitamin C or any other ingredients of BAYER ASPIRIN PLUS C,
- in children or teenagers unless directed to do so by your doctor,
- inform your doctor or pharmacist about alcohol or other medicines you are taking, especially other blood thinning agents, other pain-killers or medicines used for arthritis (inflammation (swelling and redness) in a joint), sugar diabetes or gout,
- inform your doctor if you are pregnant, intend to become pregnant or if you are breast-feeding,
- inform your doctor if you have ever had an ulcer, have a tendency to bleed, have kidney problems, diabetes, gout, asthma or other allergies,
- avoid using this product a week before you have any surgery, including dental surgery,
- this product contains sodium which may be harmful to people on a low sodium diet,
- if you have gastric (stomach) ulcers or duodenal ulcers (sore in the lining of an area of the small bowel (duodenum), haemophilia, thrombocytopenia (is a blood disorder in which there are too few platelets (a small colourless disc-shaped cell fragment) in the blood),

- if you suffer from heart failure,
- in the last trimester of pregnancy.

Using BAYER ASPIRIN PLUS C with food and drink:

BAYER ASPIRIN PLUS C should be taken after meals

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Pregnancy

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

Lactation

BAYER ASPIRIN PLUS C should not be taken when you are breastfeeding your baby.

Driving and using machinery:

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

Taking other medicines with BAYER ASPIRIN PLUS C:

Always tell your healthcare professional if you are taking any other medicine. (This includes complimentary or traditional medicine).

Concomitant therapy with other gastric (stomach) irritants, such as non-steroidal anti-inflammatory agents may increase the risk of gastric (stomach) irritation.

Aspirin may increase the risk of gastrointestinal perforation (is a hole in the wall of part of the gastrointestinal tract that includes esophagus, stomach, small intestine and large intestine), 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, valporic 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 conjuction 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.

4. HOW TO USE BAYER ASPIRIN PLUS C:

Do not share medicines prescribed for you with any other person.
Always take BAYER ASPIRIN PLUS C exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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

The usual dose is:

Adults: 1 to 2 effervescent tablets.
Repeat four hourly 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.

If you take BAYER ASPIRIN PLUS C than you should:

In the event of an overdosage consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
In children serious signs of overdosage can develop rapidly.

Aspirin: The signs of overdose include dizziness, tinnitus (noise in the ears, such as ringing, buzzing, roaring, clicking), sweating, nausea, vomiting, altered glucose metabolism, mental confusion, hyperventilation (a condition characterized by abnormally prolonged and rapid breathing, resulting in decreased carbon dioxide levels and increased oxygen levels), respiratory alkalosis (is a condition where the amount of carbon dioxide found in the blood drops to a level below normal range), metabolic acidosis (is a pH imbalance in which the body has accumulated too much acid and does not have enough bicarbonate to effectively neutralize the effects of the acid), ketosis (accumulation of excessive amounts of ketone bodies in body tissues and fluids, occurring when fatty acids are incompletely metabolized) , fluid and electrolyte losses. Depression of the central nervous system may lead coma, cardiovascular collapse and respiratory failure.
Ascorbic acid: Large doses my cause diarrhea and other gastrointestinal disturbances.

If you forget to take a dose of BAYER ASPIRIN PLUS C:

Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

BAYER ASPIRIN PLUS C can have side effects.

Table 1: The following side-effects have been reported and the frequencies are unknown	
Blood and lymphatic System disorders	Bleeding diathesis (An increased susceptibility to bleeding due to a coagulation defect, which can be genetic), blood dyscrasia (an abnormal condition or disease of the blood), anaemia (lack of enough red blood cells).
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 (noise in the ears, such as ringing, buzzing, roaring,

	clicking).
Cardiac disorders	Oedema, hypertension (high blood pressure) and cardiac failure.
Respiratory, thoracic and mediastinal disorders	Asthmatics, chronic urticarial (is a disturbing allergic condition of the skin), chronic rhinitis (is irritation and inflammation of the mucous membrane inside the nose), paroxysmal bronchospasm and dyspnoea (shortness of breath).
Gastrointestinal disorders	Peptic ulcers, perforation or gastrointestinal bleeding, sometimes fatal, Gastric ulcers (sore in the lining of the stomach), irritation of the gastric mucosa, dyspepsia (heartburn) or indigestion, nausea (the urge to vomit), vomiting, diarrhoea, flatulence (excess passing of gas), constipation, abdominal pain (stomach pain) or discomfort, erosion, ulceration stomatitis (an infectious disease of the mouth characterized by swollen spongy gums, ulcers, and loose teeth), haematemesis (the vomiting of blood), melaena (the passage of dark stools stained with altered blood, exacerbation of colitis and Crohn's disease, gastritis (inflammation of the stomach lining).
Skin and subcutaneous tissue disorder	Skin eruptions, urticarial, angioedema. Bullous reactions (skin condition with fluid filled blisters), including Stevens-Johnson syndrome (potentially life threatening condition affecting less than 10% of the skin in which cell death causes the outer layer to separate from the middle layer of the skin) and toxic epidermal necrolysis (life threatening condition affecting greater than 30% of the skin in which cell death causes the outer layer to separate from the middle layer of the skin).
Renal and urinary disorders	Gout (is a common form of inflammatory arthritis - a condition affecting the joints and musculoskeletal system).

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Unusual bleeding or bruising
- Black stools or severe diarrhoea

Not all side effects reported for BAYER ASPIRIN PLUS C are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF BAYER ASPIRIN PLUS C

- Store all medicines out of reach of children.
- Store at or below 25°C. Keep dry place.
- Store in the original package / container.
- Keep the container tightly closed.

- Do not store in a bathroom.
- Protect from light or moisture.
- Do not remove tablet from foil until immediately prior to use.
- Return any unused or expired medicine to your doctor or pharmacist for safe disposal. Do not take BAYER ASPIRIN PLUS C effervescent tablets that smell strongly of vinegar.
- Do not dispose of unused medicine in drains or sewerage systems.
- Do not use after the expiry date stated on label or carton.

7. PRESENTATION OF BAYER ASPIRIN PLUS C

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

8. IDENTIFICATION OF BAYER ASPIRIN PLUS C

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

9. REGISTRATION NUMBER

31/2.8/0473.

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Bayer (Pty) Ltd,
27 Wrench Road,
Isando,
1600.
1968/11192/07.
+27 11 921 5000.

11. DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

Date on the registration certificate: 21 January 2000.
Date of the most recently revised package insert: 21 January 2000.