DISPERSIBLE ASPIRIN 75MG TABLETS BP
PL 17907/0155-6

UKPAR

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DISPERSIBLE ASPIRIN 75MG TABLETS BP
PL 17907/0155-6

LAY SUMMARY

The MHRA granted Bristol Laboratories Limited Marketing Authorisations (licences) for the medicinal product Dispersible Aspirin 75mg Tablets BP (PL 17907/0155-6) on 10th February 2006. These pharmacy-only (P – PL 17907/0155) and prescription-only medicines (POM – PL 17907/0156) are for the secondary prevention of thrombotic cerebrovascular or cardiovascular disease and following by-pass surgery.

Dispersible Aspirin 75mg Tablets BP contains the active ingredient aspirin (salicylic acid) which acts as an anticoagulant/anti-thrombotic agent.

These applications are duplicates of a previously granted application, Dispersible Aspirin 75mg Tablets (PL 00211/0005), which was initially granted a licence in June 1982.

No new or unexpected safety concerns arose from these simple applications and it was, therefore, judged that the benefits of taking Dispersible Aspirin 75mg Tablets BP outweigh the risks, hence, Marketing Authorisations have been granted.

DISPERSIBLE ASPIRIN 75MG TABLETS BP
PL 17907/0155-6

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted marketing authorisations for the medicinal products Dispersible Aspirin 75mg Tablets BP (PL 17907/0155-6) to Bristol Laboratories Limited on 10th February 2006. The products are pharmacy-only (P – PL 17907/0155) and prescription-only medicines (POM – PL 17907/0156).

The applications were submitted as simple abridged applications according to Article 10c (formerly 10.1(a)(i)) of Directive 2001/83/EC, cross-referring to Dispersible Aspirin 75mg Tablets (PL 00211/0005), which was initially granted a licence in June 1982.

No new data was submitted nor was it necessary for these simple applications, as the data is identical to that of the previously granted cross-reference product. As the cross-reference products were granted prior to the introduction of current legislation, no PARs were generated for them.

The products contain the active ingredient aspirin, which acts as an anticoagulant/anti-thrombotic agent. Dispersible Aspirin 75mg Tablets BP are indicated for the secondary prevention of thrombotic cerebrovascular or cardiovascular disease and following by-pass surgery.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 17907/0155-6
PROPRIETARY NAME: Dispersible Aspirin 75mg Tablets BP
ACTIVE(S): Aspirin
COMPANY NAME: Bristol Laboratories Limited
E.C. ARTICLE: Article 10c (formerly 10.1(a)(i)) of Directive 2001/83/EC
LEGAL STATUS: POM

1. INTRODUCTION

This is a simple, piggy back application for Dispersible Aspirin 75mg Tablets BP submitted under Article 10c (formerly 10.1(a)(i)) of Directive 2001/83/EC. The proposed MA holder is Bristol Laboratories Limited, Unit 3, Canalside, Northbridge Road, Berkhamstead, HP4 1EG, UK.

These applications cross refer to standard abridged applications for Dispersible Aspirin 75mg Tablets (PL 00211/0005), which is currently registered in the UK. These applications are considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed names of the products are Dispersible Aspirin 75mg Tablets BP. The products have been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The products contain aspirin, equivalent to 75mg. They are to be stored in blister packs (PVC film base with paper/aluminium foil lid) contained in cardboard cartons and in polypropylene/polyethylene child-resistant containers.

For the pharmacy only product (PL 17907/0155), blister packs contain 12, 20, 24, 28, 30, 32, 48, 56, 60, 84, 96, 98 or 100 tablets and child-resistant containers 32, 50 or 100 tablets. For the prescription only product (PL 17907/0156), blister packs contain 112 tablets and child-resistant containers 500 or 1,000 tablets.

The proposed shelf-life of 2 years is consistent with the cross-reference product. The storage conditions for the blister packs are "Do not store above 25^{o}C. Store in the original package" and for the polypropylene/polyethylene containers are "Do not store above 25^{o}C. Keep the container tightly closed". These are consistent with the cross-reference product.

2.3 Legal status

On approval, the products will be subject to either sale in a pharmacy only (P: PL 17907/0155) or a medical prescription by healthcare professionals only (POM: PL 17907/0156).

2.4 Marketing authorisation holder/Contact Persons/Company

The proposed Marketing Authorisation holder is Bristol Laboratories Limited, Unit 3, Canalside, Northbridge Road, Berkhamstead, HP4 1EG, UK.

The QP responsible for pharmacovigilance is stated and their CV is included.

2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference products and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed compositions are consistent with the details registered for the cross-reference products.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference products and the maximum batch size is stated.

2.8 Finished product/shelf-life specification
The proposed finished product specification is in line with the details registered for the cross-reference products.

2.9 Drug substance specification
The proposed drug substance specification for each product is consistent with the details registered for the cross-reference products.

2.10 TSE Compliance
A European Pharmacopoeia Certificate of Suitability has been provided for lactose monohydrate. No other materials of animal or human origin are included in the product.

3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product names. The appearances of the products are identical to the cross-reference products.

5. SUMMARY OF PRODUCT CHARACTERISTICS
The proposed SmPCs are consistent with the details registered for the cross-reference products.

6. PATIENT INFORMATION LEAFLET/CARTON
PIL
The patient information leaflet has been prepared in-line with the details registered for the cross-reference products.

Carton and blister
The proposed artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS

The data submitted with the applications are acceptable. Marketing Authorisations should be granted.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with these applications and none are required for an application of this type.

CLINICAL ASSESSMENT

As these are duplicate applications to Dispersible Aspirin 75mg Tablets (PL 00211/0005), no new clinical data have been supplied and none are required.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for these applications is consistent with that previously assessed for the cross-reference product and as such has been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for applications of this type.

EFFICACY

Aspirin is a well known drug and has been used as an antithrombotic agent for many years. These applications are identical to a previously granted application for Dispersible Aspirin 75mg Tablets (PL 00211/0005).

No new or unexpected safety concerns arise from these applications.

The SPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's products are identical to the cross-reference products. Extensive clinical experience with aspirin is considered to have demonstrated the therapeutic value of the compound. The risk benefit is therefore considered to be positive.

DISPERSIBLE ASPIRIN 75MG TABLETS BP
PL 17907/0155-6

STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation applications on 26/10/2004.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 10/11/2004.
3	Following assessment of the application the MHRA requested further information on 09/02/2005, 14/02/2005 and 12/07/2005.
4	The applicant responded to the MHRA's requests, providing further information on 18/05/2005 and 28/09/2005
5	The application was determined on 24/01/2006

DISPERSIBLE ASPIRIN 75MG TABLETS BP
PL 17907/0155-6

STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

DISPERSIBLE ASPIRIN 75MG TABLETS BP
PL 17907/0155

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Dispersible Aspirin 75mg Tablets BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains aspirin 75mg

For excipients, see section 4.4 and 6.1

3 PHARMACEUTICAL FORM
Dispersible tablets.

White, flat tablets, embossed <F> on one side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
For the secondary prevention of thrombotic cerebrovascular or cardiovascular disease and following by-pass surgery.

4.2 Posology and method of administration
For Oral use

The advice of a doctor should be sought before commencing therapy for the first time. Tablets should be dissolved in water before being taken. The usual dosage, for long term use, is 75-150mg once daily. In some circumstances a higher dose may be appropriate, especially in the short term, and up to 300 mg a day may be used on the advice of a doctor.

Children:
Do not give to children aged under 16 years, unless specifically indicated (e.g. for Kawasaki's disease).

4.3 Contraindications
i) Children under 16 years unless specifically indicated (e.g. for Kawasaki's disease).
ii) Active peptic ulceration or a history of peptic ulceration
iii) Haemophilia, other coagulopathies or concurrent anticoagulant therapy.
iv) Hypersensitivity to aspirin, any other NSAIDs, or any of the excipients (see section 6.1)
v) Gout

4.4 Special warnings and precautions for use
Caution should be exercised in patients with asthma, allergic disease, impairment of hepatic or renal function (avoid if severe) and dehydration.

The elderly may be more susceptible to the toxic effects of salicylates. Continuous, prolonged use of aspirin should be avoided in the elderly because of the risk of gastrointestinal bleeding.

Caution should be used in patients with glucose 6-phosphate dehydrogenase (G6PD) deficiency as haemolytic anaemia may develop.

Aspirin may interfere with insulin and glucagon in diabetes.

Aspirin prolongs bleeding time, mainly by inhibiting platelet aggregation and therefore it should be discontinued several days before scheduled surgical procedures.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Do not take if you have a stomach ulcer.

Before commencing long-term aspirin therapy for the management of cardiovascular or cerebrovascular disease patients should consult their doctor who can advise on the relative benefits of aspirin versus the risks for the individual patient.

There is a possible association between aspirin and Reye's Syndrome when given to children. Reye's syndrome is a very rare disease, which affects the brain and liver, and can be fatal. For this reason aspirin should not be given to children aged under 16 years unless specifically indicated (e.g. for Kawasaki's disease).

4.5 Interaction with other medicinal products and other forms of interaction

Alcohol: Some of the effects of aspirin on the gastrointestinal tract are enhanced by alcohol.

Antacids and adsorbents: The excretion of aspirin is increased in alkaline urine; kaolin possibly reduces absorption.

Anticoagulants: Aspirin may enhance the effects of anticoagulants: concurrent use is contraindicated (see section 4.3)

Antiepileptics: May enhance the effects of phenytoin and sodium valproate.

Antimetabolites: The activity of methotrexate may be markedly enhanced and its toxicity increased.

ACE inhibitors: Aspirin may reduce the antihypertensive effect of ACE inhibitors.

Antibacterials: The toxicity of sulfonamides may be increased.

Antiemetics: Metoclopramide enhances the effects of aspirin by increasing the rate of absorption.

Corticosteroids: The risk of gastrointestinal bleeding and ulceration is increased. Corticosteroids reduce the plasma salicylate concentration.

Diuretics: Antagonism of the diuretic effect of spironolactone. Reduced excretion of acetazolamide with an increased risk of toxicity. Salicylate intoxication has occurred in patients on high dose salicylate regimens and carbonic anhydrase inhibitors.

Hypoglycaemic agents: Large doses of aspirin may enhance the effects of insulin and oral hypoglycaemic agents.

Leukotriene antagonists: The plasma concentration of zafirlukast is increased.

Mifepristone: The manufacturer of mifepristone recommends that aspirin should be avoided until eight to twelve days after mifepristone has been discontinued.

Other non-steroidal anti-inflammatory drugs (NSAIDs): Concurrent administration can increase side effects.

Thyroid function tests: Aspirin may interfere with thyroid function tests.

Uricosurics: Effect of probenecid and sulfinyrazone reduced.

4.6 Pregnancy and lactation

There is clinical and epidemiological evidence of the safety of aspirin in human pregnancy. Aspirin may prolong gestation, delay the onset of or prolong labour and contribute to maternal and neonatal bleeding and is best avoided at term and during breast feeding - possible risk of Reye's Syndrome.

Maternal use of aspirin prior to birth may increase the risk of intracranial haemorrhage in premature or low birth weight infants. Regular use of high doses could impair platelet function and produce hypoprothrombinaemia in the infant if neonatal Vitamin K stores are low. The use of aspirin during pregnancy may cause premature closure of the foetal ductus arteriosus and pulmonary hypertension.

4.7 Effects on ability to drive and use machines

Aspirin does not usually affect the ability to drive or operate machinery.

4.8 Undesirable effects

Side effects are generally mild and infrequent.

Blood disorders: Aspirin increases bleeding time, decreases platelet adhesiveness and, in large doses, may cause hypoprothrombinaemia. It may also cause other blood disorders including thrombocytopenia. Haemolytic anaemia can occur in patients with glucose 6-phosphate dehydrogenase deficiency (G6PD).

Immune System: Aspirin may precipitate bronchospasm, and induce asthma attacks, rhinitis, angioedema, or other hypersensitivity reactions in susceptible individuals.

Gastro-intestinal: There is a relatively high incidence of gastro-intestinal irritation with a slight asymptomatic blood loss. Aspirin may induce gastro-intestinal haemorrhage which may occasionally be major.

Skin: Skin reactions may occur in susceptible patients.

4.9 Overdose

Salicylate poisoning is usually associated with plasma concentrations >350mg/L (2.5mmol/L) Most adult deaths occur in patients whose concentrations exceed 700mg/L (5.1mmol/L). Single doses less than 100mg/kg are unlikely to cause serious poisoning.

Symptoms

Common features include vomiting, dehydration, tinnitus, vertigo, deafness, sweating, warm extremities with bounding pulses, increased respiratory rate and hyperventilation. Some degree of acid-base disturbance is present in most cases.

A mixed respiratory alkalosis and metabolic acidosis with normal or high arterial pH (normal or reduced hydrogen ion concentration) is usual in adults and children over the age of four years. In children aged four years or less, a dominant metabolic acidosis with low arterial pH (raised hydrogen ion concentration) is common. Acidosis may increase salicylate transfer across the blood brain barrier.

Uncommon features include haematemesis, hyperpyrexia, hypoglycaemia, hypokalaemia, thrombocytopaenia, increased INR/PTR, intravascular coagulation, renal failure and non-cardiac pulmonary oedema.

Central nervous system features including confusion, disorientation, coma and convulsions are less common in adults than in children.

Treatment

Give activated charcoal if an adult presents within one hour of ingestion of more than 250mg/kg. The plasma salicylate concentration should be measured, although the severity of poisoning cannot be determined from this alone and the clinical and biochemical features must be taken into account. Elimination is increased by urinary alkalinisation, which is achieved by the administration of 1.26% sodium bicarbonate. The urine pH should be monitored. Correct metabolic acidosis with intravenous 8.4% sodium bicarbonate (first check serum potassium). Forced diuresis should not be used since it does not enhance salicylate excretion and may cause pulmonary oedema.

Haemodialysis is the treatment of choice for severe poisoning and should be considered in patients with plasma salicylate concentrations >700mg/L (5.1mmol/L) or lower concentrations associated with severe clinical or metabolic features. Patients under ten years or over 70 have increased risk of salicylate toxicity and may require dialysis at an earlier stage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

B01A C (blood and blood forming organs – antithrombotic agents)

Aspirin is an analgesic and antipyretic with anti-inflammatory properties. Aspirin inhibits prostaglandin synthetase.

5.2 Pharmacokinetic properties

Absorption-
Aspirin is rapidly absorbed after oral administration, with some hydrolysis to salicylate before absorption. Absorption is delayed by the presence of food and is impaired in patients suffering migraine attacks. Absorption is more rapid in patients with achlorhydria and also following administration of polysorbates and antacids.

Blood concentration-
Peak plasma concentrations of approximately 45mcg/ml are attained 1 to 2 hours after an oral dose of 640mg, but stabilise at approximately 270mcg/ml after oral doses of 3g daily. After an oral dose of about 2g, peak plasma concentrations of approximately 15mcg/ml of aspirin are attained in about one hour and peak plasma concentrations of approximately 130mcg/ml of salicylate are attained in 2 to 4 hours.

Half-life

Plasma / Aspirin	Approximately 17 minutes
Plasma / Salicylate	Low doses 2-4 hours
	High doses up to 19 hours

Distribution-
Aspirin is found in the saliva, milk, plasma and synovial fluid at concentrations less than blood and crosses the placenta.
Salicylate - extensive protein binding.
Aspirin - protein binding to a small extent.

Metabolism-
In the blood, rapid hydrolysis to salicylic acid; glucuronic acid/glycine conjugation to form glucuronides and salicyluronic acid; oxidation of a small proportion.

Excretion-
Excreted in the urine mainly as salicyluronic acid. Salicylate reabsorbed by renal tubules in acid urine, and alkaline diuresis will increase the rate of excretion; 85% of dose excreted as free salicylate.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Saccharin E954
Citric acid E330
Calcium Carbonate E170
Maize Starch
Purified Talc E553b
Sodium Lauryl Sulphate
Lactose monohydrate

6.2 Incompatibilities
Not applicable

6.3 Shelf life
2 years.

6.4 Special precautions for storage
Do not store above 25°C.
Blister packs: store in the original package.
Polypropylene/polyethylene containers: keep the container tightly closed.

6.5 Nature and contents of container
Pack sizes 12-100 are P packs

Polypropylene/polyethylene containers:

32, 50 & 100 tablets.

Blister Pack: Blister strips consist of a 35gsm paper/9µ soft tempered aluminium foil lid and 250µ PVC film base in cartons:

Blister packs: 12, 20, 24, 28, 30, 32, 48, 56, 60, 84, 96, 98 and 100.

6.6 Special precautions for disposal
No special requirements.

7 MARKETING AUTHORISATION HOLDER
Bristol Laboratories Ltd,
Unit 3, Canalside,
Northbridge Road
Berkhamsted
HP4 1EG
UK

8 MARKETING AUTHORISATION NUMBER(S)
PL 17907/0155

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
10/02/2006

10 DATE OF REVISION OF THE TEXT
10/02/2006

DISPERSIBLE ASPIRIN 75MG TABLETS BP
PL 17907/0156

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Uncommon features include haematemesis, hyperpyrexia, hypoglycaemia, hypokalaemia, thrombocytopaenia, increased INR/PTR, intravascular coagulation, renal failure and non-cardiac pulmonary oedema.

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Plasma / Aspirin	Approximately 17 minutes
Plasma / Salicylate	Low doses 2-4 hours
	High doses up to 19 hours

Distribution-
Aspirin is found in the saliva, milk, plasma and synovial fluid at concentrations less than blood and crosses the placenta.
Salicylate - extensive protein binding.
Aspirin - protein binding to a small extent.

Metabolism-
In the blood, rapid hydrolysis to salicylic acid; glucuronic acid/glycine conjugation to form glucuronides and salicyluronic acid; oxidation of a small proportion.

Excretion-
Excreted in the urine mainly as salicyluronic acid. Salicylate reabsorbed by renal tubules in acid urine, and alkaline diuresis will increase the rate of excretion; 85% of dose excreted as free salicylate.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Saccharin E954
Citric acid E330
Calcium Carbonate E170
Maize Starch
Purified Talc E553b
Sodium Lauryl Sulphate
Lactose monohydrate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.
Blister packs: store in the original package.
Polypropylene/polyethylene containers: keep the container tightly closed.

6.5 Nature and contents of container

Pack sizes over 100 are POM packs

Polypropylene/polyethylene containers: 500 & 1000 tablets.

Blister Pack: Blister strips consist of a 35gsm paper/9µ soft tempered aluminium foil lid and 250µ PVC film base in cartons.

Blister packs: 112 tablets.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Bristol Laboratories Ltd,
Unit 3, Canalside,
Northbridge Road
Berkhamsted
HP4 1EG
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 17907/0156

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/02/2006

10 DATE OF REVISION OF THE TEXT

10/02/2006

DISPERSIBLE ASPIRIN 75MG TABLETS BP
PL 17907/0155

PRODUCT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

This leaflet provides some important information about your medicine.

Please read it carefully before you start taking Dispersible Aspirin 75mg Tablets B.P.

If you have any further questions, or if there is anything you do not understand, ask your doctor or pharmacist.

The name of this medicine is

DISPERSIBLE ASPIRIN 75MG TABLETS B.P.

WHAT IS IN YOUR MEDICINE?

Your medicine is called Dispersible Aspirin 75mg Tablets B.P. and consists of white, round tablets which have <F> embossed on one face and are plain on the other. Each dispersible tablet contains the active ingredient aspirin 75mg and also contains lactose monohydrate, calcium carbonate E170, maize starch, citric acid E330, purified talc E553b, sodium saccharin E954 and sodium lauryl sulphate. The sodium content is less than 0. 1mg per tablet. Aspirin belongs to a class of medicines called Non Steroidal Anti-Inflammatory Drugs.

Available in packs of 12, 20, 24, 28, 30, 32, 48, 50, 56, 60, 84, 96, 98 and 100 tablets.

MARKETING AUTHORISATION HOLDER

Bristol Laboratories Limited, Unit 3, Canalside, Northbridge Road, Berkhamsted, HP4 1EG, UK (PL17907/0155)

MANUFACTURER

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

WHAT IS YOUR MEDICINE FOR?

For the prevention of further heart attacks and strokes in patients with a previous history of heart attacks or stroke and following by-pass surgery.

BEFORE YOU TAKE YOUR MEDICINE

You should speak to your doctor before starting therapy as they will be able to advise you if this medicine is appropriate for your condition.

Do not take aspirin if:

- You are allergic to Aspirin or any other non-steroidal anti-inflammatory drugs, such as ibuprofen
- You are allergic to any of the other ingredients
- You have been told you suffer from haemophilia or a similar problem with blood clotting
- You are taking medicines to thin your blood such as warfarin.
- You are under 16 years old, unless your doctor has told you to take aspirin
- You have had an asthma attack after taking aspirin
- You have gout
- You have a stomach ulcer or a history of stomach ulcers.

Take special care with aspirin if:

- You have liver or kidney problems.
- You are dehydrated
- You suffer from asthma
- You are elderly
- You have been told that you have glucose-6-phosphate dehydrogenase (G6PD) deficiency
- You have been told by your doctor that you have an intolerance to some sugars
- You are diabetic.

You should let your doctor know you are taking aspirin tablets, particularly if you are going to have an operation, as you may need to stop taking your tablets several days before the operation.

You should let your doctor know if you are pregnant or breast-feeding, or wish to become pregnant or start breast-feeding whilst taking this medicine.

Taking aspirin late in pregnancy may affect the onset and duration of labour, cause a tendency to bleed in both mother and baby and affect the baby's circulation and so should be avoided. Taking aspirin while breast-feeding could cause Reye's syndrome in the baby and so should be avoided.

There may be some problems if aspirin is taken with other medicines. Example of medicines which can affect aspirin are:-

- Drugs which are used to thin the blood – you should not take aspirin if you are on heparin, warfarin, or other tablets to thin the blood.
- Methotrexate, used to reduce inflammation

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Graphic Creations

- Probenecid and sulphinpyrazone, used to treat gout.
- Antacids, used to treat indigestion.
- Kaolin , used to treat diarrhoea.
- ACE Inhibitors, such as lisinopril, used to treat high blood pressure and heart failure
- Steroids such as cortisone and hydrocortisone
- Some diuretics, such a spironolactone, used to get rid of excess fluid from the body, and acetazolamide, used to treat glaucoma.
- Insulin and other drugs used to treat diabetes.
- Zafirlukast, used to treat asthma.
- Metoclopramide, used to treat nausea and vomiting.
- Mifepristone, used to terminate pregnancies. You should not take aspirin until eight to twelve days after mifepristone.
- Other non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, used to treat pain.
- Phenytoin and sodium valproate, used in epilepsy.
- Sulfonamides such as sulphamethoxazole, used to treat infections.
- Alcohol

Aspirin may affect the results of thyroid function tests. Tell your doctor or nurse if you are taking aspirin.
If you have any doubts about whether you should take these tablets, then discuss things more fully with your doctor or pharmacist.

TAKING YOUR MEDICINE

Follow the instructions on the label about how to take your medicine. Your pharmacist may also help you if you are not sure.
Consult a doctor before commencing therapy for the first time.
Dose: Unless otherwise directed by your doctor -For oral use
- Adults, the elderly and children over 16 years: The usual dose for long term use is one or two tablets once daily, dissolved in water. In some circumstances a doctor may advise a higher dose of up to 4 tablets daily.
DO NOT GIVE TO CHILDREN AGED UNDER 16 YEARS, UNLESS ON THE ADVICE OF A DOCTOR.
DO NOT EXCEED THE STATED DOSE.
If symptoms persist consult your doctor.
If you miss a single dose of Dispersible Aspirin 75mg Tablets B.P. do not worry and take your next one at the normal time.
DO NOT DOUBLE UP ON A DOSE TO MAKE UP FOR THE MISSING ONE.
If you accidentally take a large number of tablets (overdose) you should contact the nearest hospital casualty department or tell your doctor immediately.

WHILE TAKING YOUR MEDICINE

Like many medicines, aspirin may cause side-effects in some patients, particularly when treatment is first started.
These can include irritation of the stomach lining (which can be aggravated by alcohol), skin reactions such as rash or hives, swelling of the face or eyes, difficulty with breathing, an asthma attack, wheezing, runny nose, anaemia and a tendency to bleed or bruise more easily. You should consult your doctor in all cases and stop taking the tablets immediately if you have any type of rash, swelling , breathing problems or notice blood in the vomit (looks like coffee grounds) or in stools (look tarry).
There is a possible association between aspirin and Reye's syndrome when given to children. Reye's syndrome is a very rare disease, which can be fatal. For this reason aspirin should not be given to children aged under 16 years, unless on the advice of a doctor.
If you experience any other unusual or unexpected symptoms which persist or are troublesome, consult your doctor or pharmacist.

STORING YOUR MEDICINE

Keep your medicine in the package or container in order to protect from moisture and light. Keep the bottle tightly closed.
Keep your medicine in a safe place where children cannot see or reach it. The medicine could be harmful to them.
Do not store above 25°C.
Do not use these tablets after the expiry date printed on the pack.

Date of leaflet preparation: April 2005

Artwork Same Size
Size: 130x120 mm
Graphic Creations

DISPERSIBLE ASPIRIN 75MG TABLETS BP
PL 17907/0156

PRODUCT INFORMATION LEAFLET

Front

PATIENT INFORMATION LEAFLET

This leaflet provides some important information about your medicine.
Please read it carefully before you start taking Dispersible Aspirin 75mg Tablets B.P.
If you have any further questions, or if there is anything you do not understand, ask your doctor or pharmacist.

The name of this medicine is
DISPERSIBLE ASPIRIN 75MG TABLETS B.P.

WHAT IS IN YOUR MEDICINE?

Your medicine is called Dispersible Aspirin 75mg Tablets B.P. and consists of white, round tablets which have <P> embossed on one face and are plain on the other. Each dispersible tablet contains the active ingredient aspirin 75mg and also contains lactose monohydrate, calcium carbonate E170, maize starch, citric acid E330, purified talc E553b, sodium saccharin E954 and sodium lauryl sulphate. The sodium content is less than 0. 1mg per tablet. Aspirin belongs to a class of medicines called NonSteroidal Anti-Inflammatory Drugs.
Available in dispensing pack sizes of 112 tablets, 500 and 1000 tablets.

MARKETING AUTHORISATION HOLDER
Bristol Laboratories Limited, Unit 3, Canalside, Northbridge Road, Berkhamsted, HP4 1EG, UK (PL 17907/0156)

MANUFACTURER
Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

WHAT IS YOUR MEDICINE FOR?

For the prevention of further heart attacks and strokes in patients with a previous history of heart attacks or stroke and following by-pass surgery.

BEFORE YOU TAKE YOUR MEDICINE

You should speak to your doctor before starting therapy as they will be able to advise you if this medicine is appropriate for your condition.
Do not take aspirin if:

- You are allergic to Aspirin or any other non-steroidal anti-inflammatory drugs, such as ibuprofen
- You are allergic to any of the other ingredients
- You have been told you suffer from haemophilia or a similar problem with blood clotting
- You are taking medicines to thin your blood such as warfarin.
- You are under 16 years old, unless your doctor has told you to take aspirin.
- You have had an asthma attack after taking aspirin
- You have gout
- You have a stomach ulcer or a history of stomach ulcers.

Take special care with aspirin if:

- You have liver or kidney problems.
- You are dehydrated
- You suffer from asthma
- You are elderly
- You have been told that you have glucose-6-phosphate dehydrogenase (G6PD) deficiency
- You have been told by your doctor that you have an intolerance to some sugars
- You are diabetic.

You should let your doctor know you are taking aspirin tablets, particularly if you are going to have an operation, as you may need to stop taking your tablets several days before the operation.
You should let your doctor know if you are pregnant or breast-feeding, or wish to become pregnant or start breast-feeding whilst taking this medicine.
Taking aspirin late in pregnancy may affect the onset and duration of labour, cause a tendency to bleed in both mother and baby and affect the baby's circulation and so should be avoided. Taking aspirin while breast-feeding could cause Reye's syndrome in the baby and so should be avoided.
There may be some problems if aspirin is taken with other medicines. Example of medicines which can affect aspirin are:-

- Drugs which are used to thin the blood – you should not take aspirin if you are on heparin, warfarin, or other tablets to thin the blood.
- Methotrexate, used to reduce inflammation
- Probenecid and sulphinpyrazone, used to treat gout.

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Size : 130x120 mm
Graphic Creations

Back

- Antacids, used to treat indigestion.
- Kaolin, used to treat diarrhoea.
- ACE Inhibitors, such as lisinopril, used to treat high blood pressure and heart failure
- Steroids such as cortisone and hydrocortisone
- Some diuretics, such as spironolactone, used to get rid of excess fluid from the body, and acetazolamide, used to treat glaucoma.
- Insulin and other drugs used to treat diabetes.
- Zafirlukast, used to treat asthma.
- Metoclopramide, used to treat nausea and vomiting.
- Mifepristone, used to terminate pregnancies. You should not take aspirin until eight to twelve days after mifepristone.
- Other non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, used to treat pain.
- Phenytoin and sodium valproate, used in epilepsy.
- Sulfonamides such as sulphamethoxazole, used to treat infections.
- Alcohol

Aspirin may affect the results of thyroid function tests. Tell your doctor or nurse if you are taking aspirin.
If you have any doubts about whether you should take these tablets, then discuss things more fully with your doctor or pharmacist.

TAKING YOUR MEDICINE

Follow the instructions on the label about how to take your medicine. Your pharmacist may also help you if you are not sure.
Consult a doctor before commencing therapy for the first time.
Dose: Unless otherwise directed by your doctor - For oral use
- Adults, the elderly and children over 16 years: The usual dose for long term use is one or two tablets once daily, dissolved in water. In some circumstances a doctor may advise a higher dose of up to 4 tablets daily.
DO NOT GIVE TO CHILDREN AGED UNDER 16 YEARS, UNLESS ON THE ADVICE OF A DOCTOR.
DO NOT EXCEED THE STATED DOSE.

If symptoms persist consult your doctor.
If you miss a single dose of Dispersible Aspirin 75mg Tablets B.P. do not worry and take your next one at the normal time. **DO NOT DOUBLE UP ON A DOSE TO MAKE UP FOR THE MISSING ONE.**
If you accidentally take a large number of tablets (overdose) you should contact the nearest hospital casualty department or tell your doctor immediately.

WHILE TAKING YOUR MEDICINE

Like many medicines, aspirin may cause side-effects in some patients, particularly when treatment is first started.
These can include irritation of the stomach lining (which can be aggravated by alcohol), skin reactions such as rash or hives, swelling of the face or eyes, difficulty with breathing, an asthma attack, wheezing, runny nose, anaemia and a tendency to bleed or bruise more easily. You should consult your doctor in all cases and stop taking the tablets immediately if you have any type of rash, swelling, breathing problems or notice blood in the vomit (looks like coffee grounds) or in stools (look tarry).
There is a possible association between aspirin and Reye's syndrome when given to children. Reye's syndrome is a very rare disease, which can be fatal. For this reason aspirin should not be given to children aged under 16 years, unless on the advice of a doctor.
If you experience any other unusual or unexpected symptoms which persist or are troublesome, consult your doctor or pharmacist.

STORING YOUR MEDICINE

Keep your medicine in the package or container in order to protect from moisture and light. Keep the bottle tightly closed. Keep your medicine in a safe place where children cannot see or reach it. The medicine could be harmful to them.
Do not store above 25°C.
Do not use these tablets after the expiry date printed on the pack.

Date of leaflet preparation: April 2005

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Size : 130x120 mm
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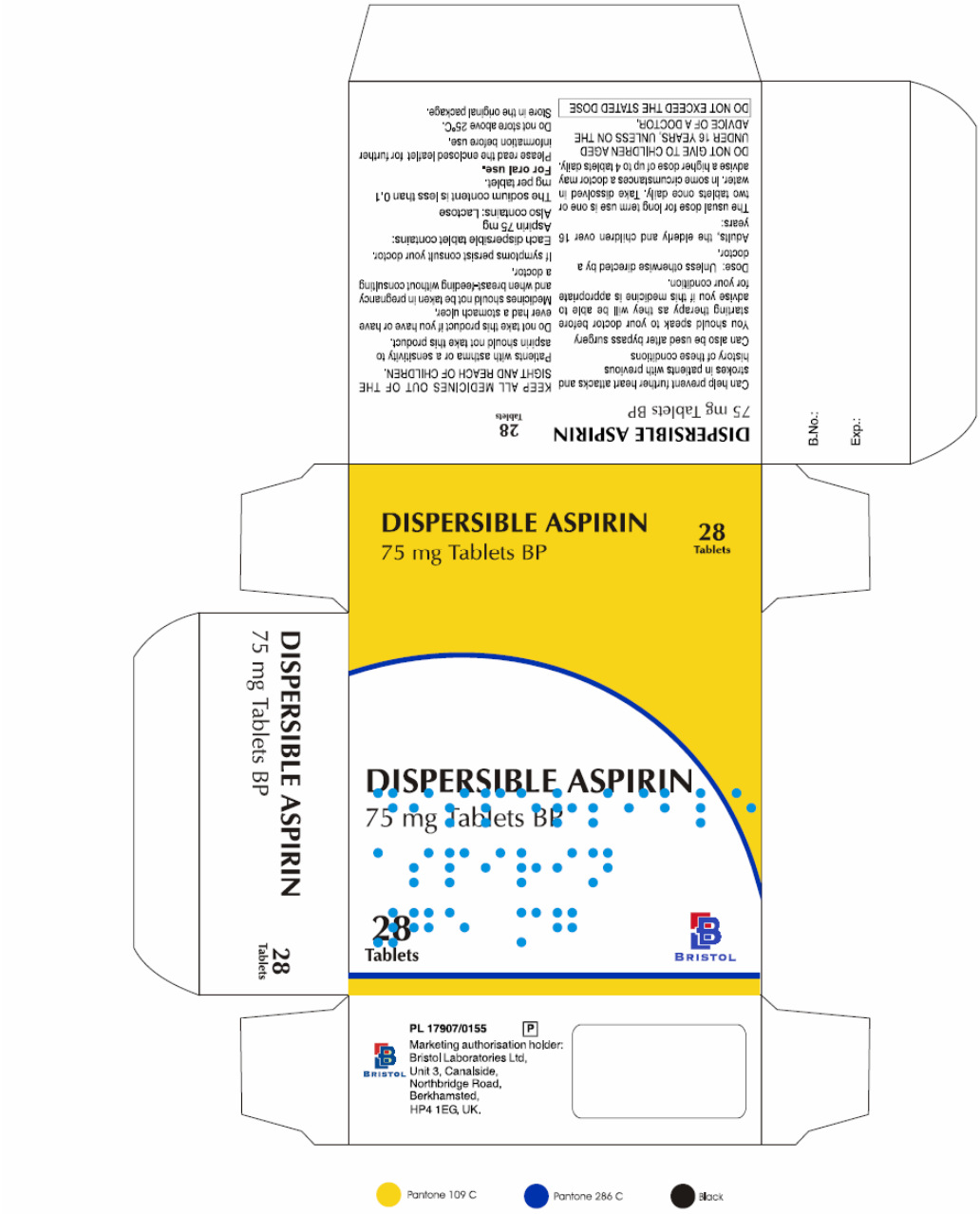
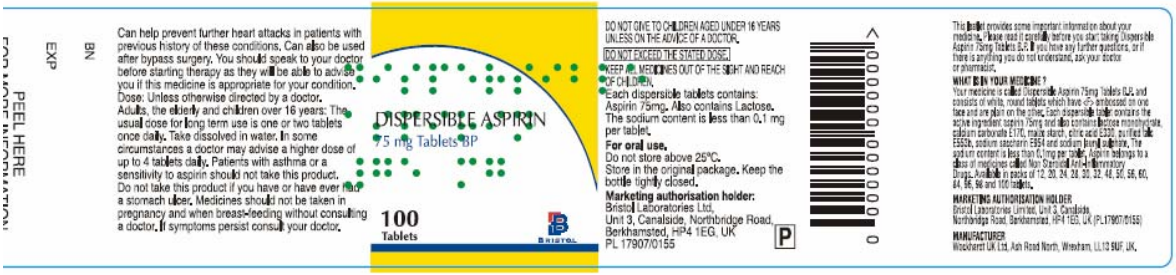
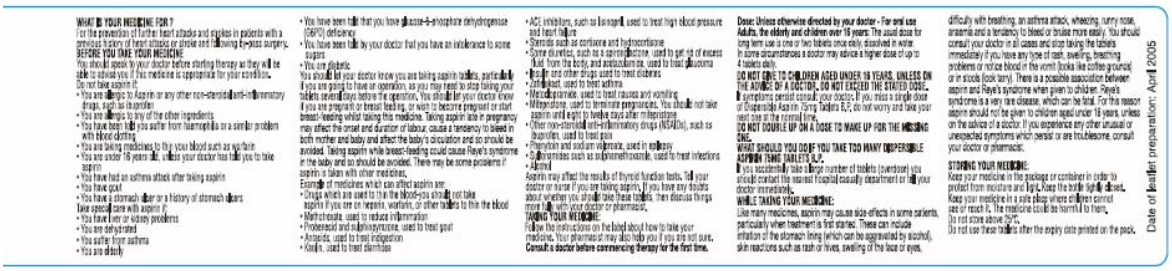
DISPERSIBLE ASPIRIN 75MG TABLETS BP
PL 17907/0155

LABELLING



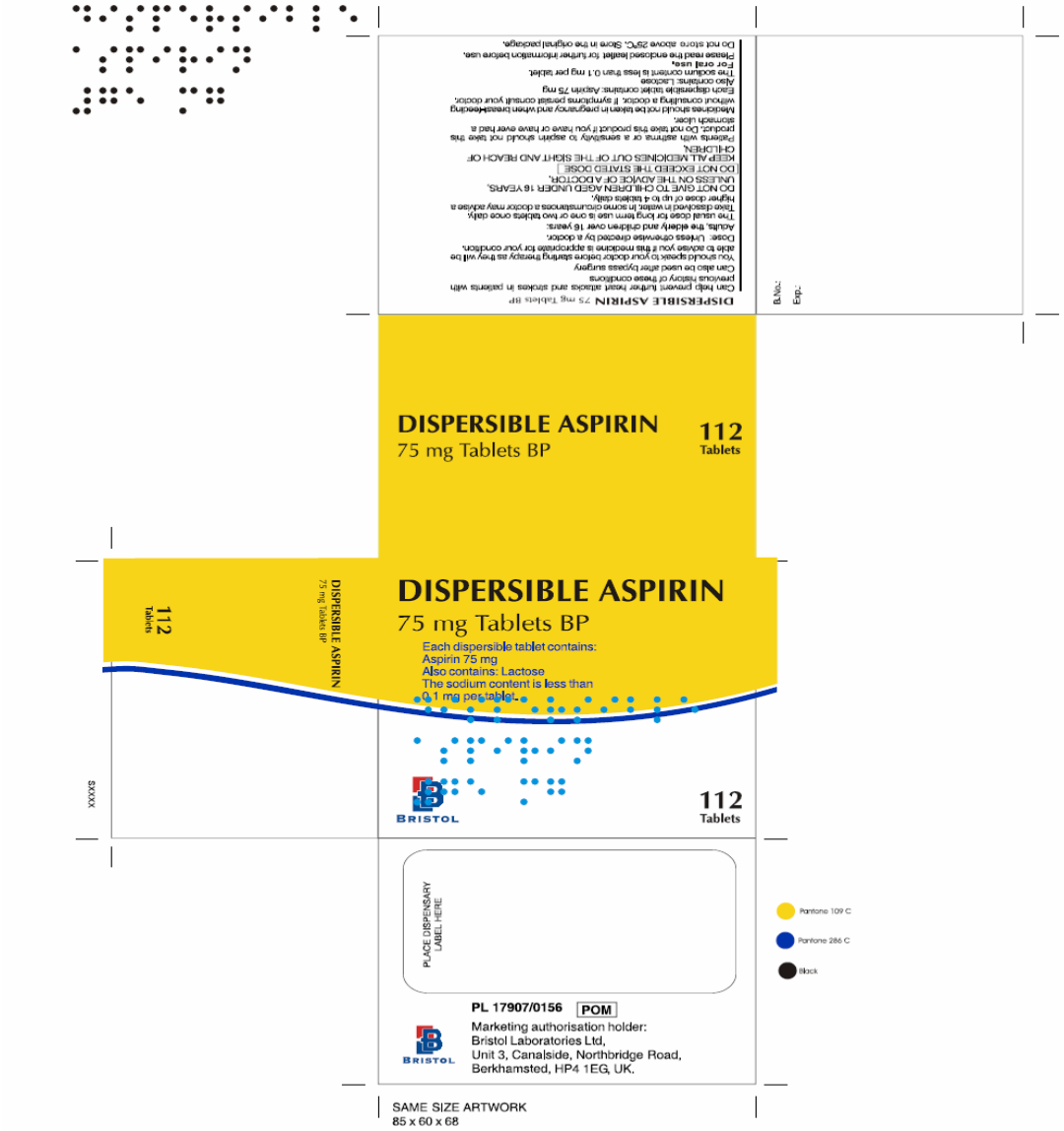

DISPERSIBLE ASPIRIN
75 mg Tablets BP
56
Tablets
DISPERSIBLE ASPIRIN
75 mg Tablets BP
56
Tablets
BRISTOL
PL 17907/0155
P
Marketing authorisation holder:
Bristol Laboratories Ltd,
Unit 3, Canalside,
Northbridge Road,
Berkhamsted,
HP4 1EQ, UK.
B.No.:
Exp.:
Pantone 109 C
Pantone 286 C
Black

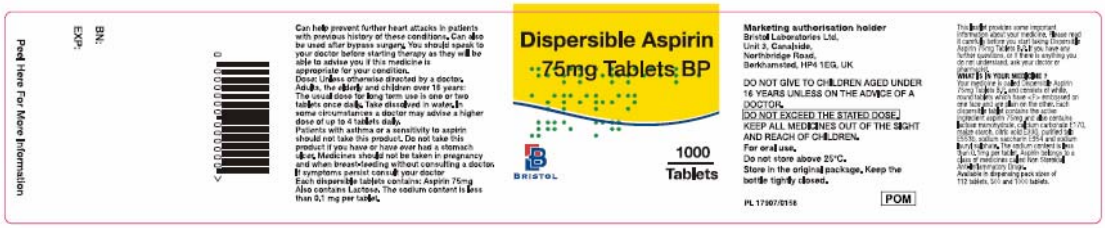

PEEL HERE
EXP
BN
Can help prevent further heart attacks in patients with previous history of these conditions. Can also be used after bypass surgery. You should speak to your doctor before starting therapy as they will be able to advise you if this medicine is appropriate for your condition.
Dose: Unless otherwise directed by a doctor.
Adults, the elderly and children over 16 years: The usual dose for long term use is one or two tablets once daily. Take dissolved in water. In some circumstances a doctor may advise a higher dose of up to 4 tablets daily. Patients with asthma or a sensitivity to aspirin should not take this product. Do not take this product if you have or have ever had a stomach ulcer. Medicines should not be taken in pregnancy and when breast-feeding without consulting a doctor. If symptoms persist consult your doctor.
DISPERSIBLE ASPIRIN
75 mg Tablets BP
100
Tablets
BRISTOL
DO NOT GIVE TO CHILDREN AGED UNDER 16 YEARS UNLESS ON THE ADVICE OF A DOCTOR.
DO NOT EXCEED THE STATED DOSE.
KEEP ALL MEDICINES OUT OF THE SIGHT AND REACH OF CHILDREN.
Each dispersible tablets contains: Aspirin 75mg. Also contains Lactose. The sodium content is less than 0.1 mg per tablet.
For oral use.
Do not store above 25°C.
Store in the original package. Keep the bottle tightly closed.
Marketing authorisation holder:
Bristol Laboratories Ltd,
Unit 3, Canalside, Northbridge Road,
Berkhamsted, HP4 1EG, UK
PL 17907/0155
P
This leaflet provides some important information about your medicine. Please read it carefully before you start taking Dispersible Aspirin 75mg Tablets B.P. If you have any further questions, or if there is anything you do not understand, ask your doctor or pharmacist.
WHAT IS IN YOUR MEDICINE?
Your medicine is called Dispersible Aspirin 75mg Tablets B.P. and consists of white, round tablets which have <5> embossed on one face and one plain on the other. Each dispersible tablet contains the active ingredient aspirin 75mg and also contains lactose monohydrate, calcium carbonate E170, maize starch, citric acid E330, purified talc E553b, sodium saccharin E954 and sodium lauryl sulphate. The sodium content is less than 0.1mg per tablet. Aspirin belongs to a class of medicines called Non Steroidal Anti-Inflammatory Drugs. Available in packs of 12, 20, 24, 28, 30, 32, 48, 50, 56, 60, 84, 96, 98 and 100 tablets.
MARKETING AUTHORISATION HOLDER
Bristol Laboratories Limited, Unit 3, Canalside, Northbridge Road, Berkhamsted, HP4 1EG, UK (PL 17907/0155)
MANUFACTURER
Woodstock UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.


WHAT IS YOUR MEDICINE FOR?
For the prevention of further heart attacks and strokes in patients with a previous history of heart attacks or stroke and following by-pass surgery.
BEFORE YOU TAKE YOUR MEDICINE
You should speak to your doctor before starting therapy as they will be able to advise you if this medicine is appropriate for your condition.
Do not take aspirin if:
• You are allergic to Aspirin or any other non-steroidal anti-inflammatory drugs, such as ibuprofen
• You are allergic to any of the other ingredients
• You have been told you suffer from haemophilia or a similar problem with blood clotting
• You are taking medicines to thin your blood such as warfarin
• You are under 16 years of age, unless your doctor has told you to take aspirin
• You have had an asthma attack after taking aspirin
• You have gout
• You have a stomach ulcer or a history of stomach ulcers (see special care with aspirin)
• You have liver or kidney problems
• You are dehydrated
• You suffer from asthma
• You are elderly
• You have been told that you have glucose-6-phosphate dehydrogenase (G6PD) deficiency
• You have been told by your doctor that you have an intolerance to some sugars
• You are diabetic
You should let your doctor know you are taking aspirin tablets, particularly if you are going to have an operation, as you may need to stop taking your tablets several days before the operation. You should let your doctor know if you are pregnant or breast feeding, or wish to become pregnant or start breast-feeding whilst taking this medicine. Taking aspirin late in pregnancy may affect the onset and duration of labour, cause a tendency to bleed in both mother and baby and affect the baby's circulation and so should be avoided. Taking aspirin while breast-feeding could cause Reye's syndrome in the baby and so should be avoided. There may be some problems if aspirin is taken with other medicines.
Examples of medicines which can affect aspirin are:
• Drugs which are used to thin the blood-you should not take aspirin if you are on heparin, warfarin, or other tablets to thin the blood
• Methotrexate, used to reduce inflammation
• Probenecid and sulphinpyrazone, used to treat gout
• Antacids, used to treat indigestion
• Kaolin, used to treat diarrhoea
• ACE inhibitors, such as lisinopril, used to treat high blood pressure and heart failure
• Steroids such as cortisone and hydrocortisone
• Some diuretics, such as a spironolactone, used to get rid of excess fluid from the body, and acetazolamide, used to treat glaucoma
• Insulin and other drugs used to treat diabetes
• Zafirlukast, used to treat asthma
• Metoclopramide, used to treat nausea and vomiting
• Mifepristone, used to terminate pregnancies. You should not take aspirin until eight to twelve days after mifepristone
• Other non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, used to treat pain
• Phenytoin and sodium valproate, used in epilepsy
• Sulfonamides such as sulphamethoxazole, used to treat infections
• Adrenal
Aspirin may affect the results of thyroid function tests. Tell your doctor or nurse if you are taking aspirin, if you have any doubts about whether you should take these tablets. Then discuss things more fully with your doctor or pharmacist.
TAKING YOUR MEDICINE
Follow the instructions on the label about how to take your medicine. Your pharmacist may also help you if you are not sure.
Consult a doctor before commencing therapy for the first time.
Dose: Unless otherwise directed by your doctor - For oral use
Adults, the elderly and children over 16 years: The usual dose for long term use is one or two tablets once daily, dissolved in water. In some circumstances a doctor may advise a higher dose of up to 4 tablets daily.
DO NOT GIVE TO CHILDREN AGED UNDER 16 YEARS, UNLESS ON THE ADVICE OF A DOCTOR. DO NOT EXCEED THE STATED DOSE.
If symptoms persist consult your doctor. If you miss a single dose of Dispersible Aspirin 75mg Tablets B.P. do not worry and take your next one at the normal time.
DO NOT DOUBLE UP ON A DOSE TO MAKE UP FOR THE MISSING ONE.
WHAT SHOULD YOU DO IF YOU TAKE TOO MANY DISPERSIBLE ASPIRIN 75MG TABLETS B.P.
If you accidentally take a large number of tablets (overdose) you should contact the nearest Hospital casualty department or tell your doctor immediately.
WHILE TAKING YOUR MEDICINE:
Like many medicines, aspirin may cause side-effects in some patients, particularly when treatment is first started. These can include irritation of the stomach lining (which can be aggravated by alcohol), skin reactions such as rash or hives, swelling of the face or eyes, difficulty with breathing, an asthma attack, wheezing, runny nose, anaemia and a tendency to bleed or bruise more easily. You should consult your doctor in all cases and stop taking the tablets immediately if you have any type of rash, swelling, breathing problems or notice blood in the vomit (looks like coffee grounds) or in stools (look tarry). There is a possible association between aspirin and Reye's syndrome when given to children. Reye's syndrome is a very rare disease, which can be fatal. For this reason aspirin should not be given to children aged under 16 years, unless on the advice of a doctor. If you experience any other unusual or unexpected symptoms which persist or are troublesome, consult your doctor or pharmacist.
STORING YOUR MEDICINE:
Keep your medicine in the package or container in order to protect from moisture and light. Keep the bottle tightly closed. Keep your medicine in a safe place where children cannot see or reach it. The medicine could be harmful to them.
Do not store above 25°C.
Do not use these tablets after the expiry date printed on the pack.
Date of leaflet preparation: April 2005

DISPERSIBLE ASPIRIN 75MG TABLETS BP
PL 17907/0156

LABELLING





MARKETING AUTHORISATION HOLDER
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MANUFACTURER
Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.
WHAT IS YOUR MEDICINE FOR ?
For the prevention of further heart attacks and strokes in patients with a previous history of heart attacks or stroke and following bypass surgery.
BEFORE YOU TAKE YOUR MEDICINE
You should speak to your doctor before starting therapy as they will be able to advise you if this medicine is appropriate for your condition.
Do not take aspirin if:
• You are allergic to Aspirin or any other non-steroidal anti-inflammatory drugs, such as ibuprofen
• You are allergic to any of the other ingredients
• You have been told you suffer from haemophilia or a similar problem with blood clotting
• You are taking medicines to thin your blood such as warfarin
• You are under 16 years old, unless your doctor has told you to take aspirin
• You have had an asthma attack after taking aspirin
• You have gout
• You have a stomach ulcer or a history of stomach ulcers
Take special care with aspirin if:
• You have liver or kidney problems
• You are dehydrated
• You suffer from asthma
• You are diabetic
• You have been told that you have glucose-6-phosphate dehydrogenase (G6PD) deficiency
• You have been told by your doctor that you have an intolerance to some sugars
• You are pregnant
You should let your doctor know you are taking aspirin tablets, particularly if you are going to have an operation, as you may need to stop taking your aspirin several days before the operation. You should let your doctor know if you are pregnant or plan on becoming pregnant or start breast-feeding while taking this medicine. Taking aspirin late in pregnancy may affect the onset and duration of labour, cause a tendency to bleed in both mother and baby and affect the baby's circulation and so should be avoided. Taking aspirin while breast-feeding could cause Reye's syndrome in the baby and so should be avoided.
There may be some problems if aspirin is taken with other medicines. Example of medicines which can affect aspirin are:
• Drugs which are used to thin the blood you should not take aspirin if you are on heparin, warfarin, or other tablets to thin the blood
• Methotrexate, used to reduce inflammation
• Probenecid and sulfinpyrazone, used to treat gout
• Antacids, used to treat indigestion
• Kaolin, used to treat diarrhoea
• ACE inhibitors, such as captopril used to treat high blood pressure and heart failure
• Steroids such as cortisone and hydrocortisone
• Some diuretics, such as a spironolactone, used to get rid of excess fluid from the body and acetazolamide, used to treat glaucoma
• Insulin and other drugs used to treat diabetes
• Sulfinpyrazone, used to treat gout
• Metoclopramide, used to treat nausea and vomiting
• Mifepristone, used to terminate pregnancies. You should not take aspirin until 8-12 days after day of mifepristone
• Other non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, used to treat pain
• Probenecid and sodium sulphinpyrazone, used in arthritis
• Sulphonamides such as cotrimoxazole, used to treat infections
• Alcohol
Aspirin may affect the results of thyroid function tests. Tell your doctor or nurse if you are taking aspirin, if you have any doubts about whether you should take these tablets, then consult your Boots name tab with your doctor or pharmacist.
TAKING YOUR MEDICINE
Follow the instructions in the box carefully. Ask your doctor or pharmacist if you are not sure how to take your medicine. Your medicine should work best if you take it regularly at the same time each day.
Consult a doctor before commencing this dose - Parental use
Dose: Unless otherwise directed by a doctor,
Adults, the elderly and children over 16 years: The usual dose for long term use is one or two tablets once daily, dissolved in water. In some circumstances a doctor may advise a higher dose of up to 4 tablets daily.
DO NOT GIVE TO CHILDREN AGED UNDER 16 YEARS, UNLESS ON THE ADVICE OF A DOCTOR.
DO NOT EXCEED THE STATED DOSE.
If symptoms persist consult your doctor. If you miss a single dose of Dispersible Aspirin 75mg Tablets BP, do not worry and take your next dose at the normal time.
IF YOU FORGET FOR TWO OR MORE DOSES, CONSULT YOUR DOCTOR OR PHARMACIST.
IF YOU STOP TAKING YOUR MEDICINE
If you stop taking your medicine your condition will return.
IF YOU TAKE TOO MUCH (OVERDOSE)
If you accidentally take a large number of tablets (overdose) you should contact the nearest hospital casualty department or your doctor immediately.
WHILE TAKING YOUR MEDICINE
Like many medicines, aspirin may cause side-effects in some patients, particularly when treatment is first started. These can include irritation of the stomach lining (which can be aggravated by alcohol), skin reactions such as rash or hives, swelling of the face or eyes, difficulty with breathing, an asthma attack, wheezing, runny nose, anaemia and a tendency to bleed or bruise more easily. You should consult your doctor in all cases and stop taking the tablets immediately if you have any type of rash, swelling, breathing problems or notice blood in the vomit (looks like coffee grounds) or in stools (look tarry). There is a possible association between aspirin and Reye's syndrome when given to children. Reye's syndrome is a very rare disease, which can be fatal. For this reason aspirin should not be given to children aged under 16 years, unless on the advice of a doctor. If you experience any other unusual or unexpected symptoms which persist or are troublesome, consult your doctor or pharmacist.
STORING YOUR MEDICINE
Keep your medicine in the package or container in order to protect from moisture and light. Keep bottle tightly closed. Keep your medicine in a safe place where children cannot see or reach it. The medicine could be harmful to them. Do not store above 25°C. Do not use these tablets after the expiry date printed on the pack.
Date of last revision: April 2005