

ASPIRIN 300MG TABLETS BP (ACETYLSALICYLIC ACID)

PL 17907/0152

PL 17907/0153

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ASPIRIN 300MG TABLETS BP (ACETYLSALICYLIC ACID)

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LAY SUMMARY

The MHRA granted Bristol Laboratories Limited Marketing Authorisations (licences) for the medicinal product Aspirin 300mg Tablets BP (PL 17907/0152, PL 17907/0153 and PL 17907/0154) on 16th January 2006. This medicine is used for the relief of mild to moderate pain, for the symptomatic relief of feverishness and for the symptomatic relief of muscular aches and pains and joint swelling and stiffness. This medicinal product is available on the shelf, over the counter or by prescription.

Aspirin tablets contain the active ingredient acetylsalicylic acid (aspirin), which is a painkiller, reduces temperature and has anti-inflammatory properties.

These applications are duplicates of a previously granted application for Aspirin Tablets BP 300mg (PL 00211/5000R) and, as such, these products can be used interchangeably.

No new or unexpected safety concerns arose from these simple applications and it was, therefore, judged that the benefits of taking Aspirin 300mg Tablets BP outweigh the risks, hence Marketing Authorisations have been granted.

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted marketing authorisations for the medicinal products Aspirin 300mg Tablets BP (PL 17907/0152, PL17907/0153 and PL17907/0154) to Bristol Laboratories Ltd on 16 January 2006. This medicinal product is available as GSL, P and POM.

The applications were submitted as informed consent abridged applications according to article 10.1(a)(i) of Directive 2001/83/EC, cross-referring to Aspirin tablets 300mg BP (PL 00211/5000R), which was granted a marketing authorisation on 19th June 1980.

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 product was granted prior to the introduction of current legislation, no public assessment report was generated for it.

The products contain the active ingredient aspirin which is an analgesic, antipyretic and has anti-inflammatory properties. Aspirin tablets are indicated for the relief of mild to moderate pain, for the symptomatic relief of influenza, feverishness, feverish colds and for the symptomatic relief of sprains, strains, rheumatic pain, sciatica, lumbago, fibrositis, muscular aches and pains, joint swelling & stiffness.

These applications for Aspirin 300mg Tablets BP were submitted at the same time and were assessed concurrently. Consequently, all sections of this Scientific Discussion refer to all products.

PHARMACEUTICAL ASSESSMENT

INTRODUCTION

These are abridged applications made under Article 10.1(a)(i) of EC Directive 2001/83 and are considered to be essentially similar products to that of PL 00211/5000R (Aspirin Tablets BP 300mg). The licence is held by The Wallis Laboratory Ltd, granted 19th June 1980.

A letter of consent has been supplied by the marketing authorisation holder for cross-reference to PL 00211/5000R in conjunction with this application.

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

A valid certificate of suitability has been supplied for the active substance.

EXPERT REPORTS

Satisfactory statements have been provided, signed by appropriately qualified experts.

PRODUCT LITERATURE

1. SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

The SPCs supplied are satisfactory and consistent with the cross-reference product.

2. LABELLING

The labels supplied are satisfactory and consistent with the cross-reference product.

3. PATIENT INFORMATION LEAFLET (PIL)

The PILs supplied are satisfactory and consistent with the cross-reference product.

4. MARKETING AUTHORISATION APPLICATION (MAA)

The MAA forms are satisfactory and consistent with the cross-reference product.

RECOMMENDATION

Grant of a Marketing Authorisation is acceptable.

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 for PL 00211/5000R, 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

Acetylsalicylic acid is a well known drug and has been used as an analgesic, antipyretic and anti-inflammatory for many years. These applications are identical to the approved marketing authorisation for Aspirin Tablets BP 300mg (PL0211/5000R).

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 product and, as such, can be used interchangeably. Extensive clinical experience with acetylsalicylic acid is considered to have demonstrated the therapeutic value of the compound. The risk benefit is therefore considered to be positive.

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STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application 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 23/02/2005, 20/06/2005, and 07/12/2005.
4	The applicant responded to the MHRA's requests, providing further information on 18/05/2005, 15/08/2005, and 01/09/2005.
5	The application was determined on 16/01/2006

ASPIRIN 300MG TABLETS BP (ACETYLSALICYLIC ACID)

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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

ASPIRIN 300MG TABLETS BP (ACETYLSALICYLIC ACID)

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SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Aspirin 300mg Tablets BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains aspirin 300mg

For excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets

White biconvex tablets; breakline on one side and debossed <A> on other side

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the relief of mild to moderate pain, including headache, migraine, neuralgia, toothache, sore throat, period pains, aches and pains.

For the symptomatic relief of influenza, feverishness, feverish colds.

For the symptomatic relief of sprains, strains, rheumatic pain, sciatica, lumbago, fibrositis, muscular aches and pains, joint swelling & stiffness.

4.2. Posology and method of administration

For oral use.

Adults and children over 16 years of age:

One to three tablets.

Dose should not be repeated more frequently than 4 hour intervals and not more than 4 times in any 24 hour period.

If symptoms persist for more than 3 days, consult your Doctor.

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

4.3. Contraindications

- Children under 16 years unless specifically indicated (e.g. for Kawasaki's disease)
- Active peptic ulceration or a history of peptic ulceration
- Haemophilia, other coagulopathies, or concurrent anticoagulant therapy
- Hypersensitivity to aspirin or other NSAIDs or any of the excipients (see section 6.1)
- 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 taken in patients with glucose-6-phosphate dehydrogenase deficiency as haemolytic anaemia may occur.

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 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.

If symptoms persist for more than 3 days consult your doctor.

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. Interactions 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: 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 sulfinpyrazone may be reduced.

4.6. Pregnancy and lactation

There is clinical and epidemiological evidence of the safety of aspirin in pregnancy.

Aspirin may prolong gestation, delay the onset of or prolong labour and may 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 late pregnancy may cause the premature closure of the foetal ductus arteriosus, possibly leading to persistent 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 (G6PD) deficiency.

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 gastrointestinal irritation with slight asymptomatic blood loss.

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.

a) 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, thrombocytopenia, 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.

b) 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

N02B A01 (Nervous system – analgesics/antipyretics)

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

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Starch
Lactose monohydrate
Purified talc (E553b)

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years.

6.4. Special precautions for storage

Do not store above 25°C.
Blister packs: store in the original package.

6.5. Nature and contents of container

Blister packs:
8, 10, 12 or 16 as GSL.

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

6.6. Instruction for use, handling and disposal

None.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

PL17907/0152

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16/01/2006

10. DATE OF REVISION OF THE TEXT

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PL 17907/0153**

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1. NAME OF THE MEDICINAL PRODUCT

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2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains aspirin 300mg

For excipients, see section 6.1.

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Tablets

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4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the relief of mild to moderate pain, including headache, migraine, neuralgia, toothache, sore throat, period pains, aches and pains.

For the symptomatic relief of influenza, feverishness, feverish colds.

For the symptomatic relief of sprains, strains, rheumatic pain, sciatica, lumbago, fibrositis, muscular aches and pains, joint swelling & stiffness.

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For oral use.

Adults and children over 16 years of age:

One to three tablets.

Dose should not be repeated more frequently than 4 hour intervals and not more than 4 times in any 24 hour period.

If symptoms persist for more than 3 days, consult your Doctor.

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

4.3. Contraindications

- Children under 16 years unless specifically indicated (e.g. for Kawasaki's disease)
- Active peptic ulceration or a history of peptic ulceration.
- Haemophilia, other coagulopathies, or concurrent anticoagulant therapy
- Hypersensitivity to aspirin or other NSAIDs or any of the excipients (see section 6.1)
- 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 taken in patients with glucose-6-phosphate dehydrogenase deficiency as haemolytic anaemia may occur.

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 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.

If symptoms persist for more than 3 days consult your doctor.

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. Interactions 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)

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

Uricosurics: Effect of probenecid and sulfinpyrazone may be reduced.

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Aspirin may prolong gestation, delay the onset of or prolong labour and may 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 late pregnancy may cause the premature closure of the foetal ductus arteriosus, possibly leading to persistent pulmonary hypertension.

4.7. Effects on ability to drive and use machines

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

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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 (G6PD) deficiency.

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 gastrointestinal irritation with slight asymptomatic blood loss.

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.

a) 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, thrombocytopenia, 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.

b) 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

N02B A01 (Nervous system – analgesics/antipyretics)

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

Aspirin inhibits prostaglandin synthetase.

5.2. Pharmacokinetic properties

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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.

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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

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Starch

Lactose monohydrate

Purified talc (E553b)

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 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 bottle tightly closed.

6.5. Nature and contents of container

Blister packs:
20, 24, 28, 30 or 32 as Pharmacy.

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

Polypropylene/polyethylene Containers:
25 tablets as Pharmacy.

6.6. Instruction for use, handling and disposal

None.

7. MARKETING AUTHORISATION HOLDER

Bristol Laboratories Ltd,
Unit 3, Canalside,
Northbridge Road,
Berkhamsted,
HP4 1EG
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1. NAME OF THE MEDICINAL PRODUCT

Aspirin 300mg Tablets BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains aspirin 300mg

For excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets

White biconvex tablets; breakline on one side and debossed <A> on other side

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the relief of mild to moderate pain, including headache, migraine, neuralgia, toothache, sore throat, period pains, aches and pains.

For the symptomatic relief of influenza, feverishness, feverish colds.

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4.2. Posology and method of administration

For oral use.

Adults and children over 16 years of age:

One to three tablets.

Dose should not be repeated more frequently than 4 hour intervals and not more than 4 times in any 24 hour period.

If symptoms persist for more than 3 days, consult your Doctor.

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

4.3. Contraindications

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

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

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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. Interactions 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: 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 sulfinpyrazone may be reduced.

4.6. Pregnancy and lactation

There is clinical and epidemiological evidence of the safety of aspirin in pregnancy.

Aspirin may prolong gestation, delay the onset of or prolong labour and may 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 late pregnancy may cause the premature closure of the foetal ductus arteriosus, possibly leading to persistent 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 (G6PD) deficiency.

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 gastrointestinal irritation with slight asymptomatic blood loss.

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.

a) 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, thrombocytopenia, 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.

b) 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

N02B A01 (Nervous system – analgesics/antipyretics)

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

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Starch

Lactose monohydrate

Purified talc (E553b)

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 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 bottle tightly closed.

6.5. Nature and contents of container

Blister packs:
48, 50, 96 or 100 as POM.

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

Polypropylene/polyethylene Containers:
50, 100, 250, 500, 1000 and 5,000.

6.6. Instruction for use, handling and disposal

None.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

PL 17907/0154

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16/01/2006

10. DATE OF REVISION OF THE TEXT

ASPIRIN 300MG TABLETS BP (ACETYLSALICYLIC ACID)

PL 17907/0152

PL 17907/0153

PL 17907/0154

PRODUCT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET FOR ASPIRIN 300MG TABLETS B.P.

This leaflet provides some important information about your medicine. Please read it carefully before you start taking Aspirin 300mg 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 YOUR MEDICINE?

Your medicine is called Aspirin 300mg Tablets B.P. and consists of white, round tablets which have <A> embossed on one face and a breakline on the other. Each tablet contains the active ingredient aspirin 300mg and also contains lactose monohydrate, starch and purified talc (E553b). Aspirin belongs to a class of medicines called non-steroidal anti-inflammatory drugs. It has analgesic (pain relieving), antipyretic (temperature reducing) and anti-inflammatory properties.

PACK SIZE

Available in packs of 8, 10, 12 or 16 tablets.

MARKETING AUTHORISATION HOLDER

Bristol Laboratories Limited, Unit 3, Canalside, Northbridge Road, Berkhamsted, HP4 1EG, UK (PL17907/0152)

MANUFACTURER

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

WHAT IS YOUR MEDICINE FOR?

For the relief of mild to moderate pain, including headache, migraine, neuralgia, toothache, sore throat, period pains, aches and pains. For the symptomatic relief of influenza, feverishness and feverish colds. For the symptomatic relief of sprains, strains, rheumatic pain, sciatica, lumbago, fibrositis, muscular aches and pains, joint swelling and stiffness.

BEFORE YOU TAKE YOUR MEDICINE

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 similar problem with blood clotting.
- You are taking medicines to thin your blood such as warfarin.
- You have a stomach ulcer or history of stomach ulcers.
- 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 been told by your doctor that you have an intolerance to some sugars.

Take special care with aspirin if:

- You are dehydrated.
- You suffer from asthma.
- You have kidney or liver problems.
- You are elderly.
- You have been told that you have glucose-6-phosphate dehydrogenase (G6PD) deficiency.
- 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.

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

- Drugs 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 sulphinyprazone used to treat gout.

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- Antacids 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 relieve pain.
- Phenyton, and sodium valproate used in epilepsy.
- Sulfonamides such as sulphamethoxazole, used to treat infections.

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.

Dose: Unless otherwise directed by your doctor- For oral use

Adults and children over 16 years: One to three tablets to be swallowed whole with water. The dose should not be taken more frequently than every 4 hours and not more than 4 times in any 24 hour period.

Maximum daily dose: 12 tablets (3.6g) in divided doses.

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 for more than 3 days, consult your Doctor.

If you miss a single dose of Aspirin 300mg 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 ASPIRIN 300MG 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 unwanted 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), inflammation of the lining of the nose, swelling of the face or eyes, difficulty in breathing or wheezing, an asthma attack, anaemia, skin rashes 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 a rash or 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.

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, so this should be avoided. Taking aspirin while breast-feeding could cause Reye's syndrome in the baby and should also be avoided.

If you experience any other side-effects or feel that this medicine is affecting you badly, tell your doctor or pharmacist.

STORING YOUR MEDICINE

Keep your medicine in the package in which it was given to you in order to protect from moisture. 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 expiry date printed on the pack.

Date of leaflet preparation: July 2005

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ASPIRIN 300MG TABLETS BP (ACETYLSALICYLIC ACID)
PL 17907/0152
PL 17907/0153
PL 17907/0154

8 TABLETS
 ALLU FOL SIZE 198 mm
 SAME SIZE ARTWORK

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**ASPIRIN 300MG TABLETS BP (ACETYSALICYLIC ACID)
PL 17907/0153**



● Pantone 107 C
● Black




**ASPIRIN 300MG TABLETS BP (ACETYSALICYLIC ACID)
PL 17907/0154**

<p align="center">48 Tablets</p> <p align="center">ASPIRIN 300 mg Tablets BP</p>	<p align="center">ASPIRIN 48 300 mg Tablets BP Tablets</p>	<p align="center">Dose: Etab:</p>
<p align="center">48 Tablets</p> <p align="center">ASPIRIN 300 mg Tablets BP</p>	<p align="center">ASPIRIN 48 300 mg Tablets BP Tablets</p> <p align="center">Each tablet contains: Aspirin 300 mg Also contains: Lactose</p> <p align="center">For The Effective Relief of Pain</p> 	<p align="center">48 Tablets</p>
<p align="center">PLACE DISPENSARY LABEL HERE</p>	<p>PL 17907/0154 POM Marketing authorisation holder: Bristol Laboratories Ltd, Unit 3, Canal Side, Northbridge Road, Berkhamsted, HP4 1EQ, UK.</p>	

SAME SIZE ARTWOK
85 x 45 x 68

Pantone 109 C
 Black

ASPIRIN 300MG TABLETS BP (ACETYLSALICYLIC ACID) PL 17907/0154

<p>Please read the enclosed leaflet for further information before use.</p> <p>For the treatment of mild to moderate pain and symptoms of: Headache, Migraine, Neuralgia, Toothache, Sore Throat, Period Pains, Influenza, Feverishness, Colds, Sprains, Strains, Sciatica, Rheumatic Pain, Lumbago, Fibrositis, Muscular Pain, Joint Swelling, Stiffness</p> <p>Dose: Unless otherwise directed by a Doctor, Adults and children over 15 years: 1 to 3 tablets to be taken with water. Do not take more frequently than every 4 hours and not more than 4 times in any 24 hour period. If symptoms persist for more than 3 days consult a doctor.</p> <p>DO NOT GIVE TO CHILDREN AGED UNDER 16 YEARS, UNLESS ON THE ADVICE OF A DOCTOR.</p> <p>WARNING: DO NOT EXCEED THE STATED DOSE</p> <p>KEEP ALL MEDICINES OUT OF THE SIGHT AND REACH OF CHILDREN.</p> <p>Do not take this product if you are allergic to any of the ingredients. Patients with asthma or a sensitivity to Aspirin should not take this product.</p> <p>Do not take this product if you have, or have ever had a stomach ulcer.</p> <p>Medicines should not be taken in pregnancy and when breast feeding without consulting a Doctor.</p> <p>For oral use. Do not store above 25°C. Keep the bottle tightly closed.</p>	 <p>ASPIRIN 300 mg Tablets BP</p> <p>Each tablet contains: Aspirin 300 mg Also contains Lactose</p> <p>For The Effective Relief of Pain</p> <p>250 Tablets</p> <p>BRISTOL</p>	<p>BN : EXP:</p> <p>POM</p> <p>PL 17907/0154</p> <p>Marketing authorisation holder: Bristol Laboratories Ltd, Unit 3, Canalside, Northbridge Road, Berkhamsted, HP4 1EG, UK.</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">PLACE DISPENSARY LABEL HERE</p>
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SAME SIZE ARTWORK
160 x 70 mm



Pantone 109 C



Black