SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Disprin

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient	mg/Tablet	Specification
Aspirin	300.00	Ph Eur

3 PHARMACEUTICAL FORM

Dispersible tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of mild to moderate pain in headaches, including migraine headaches, toothache, neuralgia, sciatica, period pains and sore throats.

Reduction of temperature in feverishness, influenza and colds.

Reduction of inflammation in rheumatism and lumbago.

4.2 Posology and method of administration

Oral administration after dissolution in water.

Adults (including children 16 years and over): Two to three tablets every 4 hours. Do not exceed 13 tablets in 24 hours.

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

There is no indication that dosage need be modified in the elderly.

4.3 Contraindications

Should not be given to patients suffering from a previous history of peptic ulceration or active peptic ulceration or haemophilia.

4.4 Special warnings and precautions for use

The product labelling will include:

Do not give to children under 16 years unless on the advice of a doctor.

Keep out of reach of children.

If you are receiving regular medical treatment, are asthmatic, allergic to aspirin or have or have had a stomach ulcer, seek your doctor's advice before taking this product.

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

Aspirin may enhance the effects of anticoagulants and inhibit the effects of uricosurics.

Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. However, the limitations of these data and the uncertainties regarding extrapolation of *ex-vivo* data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen use (see section 5.1).

4.6 Pregnancy and lactation

There is clinical and epidemiological evidence of the safety of aspirin in human pregnancy, but it may prolong labour and contribute to maternal and neonatal bleeding and is best avoided at term and during breastfeeding.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

May precipitate bronchospasm and induce attacks of asthma or hypersensitivity in susceptible subjects. May also induce gastrointestinal haemorrhage, occasionally major.

4.9 Overdose

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

Management

Give activated charcoal if an adult presents within one hour of ingestion of more than 250 mg/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 >700 mg/L (5.1 mmol/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

Aspirin:

Aspirin inhibits the cyclo-oxygenase enzyme involved in conversion of phospholipids to prostaglandins and its effects on the body are believed to result primarily from prevention of prostaglandin production. These effects include peripheral analgesia, fever reduction, reduction in inflammation and inhibition of platelet aggregation.

Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. In one study, when a single dose of ibuprofen 400mg was taken within 8 hours before or within 30 minutes after immediate release aspirin dosing (81mg), a decreased effect of aspirin on the formation of thromboxane or platelet aggregation occurred. However, the limitations of these data and the uncertainties regarding extrapolation of *ex vivo* data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be like for occasional ibuprofen use.

5.2 Pharmacokinetic properties

Aspirin is rapidly absorbed from the stomach and upper gastrointestinal tract with peak levels after around 20-30 minutes following dissolution. It is subject to first-pass metabolism with an overall bioavailability of around 70%. Metabolism is by conversion to salicylic acid and then by further conversion to other metabolites. These are excreted by the kidneys in both free and conjugated form. The plasma half-life of aspirin is around 15-20 minutes and that of salicylic acid is 2-3 hours.

5.3 Preclinical safety data

No preclinical findings of relevance have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium carbonate, maize starch, citric acid, talc, sodium lauryl sulphate, saccharin, crospovidone and lime flavour.

6.2 Incompatibilities

None known.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Store below 25°C in a dry place.

6.5 Nature and contents of container

Cardboard carton containing tablets in strips of aluminium foil with vinyl heat seal. Pack sizes: 6, 8, 12, **16**, 24, **32**, 48, 96 and 500 tablets. (Those pack sizes printed in bold are currently sold).

6.6 Special precautions for disposal

Oral administration after dissolution in water.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benekiser Healthcare (UK) Limited
Dansom Lane
Hull
HU8 7DS
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 00063/0017.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24/04/1995 / 23/02/2004

10 DATE OF REVISION OF THE TEXT

26/01/2009