SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Disprin Direct

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient	mg/Tablet	Specification
Aspirin	300	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 tension headaches, migraine headaches, toothache, neuralgia, period pains, rheumatic pain, lumbago and sciatica. To relieve the symptoms of influenza, feverishness, feverish colds and ease sore throats.

4.2 Posology and method of administration

Disprin Direct disperses on the tongue without water.

Adults and children 16 years and over: One to three tablets to a maximum of 13 tablets in 24 hours. The dose may be repeated after 4 hours, but the maximum dose in 24 hours must not be exceeded.

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

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

4.3 Contraindications

Should not be given to patients suffering from active peptic ulceration or haemophilia.

Doses > 100 mg/day during the third trimester of pregnancy.

4.4 Special warnings and precautions for use

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

The product labelling will include "Do not give to children aged under 16 years unless on the advice of a 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 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).
Metamizole may reduce the effect of acetylsalicylic acid on platelet aggregation when taken concomitantly. Therefore, this combination should be used with caution in patients taken low dose aspirin for cardioprotection.

4.6 Pregnancy and lactation

Doses of above 100 mg/day and up to 500 mg/day:

There is insufficient clinical experience regarding the use of doses above 100 mg/day up to 500 mg/day. Therefore, the recommendations below for doses of 500 mg/day and above apply also for this dose range.

Doses of 500 mg/day and above:

From the 20th week of pregnancy onward, acetylsalicylic acid use may cause oligohydramnios resulting from foetal renal dysfunction. This may occur shortly after treatment initiation and is usually reversible upon discontinuation. In addition, there have been reports of ductus arteriosus constriction following treatment in the second trimester, most of which resolved after treatment cessation. Therefore, during the first and second trimester of pregnancy, acetylsalicylic acid should not be given unless clearly necessary. If acetylsalicylic acid is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible. Antenatal monitoring for oligohydramnios and ductus arteriosus constriction should be considered after exposure to acetylsalicylic acid for several days from gestational week 20 onward. Acetylsalicylic acid should be discontinued if oligohydramnios or ductus arteriosus constriction are found.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:

- cardiopulmonary toxicity (premature constriction/closure of the ductus arteriosus and pulmonary hypertension);

- renal dysfunction (see above);

the mother and the neonate, at the end of pregnancy, to:

- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses;

-inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, acetylsalicylic acid at doses higher than 100 mg/day is contraindicated during the third trimester of pregnancy (see section 4.3), and is best avoided during breastfeeding.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

May precipitate bronchospasm and induce attacks of asthma or

hypersensitivity in susceptible subjects. May also induce gastrointestinal haemorrhage, occasionally major.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions

via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

Glycine

Maize starch

Microcrystalline cellulose

Purified talc

Saccharin

Lemon flavour 51124

6.2 Incompatibilities

None stated

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

Vinyl coated heat sealed foils (4, 6, 8, **16**, 24 and 48 tablet packs). (Only the packs printed in bold are currently marketed).

6.6 Special precautions for disposal

Disprin Direct disperses on the tongue without water.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Limited,

Dansom Lane,

Hull,
HU8 7DS
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00063/0018.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24/04/1995 / 20/05/2005

10 DATE OF REVISION OF THE TEXT

21/07/2025