Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

ASCAL Powders

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains 823mg carbasalate calcium equivalent to 650 mg acetylsalicylic acid.

3 PHARMACEUTICAL FORM

Powder for oral solution
A white, crystalline powder, odourless or weakly smelling of acetic acid, with a weak, bitter sour taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an analgesic and antipyretic agent, for the relief of mild to moderate pain and/or reduction of fever associated with such disorders as influenza, colds, headache, toothache, rheumatic pains, neuralgia, period and muscle pains.

4.2 Posology and method of administration

The usual dose is one sachet dissolved in water, repeated four to six hourly as necessary. A maximum dose of six sachets per day should not be exceeded. The sachet should be dissolved in a glass half-filled with water and stirred if necessary, and the solution taken immediately.

4.3 Contraindications

- Haemorrhagic brain infarction.
- Patients with gastric complaints and patients who have had gastric pain during earlier use.
- Active peptic ulcer.
- Hypersensitivity to aspirin (e.g. asthmatics may develop an attack or collapse).
- Impaired hepatic function.
- Haemophilia or other bleeding disorders.
- Patients who are being treated with anticoagulants.
- Use in children under 12 years.
- Breast feeding.

4.4 Special warnings and precautions for use

Do not take Ascal Powders shortly before or shortly after the extraction of teeth because of the risk of increase in bleeding time. Temporary discontinuation of the therapy has to be determined on an individual basis. In general, a period of one week will be sufficient. If complaints continue, change or return, seek medical advice.

4.5 Interaction with other medicinal products and other forms of interaction

Acetylsalicylic acid enhances:

- The activity of anticoagulants (e.g. coumarin, heparin);

- the risk of gastric bleeding with concurrent administration of
- corticosteroids;
- the effects and adverse reactions of NSAIDs;
- the effects of sulphonylurea hypoglycaemic agents;
- adverse reactions of methotrexate.

Acetylsalicylic acid diminishes:

- The effect of frusemide, uricosuric agents and spironolactone.

Do not use any of the above mentioned agents together with Ascal Powders without doctor's advice.

4.6 Pregnancy and lactation

Results of studies concerning the use of acetylsalicylic acid during pregnancy in humans cannot completely exclude any harmful effect on the foetus.

In animal studies teratogenicity has been demonstrated at high doses.

Acetylsalicylic acid can enter the foetal circulation and cause intoxication. During pregnancy Ascal Powders should only be used on doctor's advice, especially during the last three months. Acetylsalicylic acid is contraindicated in breast-feeding (Reye's Syndrome).

4.7 Effects on ability to drive and use machines

An effect on the ability to drive and use machines is not to be expected.

4.8 Undesirable effects

Gastrointestinal disturbances, loss of blood in the gastrointestinal tract (mostly occult). Long or frequent use can lead to anaemia.

Hypersensitivity reactions e.g. bronchospasm.

4.9 Overdose

Symptoms of moderately severe salicylate poisoning are: dizziness, headache, tinnitus, confusion and gastro-intestinal discomfort (vomiting, stomach ache, nausea).

Symptoms of severe salicylate poisoning are mainly caused by disturbances of the acid-base balance. Initially hyperventilation does occur, leading to respiratory alkalosis. At a later stage, respiratory acidosis occurs caused by depression of the respiratory centre.

Meanwhile, a metabolic acidosis arises as a result of the presence of salicylate.

Usually, young children will be seen in a late stage of intoxication; in most cases they will be in the stage of acidosis. Other intoxication symptoms may be: hyperthermia and transpiration leading to dehydration, restlessness, convulsions, hypoglycaemia and hallucinations.

Depression of the nervous system can lead to coma, cardiovascular collapse and respiratory depression.

The lethal dose of acetylsalicylic acid is 25-30 gram. Plasma salicylate concentrations of 300 mg/l and more, point at an intoxication.

Patients who have taken toxic doses should be admitted in a hospital. In the event of a mild intoxication, the patient

should be made to vomit; if necessary the patient's stomach should be emptied.

Alkalinisation of the urine should be considered at concentrations of 350-500 mg/l. In the event of a severe intoxication (> 700 mg/l = 5.1 mmol/l) haemodialysis is to be preferred. Further symptoms should be treated symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Analgesic, ATC Code N02BA15.

Ascal Powders contain the calcium salt of acetylsalicylic acid which is readily soluble in water. Ascal Powders have antipyretic, antiphylogistic, analgesic and platelet aggregation inhibitory properties.

5.2 Pharmacokinetic properties

Absorption

Following oral administration acetylsalicylic acid is rapidly absorbed from proximal part of the small intestine. The maximum plasma concentration is reached after 0.5-2 hours. During absorption a significant part of the dose is hydrolysed in the intestine wall. Simultaneous administration of food can delay the absorption (resulting in lower blood plasma concentrations), but does not decrease it.

Distribution

The distribution volume of acetylsalicylic acid is 0.16 l/kg body weight. The primary and anti-inflammatory active metabolite salicylic acid is bound to plasma proteins, mainly albumin, up to 90%.

Salicylic acid is slowly transported to the synovial membrane and synovial fluid by diffusion. The drug readily crosses the placental barrier and is excreted in mother's milk.

Metabolism

Acetylsalicylic acid is primarily hydrolysed into salicylic acid. The half life of acetylsalicylic acid is short with a value of approximately 15-20 minutes. Salicylic acid is metabolised into conjugates of glycine and glucuronic acid and small amounts of gentisic acid. At higher therapeutic doses, the pharmacokinetics are non-linear, resulting in a longer apparent elimination half life of salicylic acid from a few hours to approximately 24 hours.

Excretion

The excretion mainly takes place via the kidneys. The tubular reabsorption of acetylsalicylic acid is pH dependent. The urinary excretion of salicylic acid appears to be sensitive to variation in the urinary pH. The amount of unchanged acetylsalicylic acid in the urine can be increased from 10 to 80% by alkalinisation of the urine.

5.3 Preclinical safety data

Not relevant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Urea
Calcium

6.2 Incompatibilities

None.

6.3 Shelf Life

Five years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Box of 12 or 100 sachets.

The sachets have been made of a special, airtight aluminium foil (paper/polyethylene/aluminium foil/polyethylene), which precludes water absorption from the air.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Meda Health Sales Ireland Ltd
Office 10, Dunboyne Business Park
Dunboyne
Co. Meath

8 MARKETING AUTHORISATION NUMBER

PA 1332/12/1

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