Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Kelfizine W Tablets, 2g

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sulfalene (sulfametopyrazine) 2g.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Tablet
White, flat, uncoated tablets marked ‘LONGUM’ on one side.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the treatment of infections due to micro-organisms sensitive to this anti-infective, including chronic bronchitis and urinary tract infections.

4.2 Posology and method of administration

Adults and children over the age of 12 years

The usual dose is 2 grams (i.e. one tablet) weekly. Each tablet should be stirred into half a tumbler full of water or orange squash.

Elderly

As hepatic conjugation and renal clearance occur at a reduced rate in the elderly, caution is advised when prescribing the drug for long periods of time to avoid accumulation.

Children under 12 years of age

Kelfizine W tablets are contra-indicated for use in children under 12.

4.3 Contraindications

Kelfizine W Tablets are contra-indicated in:

Children aged 12 years and less.
Lactating women who are breast feeding infants.
Patients hypersensitive to sulphonamides.
Patients suffering from porphyria, jaundice, intestinal obstruction or renal failure.

4.4 Special warnings and precautions for use

This drug should only be used with great caution in patients with hepatic or renal dysfunction, dehydration or blood dyscrasias.

Absorption of this sulphonamide may be increased in patients with ulcerative lesions of the bowel.

Adequate fluid intake should be ensured during administration.

Prolonged use of any anti-infective may lead to super-infection due to organisms resistant to that anti-infective.

4.5 Interaction with other medicinal products and other forms of interaction

Use of sulphonamides in conjunction with folic acid antagonists or hypoglycaemics may increase the effects of these agents.

Sulphonamides, and thus also sulfalene, may potentiate the effects of coumarin derivatives, some oral anti-diabetic agents (sulphonylureas) and some diaminopyrimidine derivatives (trimethoprim, pyrimethamine).

Paraminobenzoic acid can antagonise the antibacterial activity of sulfalene.

4.6 Pregnancy and lactation

Some sulphonamides have been shown to be teratogenic in animal studies. No such effects have been reported with use during human pregnancy. The product should only be used during pregnancy if considered essential by the physician and should not be used during breast feeding.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Side effects include nausea, vomiting, rashes. Occasionally severe reactions such as erythema multiforme and Stevens-Johnson syndrome, epidermal necrolysis, eosinophilia, agranulocytosis, granulocytopenia, purpura, and leucopenia have been reported with sulphonamides.

4.9 Overdose

Doses of up to 8 grams have been taken over 36 hours without evidence of ill effects. To increase excretion, a high fluid intake should be maintained for seven days and the urine rendered alkaline with potassium citrate mixture BP or sodium bicarbonate. The sulphonamide will then be retained in the urine at higher concentrations in the form of the alkali metal salt.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sulfalene is a bacteriostatic agent exerting its influence via the competitive antagonism of p-aminobenzoic acid so that the micro-organisms are prevented from incorporating p-aminobenzoic acid during the formation of folic acid. Micro-organisms that rely on the formation of folic acid from the precursor p-aminobenzoic acid are, therefore, sensitive to the action of sulfalene.

5.2 Pharmacokinetic properties

Sulfalene, administered orally has been shown to be well absorbed from the gastro-intestinal tract. The rate of absorption is rapid; maximum plasma concentrations being obtained 4-8 hours after administration. Once absorbed, sulfalene has been shown to enter all body fluids and secretions. In the plasma, 64 % of the drug is bound to plasma proteins.

Sulfalene undergoes metabolic alteration in the body, most commonly occurring at the sulphamido-and amino-nitrogen atoms. Sulfalene and its metabolites are mainly excreted from the kidneys, only 5-8 % being eliminated in the bile after 24 hours. The biological half-life of the drug is approximately 65 hours, the slow rate of elimination being due to 80-90 % tubular re-absorption in the kidneys.

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 this Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Sodium carboxymethylcellulose
Maize starch
Amylose 75HA
Sodium lauryl sulphate
Purified talc
Magnesium stearate
Saccharin sodium
Mandarin orange flavour
Lemon flavour

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

Individual tablets are contained in aluminium/aluminium or aluminium/PVC blisters and packed in cartons of 5.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 236/5/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of authorisation: 01 April 1977

Date of last renewal: 01 April 2002

10 DATE OF REVISION OF THE TEXT

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