Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Colomycin Tablets 1,500,000 Units

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1,500,000 units of Colistin Sulphate.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet
Off-white smooth flat tablets with the Pharmax logo embossed on one surface and a quarter breakline on the other. The tablets can be divided into equal halves.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of gastrointestinal infections caused by sensitive Gram negative organisms. Also for bowel preparation.

Colistin sulphate is not absorbed from the gastro-intestinal tract and must not, therefore, be used for systemic infections.

4.2 Posology and method of administration

To be taken orally.

Adults and children over 30kg b.w.:

The usual dose is 1.5 to 3.0 million units every 8 hours.

Children up to 15kg:

The usual dose is 0.25 to 0.50 million units every 8 hours.

Children 15 - 30 kg:

The usual dose is 0.75 - 1.5 million units every 8 hours.

A minimum of five days treatment is recommended. Dosage may be increased when clinical or bacteriological response is slow. For bowel preparation, a 24 hour course at the normal dosage above is given. Treatment should preferably finish 12 hours before surgery.

4.3 Contraindications

Contra-indicated in patients with known sensitivity to colistin.

4.4 Special warnings and precautions for use

Colistin should only be administered with great caution in patients with renal dysfunction or decreased urinary output (as in shock) since the consequent retention of drug will increase potential for toxicity. Colistin is subject to limited and unpredictable absorption from the GI tract in infants under six months. Studies in older children and in adults have demonstrated no systemic absorption of colistin following oral administration.

Nevertheless, caution should be employed in the use of the preparation in patients receiving curariform muscle relaxants. Do not use for systemic therapy.

Prolonged administration of an anti-infective may result in the development of superinfection due to organisms resistant to that anti-infective.

4.5 Interaction with other medicinal products and other forms of interaction

Neurotoxicity has been reported in association with the concomitant use of either curariform agents or antibiotics with similar neurotoxic effects.

Respiratory arrest has been reported.

4.6 Fertility, pregnancy and lactation

Safety in human pregnancy has not been established and Colomycin is not recommended for use during pregnancy and lactation. Animal studies do not indicate teratogenic properties; however, parenteral single dose studies in human pregnancy show that Colomycin crosses the placental barrier and there is a risk of foetal toxicity if repeated doses are given to pregnant patients. Colomycin is secreted in breast milk and patients to whom the drug is administered should not breast feed an infant.

4.7 Effects on ability to drive and use machines

No specific warnings.

4.8 Undesirable effects

No significant systemic absorption has been found to occur in older children and adults following oral administration nor have any systemic side effects been reported.

These adverse effects may include transient sensory disturbances such as perioral paraesthesia and vertigo.

Neuro-toxicity and adverse effects on renal function have been reported in association with systemic over-dosage, failure to reduce dosage in patients with renal insufficiency and the concomitant use of either curariform agents or antibiotics with similar neurotoxic effects. Therapy need not be discontinued and reduction of dosage may alleviate symptoms. Permanent nerve damage such as deafness or vestibular damage has not been reported.

4.9 Overdose

No symptoms of overdosage have been reported following oral use of colistin. However, following systemic administration overdosage can result in renal insufficiency, muscle weakness and apnoea.

There is no specific antidote; manage by supportive treatment plus attempts to increase the rate of elimination of colistin, e.g. mannitol diuresis, prolonged haemodialysis or peritoneal dialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Colistin is a polypeptide antibiotic derived from *Bacillus polymyxa var. colistinus*.

It possesses a rapid bactericidal activity against a number of Gram-negative organisms, including *Pseudomonas aeruginosa* and is largely free from the development or transference of resistance.

5.2 Pharmacokinetic properties

Studies on the gastrointestinal absorption of colistin have shown no significant systemic absorption following oral administration in adults and older children.

Limited and unpredictable absorption is, however, evident in infants under 6 months.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Maize starch
Colloidal silicon dioxide
Hydrogenated castor oil

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened: 3 years

6.4 Special precautions for storage

Store below 25ºC . Store in the original container.

6.5 Nature and contents of container

Pack of 50 tablets in a plastic container with a plastic lid, in a white or grey polypropylene body and white low density polyethylene closure.

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

Forest Laboratories UK Limited
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8 MARKETING AUTHORISATION NUMBER

PA 100/1/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1977

Date of last renewal: 01 April 2007

10 DATE OF REVISION OF THE TEXT

September 2009