1. NAME OF THE MEDICINAL PRODUCT
Avro Antidiarrhoeal Mixture

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 5ml contains

Light Kaolin 1g

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
An Oral suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Symptomatic treatment of moderate to severe diarrhoea in adults and children.

4.2 Posology and method of administration

Posology:

Dosage:
Adults & children above 12 years: 30ml
Children 6 – 12 year): 15ml
Children 3- 5 years: 10ml
Infants under 3 years: 2.5ml

The appropriate dose should be taken at half hourly intervals until symptoms abate.
Normally 3 to 4 doses should be sufficient.
If symptoms persist consult your doctor.

Directions for use: Shake the bottle before use.

Method of administration:
Oral.

4.3 Contraindications
Avro Antidiarrhoeal Mixture is contraindicated in intestinal obstruction and in patients with known hypersensitivity to kaolin.
It should be in reduced dosage in all patients with severe liver disease, especially if there's evidence of jaundice, or encephalopathy. It should also be kept to a minimum in patients with renal failure, to avoid possibility of toxicity, increased sensitivity and side effects.
Concomitant use of this preparation with Analgesics, Antibacterials, Antiepileptics, Antimalerials, Antifungals and Antipsychotics should be avoided because of the reduction in absorption of these drugs when taken with Kaolin

4.4 Special warnings and precautions for use
Treatment should be accompanied by adequate fluid intake and electrolyte replacement.
Avoid prolong use
Avro Antidiarrhoel Mixture may reduce the absorption of other drugs, so avoid concurrent administration with other drugs.

4.5 Interaction with other medicinal products and other forms of interaction
As kaolin is adsorbent, the absorption of other drugs from the gastro-intestinal tract administered concomitantly may be reduced. Kaolin possibly reduces absorption of aspirin, tetracycline, chloroquine and hydroxychloroquine and phenothiazines.

4.6 Pregnancy and Lactation
No teratogenic effect has been reported with the use of kaolin. It is not excreted in breast-milk. However the policy of avoiding drug therapy especially in the first trimester of pregnancy should be borne in mind.

4.7 Effects on ability to drive and use machines
None expected at recommended doses and duration of therapy.

4.8 Undesirable effects
The most common effects associated with administration of the preparation include constipation, bloating and fullness mostly due to the large quantity taken in cases where the diarrhoea episodes recur in rapid succession over several hours.
Constipation and dehydration may also occur.

4.9 Overdose
Prolonged use or overdosage may result in diarrhoea with excessive loss of water and electrolytes, particularly potassium. Nausea and vomiting have occasionally been reported following high dose but these are not usually common.
Since kaolin is little or unabsorbed, excessive dosage can be removed by emesis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Light kaolin is a natural adsorbent antidiarrhoeal agent that has been used as an adjunct to rehydration therapy in the management of diarrhoea. Up to 24g daily can be taken orally in divided doses.
When given by mouth it adsorbs toxic and other substances from the gastrointestinal tract and increases the bulk of the faeces. It is employed in the symptomatic treatment of diarrhoea. It should be noted that a consequence of diarrhoea may be fluid and electrolyte depletion, and that rehydration therapy may be necessary, especially in infants and young children.

5.2 Pharmacokinetic properties
Kaolin is not absorbed following oral administration. It remains unchanged throughout transit of the gastrointestinal tract.

5.3 Preclinical safety data
No data of relevance to the prescriber, which is additional to that included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Kaolin Light
Methyl Hydroxylbenzoate
Glycerol
Dichlorobenzyl Alcohol
Xanthan Gum
FD & C Yellow No. 40 (Allura Red)
Deionised Water

6.2 Incompatibilities
None.

6.3 Shelf life
3 Years.

6.4 Special precautions for storage
Store below 30°C. Keep all medication out of the reach of children

6.5 Nature and contents of container

Amber 100ml bottle with aluminium screw cap in outer carton.
Pack size: 100ml.

6.6 Special precautions for disposal and other handling
None.

7 APPLICANT/MANUFACTURER

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