

# SUMMARY OF PRODUCT CHARACTERISTICS

## (SmPC)

### 1. Name of the medicinal product

Diastop Suspension

### 2. Qualitative and quantitative composition

Each 1ml contains Diastop contains 200mg of Kaolin Light B.P.

For the full list of excipients, see section 6.1.

### 3. Pharmaceutical form

Suspension.

Afaint-pink suspension.

### 4. Clinical particulars

#### 4.1 Therapeutic indications

Diastop suspension is used in arresting mild to moderate diarrhoea of any etiology in patients.

#### 4.2 Posology and method of administration

Adult & Children above 12 years: 15-30ml every 4-6 hours.

Children 6 to 12 years: 10-15ml every 4-6 hours.

Children 3 to 6 years: 5-10ml every 4-6 hours.

Children up to 3 years: Consult your Doctor.

#### Method of Administration

Oral administration only

#### 4.3 Contraindications

Hypersensitivity to Kaolin

#### **4.4 Special warnings and precautions for use**

Treatment of Diarrhoea with Diastop suspension must be accompanied by adequate intake of fluid and electrolyte replacement.

Diastop suspension 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**

- **Clindamycin (Cleocin) interacts with KAOLIN**

Kaolin might decrease how quickly the body absorbs of clindamycin (Cleocin), an antibiotic. But it probably doesn't decrease the amount of clindamycin (Cleocin) that is absorbed.

- **Digoxin (Lanoxin) interacts with KAOLIN**

Kaolin might decrease the absorption and decrease the effectiveness of digoxin (Lanoxin), a heart medication. To avoid a potential interaction, separate digoxin (Lanoxin) and kaolin doses by at least two hours.

- **Quinidine interacts with KAOLIN**

Kaolin might decrease the absorption and decrease the effectiveness of quinidine (Quinidex), a heart medication. To avoid a potential interaction, separate quinidine (Quinidex) and kaolin doses by at least two hours.

- **Trimethoprim (Proloprim) interacts with KAOLIN**

Kaolin might decrease the absorption and decrease the effectiveness of trimethoprim (Proloprim), an antibiotic. To avoid a potential interaction, separate trimethoprim (Proloprim) and kaolin doses by at least two hours.

#### **4.6 Pregnancy and Lactation**

FDA Pregnancy: Category C. Kaolin does not cross the placenta. There are no data regarding kaolin in breast-feeding.

#### **4.7 Effects on ability to drive and use machines**

No significant effects have been reported.

#### **4.8 Undesirable effects**

Side effects including constipation, particularly in children and the elderly.  
Do not inhale kaolin. It can cause lung problems.

#### **4.9 Overdose**

## Symptoms

In the unlikely event of accidental or inadvertent overdosage if the dosage is greatly exceeded or large doses are used for a long period, it is theoretically possible that symptoms of hypermagnesaemia may occur. These occur when the serum magnesium concentration exceeds 2 mmol/litre and include flushing, thirst, hypotension, weakness, drowsiness and loss of tendon reflexes. Respiratory depression, cardiac arrhythmias and ultimately cardiac arrest may result.

Similarly, metabolic alkalosis may result from overdosage of sodium bicarbonate. Symptoms include shortness of breath, muscle weakness, mental disturbances such as restlessness, convulsions and coma. Excessive doses may lead to sodium overloading and hyperosmolarity.

## Emergency Procedures and Antidotes

Hypermagnesaemia may be treated by injection of calcium gluconate to counteract respiratory depression or heart block. In normal renal function, adequate fluids should be given to assist magnesium removal but dialysis may be necessary in renal impairment or severe hypermagnesaemia.

Treatment of metabolic alkalosis and hypernatraemia consists mainly of appropriate correction of fluid and electrolyte balance.

## 5. Pharmacological properties

### 5.1 Pharmacodynamic properties

Kaolin is an adsorptive agent.

#### **Mechanism of action:**

Kaolin adsorbs water, toxins and bacteria, contributing to firmer stools, reducing fluid loss from diarrhea.

### 5.2 Pharmacokinetic properties

Kaolin is not absorbed and remains unchanged throughout transit of the gastrointestinal tract.

### 5.3 Preclinical safety data

No data available

## **6. Pharmaceutical particulars**

### **6.1 List of excipients**

Methyl paraben  
Propyl paraben  
Xanthan gum  
Bronopol  
Propylene glycol  
Citrus Pectin  
Tatrazine orange  
Orange flavour  
Allura Red colour

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

3 years.

### **6.4 Special precautions for storage**

Store below 30 ° C.

### **6.5 Nature and contents of container**

Diastop suspension is packaged in white HDPE plastic bottle of 100ml

### **6.6 Special precautions for disposal and other handling**

No special requirements for disposal

## **7. APPLICANT/MANUFACTURER**

Afrab Chem Limited  
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