BIORAJ PHARMACEUTICALS LIMITED	
BRAND NAME: DIANON SUSPENSION	**GENERIC NAME: Kaolin Light 200mg/ml**
SUMMARY OF PRODUCT CHARACTERISTICS	

1. NAME OF THE MEDICINAL PRODUCT

Dianon Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Kaolin Light 200mg/ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DIANON suspension is used for the symptomatic management of mild to chronic diarrhea.

4.2 Posology and method of administration

Age	Dose	Frequency
Adults	15-30ml	Every 4-6hours
Children (6-12years)	5-1 0ml	Every 4-6hours
Children (3-6years)	5-10ml	Every 4-6hours
Children (below 3years)	Consult your doctor	Consult your doctor

4.3 Contraindications

DIANON suspension is contraindicated in patients with obstructive bowel lesions.

4.4 Special warnings and precautions for use

As this product contains sodium hydrogen carbonate, it should not be administered to patients with metabolic or respiratory alkalosis, hypocalcaemia or hypochlorhydria, and should be administered with caution in patients with congestive heart failure, renal impairment, cirrhosis of the liver, hypertension and to patients receiving corticosteroids.

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.

Sodium hydrogen carbonate may also reduce or delay absorption of other drugs as a result of its antacid effect.

4.6 Fertility, pregnancy and lactation

This product should not be used in pregnancy or whilst breastfeeding unless recommended by a doctor.

4.7 Effects on ability to drive and use machines

When taken at therapeutic dose, DIANON suspension is usually free from side effects since light kaolin is not absorbed from the gastro-intestinal tract. Excessive doses may lead to constipation.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

Treatment should consist of naloxone administration, aspiration and gastric lavage with assisted respiration (if necessary), and maintenance of fluid and electrolytes.

Excessive administration of sodium hydrogen carbonate may lead to metabolic alkalosis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Kaolin is an adsorbent, it adsorbs toxic and other substances from the alimentary tract and increases the bulk of the faeces.

Sodium hydrogen carbonate is an alkalising agent and antacid.

5.2 Pharmacokinetic properties

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

Sodium hydrogen carbonate is neutralised in the stomach with the formation of carbon dioxide. Any remaining is absorbed and excreted as bicarbonate and sodium ions in the urine in the absence of a plasma deficit.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose

Ethanol 96 %

Sodium CMC

Sodium benzoate

Methyl paraben

Propyl paraben

Peppermint oil

Tween 80

Aerosol powder

Tartrazine yellow

Ponceau 4R

6.2 Incompatibilities

None.

6.3 Shelf life

36 Month

6.4 Special precautions for storage

Store below 30°C. Keep tightly closed.

6.5 Nature and contents of container

100ml: Pet bottle with polypropylene cap.

6.6 Special precautions for disposal and other handling

None.

7. MANUFACTURER

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