1. **NAME OF THE MEDICINAL PRODUCT**
Ultracoal 250mg Tablet

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**
Each film coated tablet contains Ultracoal 250mg

3. **PHARMACEUTICAL FORM**
Tablet

4. **CLINICAL PARTICULARS**

4.1. Therapeutic indications

Emergency treatment of acute oral poisoning or drug overdose. Ultracoal adsorbs toxic substances and reduces or prevents systematic absorption. The shorter the time interval between ingestion of the toxicant and the administration of Ultracoal, the greater is the benefit for the patient. However, as the absorption of massive drug overdoses is often retarded in acute conditions of intoxication, even the delayed administration of Ultracoal may be beneficial. In severe intoxication, repeated administration of Ultracoal is recommended to prevent absorbed drug being released (in an unbound state) in the lower intestinal tract or to expedite the elimination and prevent the re-absorption of any drug undergoing enterohepatic circulation.

4.2. Posology and method of administration

Posology

Adults

By mouth:

For drug overdose or poisoning: 50-100 grams of activated charcoal is given at first, followed by charcoal every 2-4 hours at a dose equal to 12.5 grams per hour. Sometimes a single dose of 25-100 grams of activated charcoal may be used.

Children.

By mouth:

For drug overdose or poisoning: Activated charcoal 10-25 grams is recommended for children up to one year of age, while activated charcoal 25-50 grams is recommended for children 1-12 years of age. Activated charcoal 10-25 grams is recommended if multiple doses of activated charcoal are needed.

4.3. Contraindications

There are no contraindications to the use of Ultracoal

4.4. Special warnings and precautions for use

The value of Ultracoal in the treatment of poisoning by strong acids, alkalis and other corrosive substances is limited. It should also be borne in mind that the presence of charcoal will render difficult any immediate endoscopy that may be required. Ultracoal is poor at binding cyanide, iron salts and some solvents including methanol, ethanol and ethylene glycol. In cases where the toxicant has diuretic properties or has been ingested with alcohol, plenty of fluid should be given after the administration of Ultracoal. Ultracoal should not be used concurrently with systemically active oral emetics or oral antidotes such as methionine since such agents would be adsorbed by the charcoal.

Ultracoal should only be administered to unconscious patients who have a cuffed endotracheal tube in place to protect the airway.

Ultracoal contains glycerol as an excipient, which may cause headache, stomach upset and diarrhoea.

4.5. Interaction with other medicinal products and other forms of interaction

The purpose of the product is to interact with other medicaments and toxicants taken in overdosage. There are no systemic interactions because the product is not absorbed from the gut.

4.6. Pregnancy and lactation

There is no evidence to suggest that Ultracoal should not be used during pregnancy or lactation. The product is not systemically absorbed.

4.7. Effects on ability to drive and use machines.

None (the product is not systemically absorbed).

4.8 Undesirable effects

In general, Ultracoal is well tolerated. Some patients may however experience constipation or diarrhoea. Activated charcoal has been associated with bezoar formation, intestinal obstruction and, rarely, intestinal perforation following multiple dosing – although a direct causative association has not been demonstrated.

Faecal impaction has been reported in a patient treated for an overdose of a diuretic with alcohol.

Aspiration of activated charcoal has been reported to cause airway obstruction and appropriate precautions should be taken.

Activated charcoal will produce black stools which may be alarming to the patient but is medically insignificant.

4.9 Overdose

Not applicable. In theory severe constipation would result from excessive use and this could be treated with laxatives.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Activated charcoal has well documented adsorptive properties and is effective in reducing the absorption of a wide range of toxicants, including drugs taken in overdose. From the gut, in addition, there is evidence that the administration of activated charcoal can enhance the elimination of some compounds by creating an effective concentration gradient from the circulation to the gut.

5.2 Pharmacokinetic properties

Activated charcoal is not systemically absorbed.

5.3 Preclinical safety data

No findings have been reported which add to the prescribing information given in other sections.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

6.2 Incompatibilities

Not applicable

6.3 Shelf life

6.4 Special precautions for storage

Store below 30°C in the original blister in the provided carton and protect from direct sunlight.
Keep all medicines out of the reach of children.

6.5 Nature and contents of container

1 X 10 tablets packed in ALU/PVC blisters placed in a inner carton with insert.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Supplier and Manufacture

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