1.5 PRODUCT INFORMATION

1.5.1 Prescribing Information (Summary of Products Characteristics)

1. NAME OF DRUG PRODUCT

1. Name of drug product

Activated Charcoal Tablets 0.25 g

1.1 (Trade) name of product

AGOCARB TABLETS

1.2 Strength

Each uncoated tablet contains:
Activated Charcoal BP 0.25 g

1.3 Pharmaceutical Dosage Form

Uncoated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

2.1 Qualitative Declaration

Each uncoated tablet contains:
Activated Charcoal BP 0.25 g

2.2 Quantitative Declaration

Ingredients	Specification	Label Claim	Qty. / Tab.
ACTIVE			
Activated charcoal	BP	0.25 g	255.00 mg
NON ACTIVE			
Sucrose	BP	-	100.00 mg
Gelatin	BP	-	7.00 mg
Maize starch (10% extra added to compensate LOD.)	BP	-	133.328 mg
Magnesium Stearate	BP	-	6.000 mg
Gum tragacanth	BP	-	25.00 mg
Microcrystalline cellulose Powder	BP	-	75.00 mg
Purified talc	BP	-	10.00 mg
Poly Vinyl Pyrrolidone	BP	-	0.500 mg
Sodium starch glycolate	BP	-	21.00 mg

BP = British Pharmacopoeia 2019.

3. PHARMACEUTICAL DOSAGE FORM

Uncoated tablets

Black coloured, circular, biconvex, uncoated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Activated charcoal is used as an antidote to poisoning, as an antiflatulent, and as a potential treatment for reducing blood lipid concentrations in patients with uremia and diabetes.

4.2 Posology and Method of Administration

Acute oral poisoning

Adult: 25-100 g as a single dose. For multiple-dose treatment: 50-100 g as an initial dose followed by not <12.5 g every hr. Alternatively, 25 mg every 2 hr or 50 mg every 4 hr.

Child: <1 yr: 1 g/kg/dose; 1-12 yr: 25-50 g/dose.

Gastrointestinal disorders

Adult: 0.975 - 3.9 g tid.

Food(before/after)

Should be taken on an empty stomach (i.e. At least one hour before food or two hours after food). (Take on an empty stomach w/ plenty of liqd. Allow to disintegrate in water w/ stirring or take whole w/ liqd. Take at least 2 hr before or 2 hr after other medications. Avoid milk, ice cream & cocoa.)

Method of administration : Oral

4.3 Contraindications

Single-dose activated charcoal is contraindicated in patients with unprotected airways and decreased levels of consciousness who are not intubated. Activated charcoal is also contraindicated if its use increases the risk and severity of aspiration, particularly with low viscosity, aliphatic hydrocarbons (eg, kerosene, lighter fluid, lamp oil). In cases of hydrocarbons with systemic toxicity (ie, benzene) or coingestion with a systemic toxin, charcoal use may be considered. Patients who are at risk of

hemorrhage or GI perforation caused by pathology, recent surgery, or medical conditions could be further compromised by single-dose activated charcoal. The presence of activated charcoal in the GI tract may obscure endoscopic visualization, but a corrosive is not an absolute contraindication when charcoal is used for coingested agents that are systemic toxins. The acronym PHAILS represents the following situations in which activated charcoal use is not helpful, requires caution, or is contraindicated: P–Pesticides, petroleum distillated, unprotected airway; H–Hydrocarbons, heavy metals, greater than 1 hour; A–Acids, alkali, alcohols, altered level of consciousness, aspiration risk; I–Iron, ileus, intestinal obstruction; L–Lithium, lack of gag reflex; S–Solvents, seizures.

4.4 Special Warnings and Precautions for Use

Decreased peristalsis: administer within 1 hr of ingestion. Induce vomiting of ipecac syr before admin of charcoal to prevent adsorption of ipecac. Petroleum distillate, caustic ingestions may harm gastric lining upon induction of vomiting by charcoal. Limit admin of charcoal in sorbitol doses to prevent loss of fluid and electrolyte. Monitor for active bowel sounds before administering charcoal. Pregnancy.

4.5 Interaction with Other Drugs, Other Forms of Interactions

Reduces absorption of most drugs from GI tract. Decreases effectiveness of methionine via adsorption. Decreases ipecac effect.

Food Interaction: Milk products eg, milk, ice crm or sherbet, marmalade reduces charcoal effect. Food, nutritional supplements or herbs must not be taken within two hr of ingestion of charcoal.

4.6 Use in Pregnancy and Lactation

Caution when used during Pregnancy.

4.7 Effects on ability to drive and operate machine

Patients experiencing visual disturbances, dizziness, vertigo, somnolence, or other central nervous system disturbances while taking Activated Charcoal Tablets should refrain from driving or using machines.

4.8 Undesirable effects

Vomiting, constipation, diarrhoea, black stools, swelling of abdomen, bowel obstruction; platelet aggregation, charcoal embolism, thrombocytopenia, haemorrhage, hypoglycaemia, hypocalcaemia, hypothermia, hypotension (haemoperfusion with activated charcoal); blackening of teeth and mouth; hypernatraemia, hypokalaemia, hypermagnesemia (with concomitant admin with cathartics).

4.9 Overdoses

In theory severe constipation would result from excessive use and this could be treated with laxatives.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmaco-Kinetic Properties

Absorption: Unabsorbed via the GI tract.

Metabolism: Unmetabolised.

Excretion: Via faeces (as unchanged form).

5.2 Pharmaco-dynamic properties

Charcoal due to its large surface area, inhibits the GI absorption of toxic substances or irritants eg, aromatic or benzenoid-type substances through adsorption. As a laxative, the addition of sorbitol provides hyperosmotic environment thus causing catharsis. Moreover, charcoal interferes with the enterohepatic circulation of bile acids resulting to a lower cholesterol level.

5.3 Pre-clinical safety data

Minimal toxicity is associated with the use of charcoal in hemoperfusion.

Charcoal is produced by pyrolysis and high temperature oxidation of organic materials. Animal charcoal is obtained from items such as charred bones, meat, and blood. Activated charcoal is obtained from charred wood or vegetable matter and treated with various substances to increase its adsorptive power. Amorphous carbons (or charcoals) are taken from the incomplete combustion of natural gas, fats, oils, or resins.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sucrose	BP	100.00 mg
Gelatin	BP	7.00 mg
Maize starch	BP	133.328 mg
Magnesium stearate	BP	6.00 mg
Gum tragacanth	BP	25.00 mg
Microcrystalline cellulose Powder	BP	75.00 mg
Purified talc	BP	10.00 mg
Poly vinyl Pyrrolidon K-30	BP	0.500 mg
Sodium starch glycolate	BP	21.00 mg

6.2 Incompatibilities

None reported

6.3 Shelf-Life

36 months from the date of manufacture.

6.4 Special Precautions for Storage

Store below 30°C.
Protect from light.

6.5 Nature and Contents of Container

Jar pack of 100 tablets

Material of construction of primary packaging material is attached.

ANIL K. PANDEY
DIRECTOR

Date :
Director of the manufacturer
(Signature, Full name, Stamp)

AGOG PHARMA LTD. VASAI

ANIL K. PANDEY
DIRECTOR

Date :
Director of applicant company
(Signature, Full name, Stamp)

AGOG PHARMA LTD. VASAI