PACKAGE INSERT TEMPLATE FOR ACTIVATED CHARCOAL TABLET/CAPSULE/GRANULE/POWDER

Brand or Product Name

[Product name] Dosage Form, Strength

Name and Strength of Active Substance(s)

Activated charcoal ……mg or %w/w

Product Description

[Visual description of the appearance of the product (eg colour, shape etc)
eg Black, round tablets, flat on both sides

Pharmacodynamics

Activated charcoal is widely accepted as adsorbent for numerous drugs, bacteria and toxins.
The adsorption of a partly absorbed active ingredient to activated charcoal will cause a concentration gradient between circulating plasma and bowel contents. Therefore passively absorbed substances can diffuse in the opposite direction again to the intestines.

Pharmacokinetics

After oral application it is not adsorbed by the gastrointestinal tract and is eliminated quantitatively via the feces.

Indication

Acute diarrhea
Acute Poisoning
Prevention of absorption in oral intoxications and acceleration of elimination in intoxication with substances subject to enterohepatic circulation

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Recommended Dosage

Tablets/ Capsules

Diarrhoea:
Depending on the severity of the case, 400mg-1000mg is administered 3 – 4 times daily. Half of this dose is recommended for children.

The medication should be taken on an empty stomach with plenty of liquid.
The medication should be used until the stools have returned to normal if the patient has not responded to treatment after about 3 days; other therapeutic or diagnostic measures must be taken.

Intoxications:
In acute intoxications, depending on the individual case, activated charcoal must be administered in higher doses (0.5 – 1g/kg body weight).

Adults receive 500mg-1000mg per kg body weight, children 200mg-500mg per kg per weight.

In unconscious patients a doctor or a nurse under medical supervision, should administer the suspension tablets in water by gastric tube.

Administration may be repeated at intervals of 2 – 4 hours. Due to the risk of hyperchloraemia the suspension should be given in isotonic saline or full electrolyte solution where multiple doses are administered. It is recommended to additionally administer 1 tablespoonful (adults) or ½ - 1 tablespoonful (children) of sodium sulfate (Glauber's salt) in 1 glass of water 30 – 60 minutes later. This saline laxative induces rapid intestinal passage. By this measure the poison, which is bound to the charcoal, is removed from the intestinal tract before part of the poisonous substances can be liberated. To accelerate elimination in intoxications with substances subject to enterohepatic circulation 200mg/1 – 2 kg body weight should be given. This measure can be repeated every 2 – 4 hours.

Granules/ Suspension

Adults and children from 12 years of age:
Activated charcoal is given orally or via a nasogastric tube usually as slurry in water. A usual dose for reduction of absorption is 50g, but higher doses (100 g) have been used. For maximum efficacy, activated charcoal should be given as soon as possible (within 1 hour) after ingestion of the toxic compound. For some drugs such as those that undergo enterohepatic or enteroenteric recycling (e.g. phenobarbital and theophylline) repeated doses of activated charcoal are of value

in enhancing faecal elimination. Doses for repeated administration in active elimination have varied but typically 50g may be given every 4 hours; 25g every 2 hours or 12.5 g hourly may be better tolerated, but efficacy may be affected.

Children up to 12 years of age:

Activated charcoal is used in children for the treatment of acute oral poisoning. For the reduction of absorption of poisons, a usual dose is 1g/kg (to a maximum of 50g) given orally or via a nasogastric tube. This dose may be repeated every 4 hours for the active elimination of poisons. If vomiting is a problem, smaller amounts of charcoal given hourly or every 2 hours may cause less gastric irritation.

Mode of Administration

Oral

Contraindications

Activated charcoal is contraindicated in those patients with absence of bowel sounds, GI perforation, intestinal obstruction, recent surgery, risk of GI haemorrhage, febrile diarrhoea and hypersensitive to any other excipients.

Warnings and Precautions

Warnings:

Activated Charcoal is not recommended for treatment of diarrhoea in children under 6 years of age

Activated charcoal may interfere with the absorption of other drugs, including antibiotics, when administered concurrently.

Precautions:

Appropriate fluid and electrolyte therapy should be given to protect against dehydration. Oral rehydration therapy which is the use of appropriate fluids including oral rehydration salts remains the most effective treatment for dehydration due to diarrhoea. The intake of as much of these fluids as possible is therefore imperative.

Interactions with Other Medicaments

Activated charcoal has the potential to reduce the absorption of many drugs from the gastrointestinal tract and simultaneous oral therapy should therefore be avoided. In the management of acute poisoning, concurrent medication should be given parenterally.
Care is needed if a specific oral antidote such as methionine is given since adsorption of the antidote may decrease its efficacy; it has been recommended that activated charcoal should be cleared from the stomach or avoided if oral antidotes are to be used.
The adsorptive capacity of activated charcoal may be reduced by food; larger doses of activated charcoal may be needed if a large meal was eaten before treatment.

Statement on Usage During Pregnancy and Lactation

Pregnancy and Lactation
Available evidence is inconclusive or is inadequate for determining foetal risk when used in pregnant women or women of childbearing potential and during breast feeding. Weigh the potential benefits of drug treatment against potential risks before prescribing this drug during pregnancy.

Adverse Effects / Undesirable Effects

Activated charcoal is relatively non-toxic when given orally but gastrointestinal disturbances such as vomiting, constipation, or diarrhoea have been reported.
It may colour the faeces, tongue, and mucous membranes black.

Overdose and Treatment

Unknown

Storage Conditions

[eg Store below….°C]

Dosage Forms and Packaging Available

[Packaging type & pack size]

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Name and Address of Manufacturer

[Name & full address of manufacturer]

Name and Address of Marketing Authorization Holder

[Name & full address of marketing authorization holder]

Date of Revision of Package Insert

[day/month/year]

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