

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Liqui-Char Oral Suspension

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Activated charcoal USP 25 g and 50 g unit dose packs.

#### 3 PHARMACEUTICAL FORM

Oral suspension.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

Poisoning, including drug overdose

##### 4.2 Posology and method of administration

*Adults (including the elderly):* 50g, repeated if necessary

*Children under 12 years:* Dosage should be adjusted according to the weight and age of the patient. Generally 25g should be given and repeated if necessary, although in cases where a large quantity of toxicant has been ingested or there is a risk to life, an initial dose of 50g is recommended.

Liqui-Char should be given as soon as possible after the ingestion of the toxicant. In severe cases of poisoning or where sustained release drugs are involved, absorption of the toxicant may be prolonged and even the delayed administration of Liqui-Char may be beneficial.

Repeated administration may be used to enhance the elimination of some toxic substances by preventing their re-absorption following active secretion in bile or their diffusion back into the gut from the circulation.

The tube should be kneaded and shaken thoroughly before use. The tip should be carefully cut and the suspension may then be squeezed into a container for the patient to drink or administered through a gastric tube using the adapter provided.

##### 4.3 Contraindications

None, but refer to “precautions” and “interactions” sections for inappropriate use.

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

Before administration, it should be confirmed the patient is breathing and any potential obstructions such as food or false teeth should be removed from the mouth.

If ipecacuanha or any other oral emetic is used to induce vomiting, it should be administered and allowed to take effect before Liqui-Char is administered. Activated charcoal should not be used concurrently with systemically acting oral antidotes such as methionine, since such agents would be adsorbed by the charcoal.

Activated charcoal is not recommended for the treatment of poisoning by strong acids and alkalis or other corrosive substances. It is poor at binding cyanide, iron salts and some solvents such as methanol, ethanol and ethylene glycol.

It should be borne in mind that endoscopy will be made difficult or impossible in the presence of charcoal.

If the toxic substance is known to have diuretic properties, plenty of fluid should be given after the administration of Liqui-Char.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

The mode of action of the product depends on its interaction with poisons and drugs taken in overdose. The effectiveness of other oral medications, including oral antidotes such as methionine, that may be administered concurrently may be decreased because of adsorption by activated charcoal. Systemic interactions cannot occur because activated charcoal is not absorbed from the gastrointestinal tract.

#### **4.6 Pregnancy and lactation**

There is no evidence to suggest that Liqui-Char should not be used during pregnancy or lactation. Systemic absorption of activated charcoal does not occur.

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

None.

#### **4.8 Undesirable effects**

Administration of activated charcoal will cause stools to be coloured black which may be alarming to the patient but is medically insignificant.

In general, activated charcoal is well tolerated, although constipation or diarrhoea have been reported.

#### **4.9 Overdose**

Not applicable. Excessive use could theoretically result in severe constipation which could be treated with laxatives.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Activated charcoal adsorbs a wide range of toxic substances, including drugs taken in overdose, thereby reducing their absorption from the gut.

Repeated dosing with activated charcoal can enhance the elimination of many drugs and other poisons. After adsorption, a toxic substance may re-enter the gut by active secretion in bile or by passive diffusion into gastrointestinal fluids. Repeated oral charcoal is believed to act in two ways: it adsorbs and binds drugs or labile conjugates which are secreted in bile and prevents their re-absorption, and it binds and removes any toxic substances which diffuse back into the gut. This creates “sink” conditions, where a concentration gradient is maintained and the toxic substance passes continuously from the circulation into the gut lumen, where it is bound by the charcoal. This process has been called “gastrointestinal dialysis”.

#### **5.2 Pharmacokinetic properties**

Activated charcoal is not systemically absorbed and passes unchanged through the gastrointestinal tract.

### 5.3 Preclinical safety data

Not applicable: activated charcoal is not pharmacologically active except for its adsorptive ability.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Purified water  
Colloidal silicon dioxide  
Propylene glycol  
Sodium benzoate  
Sodium methyl hydroxybenzoate  
Sodium propyl hydroxybenzoate

### 6.2 Incompatibilities

None known.

### 6.3 Shelf Life

24 months from date of manufacture. The product should be used within 24 hours of opening.

### 6.4 Special precautions for storage

Store below 25°C. Do not refrigerate.

### 6.5 Nature and contents of container

Liqui-Char is supplied in white, printed, blind-ended low-density polyethylene tubes with low density polyethylene adapters, to facilitate administration by gastric intubation. Tubes containing 25 g and 50 g activated charcoal are available.

### 6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Activated charcoal may stain clothing if spilled.

## 7 MARKETING AUTHORISATION HOLDER

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## 8 MARKETING AUTHORISATION NUMBER

PA 0961/001/001

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 November 2001