CHARCOTRACE® INJECTION

(ACTIVATED CHARCOAL120 MG IN 3 ML)

1 NAME OF THE MEDICINE

Activated charcoal

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Charcotrace contains activated charcoal 120 mg in water for injections to 3 mL.

For the full list of excipients, see Section 6.1 List of Excipients.

3 PHARMACEUTICAL FORM

Charcotrace is a sterile suspension.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

As an aid in stereotactic or ultrasonic localisation of small impalpable lesions of the breast for later surgical excision.

4.2 DOSE AND METHOD OF ADMINISTRATION

Roll gently before use.

Following stereotactic or ultrasound location of the lesion, Charcotrace (about 0.3 mL to 1 mL) should be injected using an 18 G needle close to the lesion and the injection continued while slowly withdrawing the needle with a to-and-fro movement to form a visible track. The barrel of the syringe should be kept horizontal while injecting to minimise any large particles entering the bore of the needle.

Use in one patient on one occasion only and discard.

4.3 CONTRAINDICATIONS

For injection by the subcutaneous route only; contraindicated in all other routes of injection.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Only small volumes (0.3 mL to 1 mL) of Charcotrace need to be injected to form a visible track.

Charcotrace should only be administered for localisation of breast lesions when there is high expectation of subsequent surgical resection. In cases where injection of activated charcoal has not been followed by excision, carbon granulomas, presenting as breast masses, have been reported in some patients within 6 months.

Use of larger than recommended volumes of Charcotrace may result in leakage from the injection sites or spread into tissues outside the breast.

Use in special populations

None.

Use in the elderly

No data available.

Paediatric use

No data available.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

None.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

There are no animal studies of the potential for impairment of fertility by activated charcoal injection.

Use in pregnancy

Australian Pregnancy Category B2.

No animal embryo/fetal development studies have been conducted with subcutaneous, activated charcoal injection.

Use in lactation

There are no animal or human data regarding the injection of activated charcoal to the breast during lactation. Subcutaneous, activated charcoal injection will be retained in human breast tissue until surgical excision.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Local pain and stinging may be experienced at the injection site. Other adverse reactions are uncommon (≥ 0.1% and < 1%).

Granuloma and foreign body reactions have been reported on occasions if carbon particles are left *in situ* for more than six months.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at http://www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Overdosage has not been reported. If too much Charcotrace has been used, it should be removed by the surgeon.

For information on the management of overdose, contact the Poisons Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Carbon (charcoal) is an inert material when injected subcutaneously. Charcoal particles may remain *in situ* for up to 60 days without a foreign body reaction during the period between the diagnostic location of the lesion and excision of the tumour by the surgeon. The charcoal particles in the suspension are small (10 - 30 microns) and form a black track under the skin, which can be followed by a surgeon for the localisation and excision of small non-palpable breast tumours. Charcoal particles are not mobilised in the subcutaneous tissue.

Clinical trials

The use of activated charcoal injection as an aid in the localisation of small impalpable breast lesions was first reported in Sweden in 1983. A number of retrospective and prospective studies have subsequently been carried out in several countries. A synopsis is included below. The success rate in the pivotal studies (more than 1,000 patients) ranges between 96% and 100%. Activated charcoal injection leaves a fixed black track from the lesion to the skin. The activated charcoal particles do not interfere with subsequent histological examination of the excised tissue.

Table 1: Published studies using activated charcoal injection as a localisation technique in impalpable breast cancer

Authors	Number of Patients	Localisation Success (%)	Charcoal Concentration
Svane 1983	56	96	1 - 4%
Azavedo *et al.* 1989	567	100	4%
Langlois & Carter 1991	56	100	4% (1 - 2 mL)
Mullen *et al.* 2001	247	100	4% (0.3 mL)
Moss *et al.* 2002	138	100	4%
Rose *et al.* 2003	219	99	4% (1 - 2 mL) Charcotrace, Phebra

5.2 PHARMACOKINETIC PROPERTIES

Absorption

Charcoal by this route of administration is not absorbed.

Distribution

No data available.

Metabolism

Charcoal by this route of administration is not metabolised.

Excretion

Charcoal by this route of administration is not excreted.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

There are no animal or human data regarding the potential for genotoxicity of subcutaneous, activated charcoal injection.

Carcinogenicity

There are no animal or human data regarding the potential for carcinogenicity of subcutaneous, activated charcoal injection.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Sodium chloride, water for injections to 3 mL, and sodium hydroxide and hydrochloric acid are used for pH adjustment when required. Contains no antimicrobial preservative.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG)[1]. The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

Charcotrace is presented as 3 mL of suspension in a 7 mL glass vial in a pack of 10 vials.

Phebra product code - INJ107

The vial stopper is not made with natural rubber latex.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

The molecular weight of the compound is 12 and the molecular formula is C.

[1] AUST R 100313

Chemical structure

No data available.

CAS number

7440-44-0

7 MEDICINE SCHEDULE (POISONS STANDARD)

Unscheduled.

8 SPONSOR

Phebra[2] Pty Ltd 19 Orion Road, Lane Cove West NSW 2066, Australia.
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9 DATE OF FIRST APPROVAL

20 Jul 2005

10 DATE OF REVISION

05 May 2020

11 REFERENCES

Azavedo E, Svane G, Auer G
Stereotactic fine-needle biopsy in 2594 mammographically detected non-palpable lesions. Lancet 1989 May; 1033-1035.

Langlois SL, Carter ML
Carbon localisation of impalpable mammographic abnormalities. Australas Radiol 1991 Aug;35(3):237-41.

Mullen DJ, Eisen RN, Newman RD, Perrone PM, Wilsey JC
The Use of Carbon Marking after Stereotactic Large-Core-Needle Breast Biopsy. Radiology 2001 Jan; 218: 255-260.

Moss HA, Barter SJ, Nayagam M, Lawrence D, Pittam M
The use of carbon suspension as an adjunct to wire localisation of impalpable breast lesions. Clin Radiol; 2002 Oct; 57(10):937-44.

Rose A, Collins JP, Neerhut P, Bishop CV, Mann GB
Carbon localisation of impalpable breast lesions. The Breast 2003;12: 264-269.

Svane G
A stereotactic technique for preoperative marking of non-palpable breast leasions. Acta Radiologica Diagnosis 1983 24(2):145-151.

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SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
NA	PI reformatted to align with new format
5.1	Minor editorial change
6.5	Minor editorial change