Isoflurane, 100% active

3. PHARMACOLOGICAL FORM

Inhalation vapour, liquid

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

General anaesthesia for use in induction and maintenance.

4.2 Possibility and Mode of Administration

Isoflurane has a slight pungent ethanol odour, which may limit the rate of gas induction but, despite this, induction and particularly recovery are rapid.

Anaesthesia by means of Isoflurane — specific vapourizers will facilitate accurate control of the administered concentration of anaesthetic.

The MAC (Minimum Alveolar Concentration) the standard measure of potency for anaesthetics, is 0.1% in pure oxygen decreasing to 0.5 when given with 70% nitrous oxide. For females of child-bearing age, the MAC is significantly higher in children and is lower in the elderly.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Isoflurane is a profound respiratory depressant, this effect being accentuated by the use of a short acting barbiturate, or other intravenous induction agent, in patients with pre-existing liver disease.

5.2 Pharmacokinetic Properties

5.3 Carcinogenicity

No increase in hepatic tumour incidence was observed in rodents or in animals after repeated exposure at anaesthetic concentrations. In both species there was no increase in renal tumour incidence. Isoflurane was tested extensively from 1972 onwards, in a wide range of species, including man. Carcinogenicity studies also indicated no increase in hepatic tumour incidence. Isoflurane was tested extensively from 1972 onwards, in a wide range of species, including man.

6. PRECAUTIONS FOR USE

6.1 Summary of Other Pharmacological Actions

6.2 Incompatibilities

6.3 Interactions

6.4 Special Warnings and Special Precautions for Use

7. ADVERSE EFFECTS OF THERAPEUTIC DOSAGE

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

10. DATE OF (PARTIAL) REVISION OF THE TEXT