

Patient Information Leaflet

SCHEDULING STATUS:

S5

PROPRIETARY NAME AND DOSAGE FORM:

ULTANE Liquid

Sevoflurane

Read all of this leaflet carefully before you receive **ULTANE**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist

WHAT **ULTANE** CONTAINS:

ULTANE contains sevoflurane, which is a clear colourless liquid.

WHAT **ULTANE** IS USED FOR:

ULTANE is a breathed in (inhalation) anaesthetic used to induce and maintain a deep, pain-free sleep (general anaesthesia) in adults and children during an operation.

BEFORE YOU RECEIVE **ULTANE**:

Do not receive **ULTANE**:

- If you are hypersensitive (allergic) to *sevoflurane* or to any other inhaled anaesthetic.
- If you have a neuromuscular disease, especially one called Duchene muscular dystrophy.
- If you or any member of your family has experienced a condition called malignant hyperthermia (rapid rise in body temperature) during an operation.

Take special care with ULTANE:

- Tell your doctor, surgeon or anaesthetist if you have previously been exposed to general anaesthetics, particularly if repeated over a short period of time. Some anaesthetics can cause problems in the liver which can cause yellowing of the skin (jaundice).
- Tell your doctor, surgeon or anaesthetist if you are suffering from any illness, other than those connected with your operation, such as kidney, brain or heart problems, severe headaches, nausea, vomiting, or a neuromuscular disease (a condition that affects muscles e.g. Duchenne muscular dystrophy).

Pregnancy and Breastfeeding:

Safety of **ULTANE** in pregnancy and breastfeeding has not been established. The safety of

ULTANE in labour and delivery has not been demonstrated.

ULTANE may be used for anaesthesia during Caesarean section.

If you are pregnant or could be pregnant or breastfeeding your baby while receiving **ULTANE**, it is important to consult your ward doctor, surgeon or anaesthetist.

Driving and using machinery:

You should NOT drive or operate machinery after your operation or procedure, for which the anaesthetic has been administered, until your doctor advises that you may do so. Your ability to drive or operate machinery may be impaired for some time.

Taking other medicines with ULTANE:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **ULTANE** with these medicines may cause undesirable interactions. Please consult your ward doctor, surgeon or anaesthetist for advice.

HOW TO RECEIVE ULTANE:

The dose of **ULTANE** that you receive will be decided by your anaesthetist and will vary depending on your age, weight and type of operation that you are having.

ULTANE is a breathed in (inhalation) anaesthetic gas. **ULTANE** liquid is changed to gas in a vapourizer. Occasionally, patients may be asked to breathe in the **ULTANE** gas via a mask but usually they will receive an injection of another anaesthetic to make them go to sleep before they receive **ULTANE**.

ULTANE has a pleasant smell and you will go to sleep very rapidly and smoothly.

POSSIBLE SIDE EFFECTS:

ULTANE can have side effects.

The side effects include:

- Restlessness (agitation)
- Slow heart beat (bradycardia)
- Slow heart beat (bradycardia) in patients with Down syndrome
- Low blood pressure (hypotension)
- Coughing
- Nausea and vomiting
- Drowsiness (somnolence)
- Dizziness
- Headache

- Fast heart rate (tachycardia)
- Increased blood pressure (hypertension)
- Slow shallow breathing (respiratory depression), wheezing or breathlessness
- Throat spasm
- Watering mouth (salivary hypersecretion)
- Chills
- Fever (pyrexia)
- Low blood temperature (hypothermia)
- Abnormal sugar (glucose) level
- Abnormal liver function test
- Abnormal white blood cell count
- Delirium

Not all side effects reported for **ULTANE** are included in this leaflet. Should your general health worsen after taking **ULTANE**, please consult your doctor, pharmacist or other health care professional for advice.

STORING AND DISPOSING OF ULTANE:

Store at room temperature (below 25 °C). Protect from light.

Keep all medicines out of the reach and sight of children.

PRESENTATION OF ULTANE:

ULTANE is supplied in 100 or 250 ml amber glass bottles or 250 ml polyethylene naphthalate (PEN) bottles.

IDENTIFICATION OF ULTANE:

ULTANE is a clear, colourless liquid.

REGISTRATION NUMBER:

29/2.1/0748

NAME AND ADDRESS OF REGISTRATION HOLDER:

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