Heliox21
Medicinal gas, compressed
Package Leaflet: Information for the User

Heliox21
Helium 79%, Oxygen 21%
Medicinal gas, compressed

Read all of this leaflet carefully before you start using this medicine.

• Keep this leaflet as you may need to read it again.
• If you have further questions, ask your healthcare professional (doctor or pharmacist).
• This medicine has been prescribed for you.
• Do not pass it on to others as it may harm them, even if their symptoms are the same as yours.
• If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your healthcare professional immediately.

This leaflet gives you information about:

1. What is Heliox21 and what is it used for
2. Things to consider before use
3. How to use Heliox21
4. Possible side effects
5. How to store Heliox21 cylinders
6. Further Information

1. WHAT IS HELIOX21 AND WHAT IS IT USED FOR?

Heliox21 is a gas mixture of medical oxygen and medical helium.

Heliox21 is used to assist the flow of oxygen into the lung in patients with severely restricted airways.

2. THINGS TO CONSIDER BEFORE USE

Take special care with Heliox21

• If you use Heliox21 for a long time the gas may cause drying of the mucus membranes (the moist body linings) in the nose, mouth and throat,
• In small children as there is a risk of a decrease in body temperature.

Pregnancy and breast feeding

Ask your healthcare professional for advice before you are given any medicine during pregnancy and breastfeeding.

The risk associated to the clinical use of helium/oxygen mixture during pregnancy and breastfeeding seems minimal.
Driving and using machines
There is no effect of Heliox21 on the ability to drive or use machines.

3. HOW TO USE HELIOX21

- Always use Heliox21 exactly as your healthcare professional has told you. You should check with your healthcare professional if you are not sure.
- Heliox21 will always be given to you by a healthcare professional.
- Heliox21 is given by inhalation. You usually breathe Heliox21 through a facemask. Either you breathe by yourself (spontaneously) or you are helped to breathe by means of a respirator/ventilator.
- The duration of inhalation is different for each individual patient and is decided by your healthcare professional.
- Heliox21 can be mixed with medicinal oxygen when a higher concentration of oxygen is required.
- Do not smoke or keep open flames in the room where Heliox21 is used, as if oxygen has been added it will increase the risk of fire.

If you have any further questions on the use of this product, please ask your healthcare professional.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Heliox21 can have side effects, although not everybody gets them.

The following is a very common side effect affecting more than 1 in 10 breathing Heliox21:
- Breathing Heliox21 will change your voice into a more high-pitched mode making it sound squeaky, this will disappear shortly after using the gas

The following are common side effects affecting more than 1 in 100 breathing Heliox21:
- Treatment with Heliox21 may cause dry mucous membranes (the moist body linings) in the nose, mouth and throat
- Treatment with Heliox21 may cause a decrease in body temperature

Reporting of side effects
If you experience any of these side effects, or if you notice any side effects not listed in this leaflet, contact your healthcare professional immediately. You can also report side effects directly to the Medicines and Healthcare Products Regulatory Agency (MHRA) via the Yellow Card Scheme www.mhra.gov.uk/yellowcard and to BOC Healthcare. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE HELIOX21 CYLINDERS

Keep out of reach and sight of children

Do not use Heliox21 after the expiry date which is stated on the cylinder label.

Product should be used in strict rotation so that cylinders with the earliest expiry date are used first

You MUST NOT smoke or have a naked flame near a compressed gas cylinder or hospitals pipeline outlet or in confined spaces where high pressure gas is used or stored.

Your cylinder and regulator must be kept clean and under no circumstances any oils or grease used as this may cause a spontaneous ignition.

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6. FURTHER INFORMATION

What Heliox21 contains
- The active substances are 21% Oxygen and 79% helium.
- There are no other ingredients

What Heliox21 looks like and the contents of the pack
Heliox21 is a medicinal gas. The gas is colourless and odourless.

The shoulders of the gas cylinders are brown and white (indicating helium/oxygen). The body of the gas cylinders are white (medicinal gas).

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<table>
<thead>
<tr>
<th>Cylinder Size</th>
<th>Cylinder Contents (Litres)</th>
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<tbody>
<tr>
<td>HX</td>
<td>1750</td>
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<tr>
<td>HL</td>
<td>8750</td>
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The HX size cylinder has an integral pressure regulator built into the cylinder valve. The HL size cylinder requires a separate pressure regulator to be fitted to the cylinder valve before use.