MEDICAL OXYGEN 100% MEDICINAL GAS, COMPRESSED
PL 19156/0091

LIQUID MEDICAL OXYGEN 100% MEDICINAL GAS, CRYOGENIC
PL 19156/0092

UKPAR

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LAY SUMMARY

On 7 December 2012, the MHRA granted Jubilant Pharmaceuticals nv Marketing Authorisations (licences) for the medicinal products Medical Oxygen 100% Medicinal gas, compressed (PL 19156/0091) and Liquid Medical Oxygen 100% Medicinal gas, cryogenic (PL 19156/0092). These are general sales licence medicines (legal status GSL) containing the active substance oxygen.

These products contain oxygen, a gas that is essential for life. Treatment with oxygen can take place under normal pressure (normobaric oxygen therapy) and under high pressure (hyperbaric oxygen therapy).

Oxygen therapy at normal pressure can be used to treat:
• low oxygen concentration of the blood or of a specific organ, or to prevent this from happening
• cluster headaches (a specific headache with short and very severe attacks on one side of the head)

Oxygen therapy at high pressure should only be administered by qualified healthcare professionals in order to avoid the risk of injury due to strong fluctuations in pressure. Oxygen therapy at high pressure can be used:
• for the treatment of serious carbon monoxide poisoning (e.g., when the patient is unconscious)
• for the treatment of the bends (decompression disease)
• for the treatment of a obstruction in the heart or blood vessels caused by bubbles (gas or air embolism)
• for the support treatment in cases of bone loss after radiotherapy
• for the support treatment in cases of dying tissue as a result of an injury infected with gas-producing bacteria.

No new or unexpected safety concerns arose from these applications and it was, therefore, judged that the benefits of taking Medical Oxygen 100% Medicinal gas, compressed (PL 19156/0091) and Liquid Medical Oxygen 100% Medicinal gas, cryogenic (PL 19156/0092) outweigh the risks, hence Marketing Authorisations have been granted.
MEDICAL OXYGEN 100% MEDICINAL GAS, COMPRESSED
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PL 19156/0092

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted Marketing Authorisations for the medicinal products Medical Oxygen 100% Medicinal gas, compressed (PL 19156/0091) and Liquid Medical Oxygen 100% Medicinal gas, cyrogenic (PL 19156/0092) on 7 December 2012 to Jubilant Pharmaceuticals nv.

These are applications for Medical Oxygen 100% Medicinal gas, compressed and Liquid Medical Oxygen 100% Medicinal gas, cyrogenic, submitted as abridged simple applications according to Article 10c of Directive 2001/83/EC, cross-referring to Medical Oxygen 100% Medicinal gas, compressed (PL 35326/0008) and Liquid Medical Oxygen 100% Medicinal gas, cyrogenic (PL 35326/0006), which were originally granted licences to SOL SpA on 17 January 2012.

These are general sales licence medicines (legal status GSL), indicated for the following:

**Normobaric oxygen therapy:**
- Treatment or prevention of acute or chronic hypoxia.
- Treatment of cluster headache.

**Hyperbaric oxygen therapy**
- Treatment of serious carbon monoxide poisoning. (In the case of carbon monoxide poisoning, hyperbaric oxygen therapy is considered essential for patients who have lost consciousness; neurological symptoms, cardiovascular failure or serious acidosis; or pregnant patients (all of these indications irrespective of COHb content)).
- Treatment of decompression sickness, or of air/gas embolism of a different origin.
- As supporting treatment in cases of osteoradionecrosis.
- As supporting treatment in cases of clostridial myonecrosis (gas gangrene).
PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 19156/0091-2
PROPRIETARY NAME: Medical Oxygen 100% Medicinal gas, compressed and Liquid Medical Oxygen 100% Medicinal gas, cryogenic
ACTIVE(S): Oxygen
COMPANY NAME: Jubilant Pharmaceuticals nv
LEGAL STATUS: GSL

1. INTRODUCTION
These are simple, piggyback applications for Medical Oxygen 100% Medicinal gas, compressed (PL 19156/0091) and Liquid Medical Oxygen 100% Medicinal gas, cryogenic (PL 19156/0092) submitted under Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC). The proposed MA holder is Jubilant Pharmaceuticals nv, Axxes Business Park, Guldensporenpark 22 – Block C, 9820 Merelbeke, Belgium.

The applications cross-refer to Medical Oxygen 100% Medicinal gas, compressed (PL 35326/0008) and Liquid Medical Oxygen 100% Medicinal gas, cryogenic (PL 35326/0006), which were originally granted licences to SOL SpA on 17 January 2012.

The current applications are considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 NAME(S)
The proposed names of the products are Medical Oxygen 100% Medicinal gas, compressed and Liquid Medical Oxygen 100% Medicinal gas, cryogenic. The products have been named in-line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
Medical Oxygen is stored in gas cylinders in a gaseous state and under a pressure of 200 bar (at 15°C). The cylinders are made of steel or aluminium. The valves are made of brass, steel or aluminium. The products are stored in a range of sizes, each containing a specific volume of oxygen.

The proposed shelf-life (see Section 6.3 of the SmPC for each product) and storage conditions (see Section 6.4 of the SmPC for each product) are consistent with the details registered for the cross-reference products.

2.3 Legal status
On approval, the products will be available as general sales licence (legal status GSL) medicines.

2.4 Marketing authorisation holder/Contact Persons/Company
Jubilant Pharmaceuticals nv, Axxes Business Park, Guldensporenpark 22 – Block C, 9820 Merelbeke, Belgium.

The QP responsible for pharmacovigilance is stated and his CV is included.
2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed composition is consistent with the details registered for the cross-reference products.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference products and the maximum batch sizes are stated.

2.8 Finished product/shelf-life specification
The proposed finished product specifications are in line with the details registered for the cross-reference products.

2.9 Drug substance specification
The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance
There are no excipients in either product. This is consistent with the cross-reference products.

3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the applications. Signed declarations and copies of the experts’ CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product names. The appearance of the products is identical to the cross-reference products.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The proposed SmPCs are consistent with the details registered for the cross-reference products.

6. PATIENT INFORMATION LEAFLET (PIL)/CARTON PIL
The patient information leaflet has been prepared in-line with the details registered for the cross-reference products.

Carton and blister
The proposed artwork is comparable to the artwork registered for the cross-reference products and complies with statutory requirements. The applicant has provided a suitable justification for not including Braille on the outer packaging. As these products will be used by healthcare professionals, this is accepted.
7. CONCLUSIONS
The data submitted with these applications are acceptable. From a quality perspective, Marketing Authorisations should be granted.

NON-CLINICAL ASSESSMENT

No new non-clinical data have been supplied with these applications and none are required for applications of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with these applications and none are required for applications of this type.
OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY
Medical Oxygen 100% Medicinal gas, compressed and Liquid Medical Oxygen 100% Medicinal gas, cyrogenic are identical to the already licensed reference products. The products are, therefore, pharmaceutically satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for applications of this type.

CLINICAL PHARMACOLOGY/EFFICACY
No new clinical pharmacology/efficacy data have been submitted with these applications and none are required for applications of this type.

SAFETY
No new safety data have been submitted with these applications and none are required for applications of this type.

No new or unexpected safety concerns arise from these applications.

The SmPCs, PIL and labelling are satisfactory.

BENEFIT-RISK ASSESSMENT
The quality of the products is acceptable and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with oxygen is considered to have demonstrated the therapeutic value of the compound. The benefit/risk is, therefore, considered to be positive.
MEDICAL OXYGEN 100% MEDICINAL GAS, COMPRESSED
PL 19156/0091

LIQUID MEDICAL OXYGEN 100% MEDICINAL GAS, CRYOGENIC
PL 19156/0092

STEPS TAKEN FOR ASSESSMENT

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<tr>
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<th>Description</th>
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<tr>
<td>1</td>
<td>The MHRA received the marketing authorisation applications on 07 February 2012</td>
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<tr>
<td>2</td>
<td>Following standard checks and communication with the applicant, the MHRA considered the applications valid on 27 April 2012</td>
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<td>3</td>
<td>Following assessment of the application, the MHRA requested further information relating to the dossiers on 13 July 2012</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on 24 July 2012</td>
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<td>5</td>
<td>The applications were determined on 7 December 2012</td>
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MEDICAL OXYGEN 100% MEDICINAL GAS, COMPRESSED  
PL 19156/0091

LIQUID MEDICAL OXYGEN 100% MEDICINAL GAS, CRYOGENIC  
PL 19156/0092

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

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<th>Application type</th>
<th>Scope</th>
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Summary of Product Characteristics and Patient Information Leaflet
The current approved UK versions of the Summary of Product Characteristics (SmPCs) and Patient Information Leaflet (PILs) for these products is available on the MHRA website.
Medical Oxygen

Valve with integrated pressure regulator

Oxygen 100% v/v
Inhalation gas
For Respiratory Use

Nominal fill volume:
212 litres filled to 200 bar @ 15°C.
Valve with integrated pressure regulator

Keep out of the reach and sight of children.

Oxygen, compressed

May cause or intensify fire; oxidiser.
Contains gas under pressure; may explode if heated.
Keep/Store away from clothing/combustible materials.
Keep valves and fittings free from oil and grease.
In case of fire: Stop leak if safe to do so.
Store in a well-ventilated place.

Open valve slowly - After use close valve
Leave residual pressure - Do not smoke while handling product.

UN 1072 EC 231-996-9

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Oxygen 100% v/v
Inhalation gas
For Respiratory Use

Nominal fill volume:
426 litres filled to 200 bar @ 15°C.
Valve with integrated pressure regulator

Keep out of the reach and sight of children.

Oxygen, compressed

May cause or intensify fire; oxidiser.
Contains gas under pressure; may explode if heated.
Keep/Store away from clothing/combustible materials.
Keep valves and fittings free from oil and grease.
In case of fire: Stop leak if safe to do so.
Store in a well-ventilated place.

Open valve slowly - After use close valve
Leave residual pressure - Do not smoke while handling product.

UN 1072 EC 231-996-9
Oxygen 100% w/v Inhalation gas For Respiratory Use
Nominal fill volume:
170000 litres filled to 200 bar @ 15°C.
Valve with integrated pressure regulator
Keep out of the reach and sight of children.

Marketing Authorisation Number:
PL 19156/0091-2
Marketing Authorisation Holder:
Jubilant Pharmaceuticals Ltd
Green Business Park
Carnon Drive, Truro
TR6 9BN

Oxygen 100% w/v Inhalation gas For Respiratory Use
Nominal fill volume:
212000 litres filled to 200 bar @ 15°C.
Valve with integrated pressure regulator
Keep out of the reach and sight of children.

Marketing Authorisation Number:
PL 19156/0091
Marketing Authorisation Holder:
Jubilant Pharmaceuticals Ltd
Green Business Park
Carnon Drive, Truro
TR6 9BN

Medical Oxygen
Oxygen, compressed
May cause or intensify fire; oxidiser.
Contains gas under pressure; may explode if heated.
Keep out of the reach and sight of children.

Emergency Telephone No.
0444 381 44 02

UN 1072
EC 231-966-9

Medical Oxygen
Oxygen, compressed
May cause or intensify fire; oxidiser.
Contains gas under pressure; may explode if heated.
Keep out of the reach and sight of children.

Emergency Telephone No.
0444 381 44 02

UN 1072
EC 231-966-9
Medical Oxygen

Pin Index valve

Oxygen 100% v/v
Inhalation gas
For Respiratory Use
Nominal fill volume:
212 litres filled to 200 bar @ 15°C.
Pin Index valve

Keep out of the reach and sight of children.

Marketing Authorisation Number:
PL 19156/0091
Marketing Authorisation Holder:
Jubilant Pharmaceuticals Ltd
Avenue Business Park
Ghansoli, Navi Mumbai-400705

Emergency Telephone No.:
0844 381 44 02

Medical Oxygen
Oxygen, compressed
May cause or intensify fire; oxidiser.
Contains gas under pressure; may explode if heated.
Store away from clothing/combustible materials.
Keep valves and fittings free from oil and grease.
In case of fire: Stop/leak if safe to do so.
Store in a well-ventilated place.

Open valve slowly - After use close valve
Leave residual pressure - Do not smoke while handling product.

UN 1072
EC 251-996-9

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Oxygen 100% v/v
Inhalation gas
For Respiratory Use
Nominal fill volume:
425 litres filled to 200 bar @ 15°C.
Pin Index valve

Keep out of the reach and sight of children.

Marketing Authorisation Number:
PL 19156/0091
Marketing Authorisation Holder:
Jubilant Pharmaceuticals Ltd
Avenue Business Park
Ghansoli, Navi Mumbai-400705

Emergency Telephone No.:
0844 381 44 02

Medical Oxygen
Oxygen, compressed
May cause or intensify fire; oxidiser.
Contains gas under pressure; may explode if heated.
Store away from clothing/combustible materials.
Keep valves and fittings free from oil and grease.
In case of fire: Stop/leak if safe to do so.
Store in a well-ventilated place.

Open valve slowly - After use close valve
Leave residual pressure - Do not smoke while handling product.

UN 1072
EC 251-996-9
UKPAR Medical Oxygen 100% Medicinal Gas

Oxygen 100% v/v Inhalation gas For Respiratory Use
Nominal fill volume: 1125 litres filled to 200 bar @ 15°C.
Pin Index valve
Keep out of the reach and sight of children.

Marketing Authorisation Number: PL 19156/0091-2
Marketing Authorisation Holder: Jubilant Pharmaceuticals Ltd
Aviva Business Park, Gables Business Park, 22-Block C
9221 Merakala, Belgium

Emergency telephone No. 0844 381 44 02

Oxygen 100% v/v Inhalation gas For Respiratory Use
Nominal fill volume: 2120 litres filled to 200 bar @ 15°C.
Pin Index valve
Keep out of the reach and sight of children.

Marketing Authorisation Number: PL 19156/0091
Marketing Authorisation Holder: Jubilant Pharmaceuticals Ltd
Aviva Business Park, Gables Business Park, 22-Block C
9221 Merakala, Belgium

Emergency telephone No. 0844 381 44 02

Oxygen 100% v/v Inhalation gas For Respiratory Use
Nominal fill volume: 4330 litres filled to 200 bar @ 15°C.
Pin Index valve
Keep out of the reach and sight of children.

Marketing Authorisation Number: PL 19156/0091
Marketing Authorisation Holder: Jubilant Pharmaceuticals Ltd
Aviva Business Park, Gables Business Park, 22-Block C
9221 Merakala, Belgium

Emergency telephone No. 0844 381 44 02

Oxygen 100% v/v Inhalation gas For Respiratory Use
Nominal fill volume: 6370 litres filled to 200 bar @ 15°C.
Pin Index valve
Keep out of the reach and sight of children.

Marketing Authorisation Number: PL 19156/0091
Marketing Authorisation Holder: Jubilant Pharmaceuticals Ltd
Aviva Business Park, Gables Business Park, 22-Block C
9221 Merakala, Belgium

Emergency telephone No. 0844 381 44 02

Medical Oxygen
Oxygen, compressed
May cause or intensify fire; oxidiser.
Contains gas under pressure; may explode if heated.
Keep/Stor away from clothing/combustible materials.
Keep valves and fittings free from oil and grease.
In case of fire: Stop leak, if safe to do so.
Store in a well-ventilated place.

Open valve slowly - After use close valve
Leave residual pressure - Do not smoke while handling product.
UKPAR Medical Oxygen 100% Medicinal Gas

Oxygen 100% v/v Inhalation gas For Respiratory Use
Nominal fill volume: 10810 litres filled to 200 bar @ 15°C.
Pin Index valve
Keep out of the reach and sight of children.

Marketing Authorisation Number: PL 19156/0091-2
Marketing Authorisation Holder: JUBILANT Pharmaceuticals Ltd
Gusdhonsonpark 22, Block C
9820 Vindersole, Belgium

Emergency Telephone No. 0844 831 44 02

Medical Oxygen
Oxygen, compressed
May cause or intensify fire; oxidiser. Contains gas under pressure; may explode if heated. Keep/Store away from clothing/combustible materials. Keep valves and fittings free from oil and grease. In case of fire: Stop leak if safe to do so. Store in a well-ventilated place.
Open valve slowly - After use close valve Leave residual pressure - Do not smoke while handling product.

UN 1072 EC 231-966-9

UN 1072 EC 231-966-9

UN 1072 EC 231-966-9

UN 1072 EC 231-966-9
UKPAR Medical Oxygen 100% Medicinal Gas

Oxygen 100% v/v
Inhalation gas
For Respiratory Use

Nominal fill volume:
170000 litres filled to 200 bar @ 15°C.
Pin Index valve

Keep out of the reach and sight of children.

Marketing Authorisation Number: PL-19156/0091-2
Marketing Authorisation Holder: Jubilant Pharmaceuticals Ltd
Arpes Business Park
Goulter's Lane
Berkhamsted
Hertfordshire
HP4 1BH

Emergency telephone No.: 0844 381 44 02

UKPAR Medical Oxygen 100% Medicinal Gas

Oxygen 100% v/v
Inhalation gas
For Respiratory Use

Nominal fill volume:
212000 litres filled to 200 bar @ 15°C.
Pin Index valve

Keep out of the reach and sight of children.

Marketing Authorisation Number: PL-19156/0091
Marketing Authorisation Holder: Jubilant Pharmaceuticals Ltd
Arpes Business Park
Goulter’s Lane
Berkhamsted
Hertfordshire
HP4 1BH

Emergency telephone No.: 0844 381 44 02

Medical Oxygen
Oxygen, compressed
May cause or intensify fire; aids fire.
Contains gas under pressure; may explode if heated.
Keep away from clothing/combustible materials.
Keep valves and fittings free from oil and grease.
In case of fire: Stop leak if safe to do so.
Store in a well-ventilated place.
Open valve slowly - After use close valve
Leave residual pressure - Do not smoke while handling product.

UN 1072
EC 231-989-9

Medical Oxygen
Oxygen, compressed
May cause or intensify fire; aids fire.
Contains gas under pressure; may explode if heated.
Keep away from clothing/combustible materials.
Keep valves and fittings free from oil and grease.
In case of fire: Stop leak if safe to do so.
Store in a well-ventilated place.
Open valve slowly - After use close valve
Leave residual pressure - Do not smoke while handling product.

UN 1072
EC 231-989-9
Medical Oxygen

BS 341 No. 3 valve
UKPAR Medical Oxygen 100% Medicinal Gas

Oxygen 100% v/v
Inhalation gas
For Respiratory Use

Nominal fill volume:
170000 litres filled to 300 bar @ 15°C.
BS 341 No. 3 valve

Keep out of the reach and sight of children.

Marketing Authorisation Number:
PL 19156/0091-2
Marketing Authorisation Holder:
Jubilant Pharmaceuticals Ltd
Asia Business Park
Gurukulamangalam 25, Block C
9820 Meerbeek, Belgium

Oxygen, compressed
May cause or intensify fire; oxidiser.
Contains gas under pressure; may explode if heated.
Keep/Store away from clothing/combustible materials.
Keep valves and fittings free from oil and grease.
In case of fire: Stop leak if safe to do so.
Store in a well-ventilated place.

Open valve slowly - After use close valve
Leave residual pressure - Do not smoke while handling product.

UN 1072
EC 331-946-9

Oxygen 100% v/v
Inhalation gas
For Respiratory Use

Nominal fill volume:
212000 litres filled to 200 bar @ 15°C.
BS 341 No. 3 valve

Keep out of the reach and sight of children.

Marketing Authorisation Number:
PL 19156/0091-2
Marketing Authorisation Holder:
Jubilant Pharmaceuticals Ltd
Asia Business Park
Gurukulamangalam 25, Block C
9820 Meerbeek, Belgium

Oxygen, compressed
May cause or intensify fire; oxidiser.
Contains gas under pressure; may explode if heated.
Keep/Store away from clothing/combustible materials.
Keep valves and fittings free from oil and grease.
In case of fire: Stop leak if safe to do so.
Store in a well-ventilated place.

Open valve slowly - After use close valve
Leave residual pressure - Do not smoke while handling product.

UN 1072
EC 331-946-9
UKPAR Medical Oxygen 100% Medicinal Gas

Liquid Medical Oxygen

**Oxygen 100% v/v**

For Respiratory Use

Nominal B volume: XXX litres
Nominal working pressure: 200 bar
Room temperature when stored: 853 bar
of breathable oxygen (oxygen gas)

Strongly supports combustion.
Liquid causes burns on contact with the skin.
Keep out of the reach and sight of children.

Marketing Authorisation Number: PL 19156/0091-2

Liquid medical oxygen should only be used by trained personnel using appropriate respirating equipment.
Store container below 20ºC, avoid extremes of temperature.
Do not smoke when using the product.
No smoking or naked lights permitted in the vicinity of equipment.

Emergency telephone No. 0844 301 44 02

UN 1073
EC 991-965-9

**Liquid Medical Oxygen**

Caution
May cause or intensify fire, explosion.
Contains flammable gas that can cause explosion.

Keep away from clothing and flammable materials.
Keep valves and fittings free from oil and greases.
Wear cool-temperature gloves, protective clothing, and eye protection.

Store in well-ventilated areas.
Do not put affected area in direct sunlight.

Stow in well-ventilated place.