

Summary Public Assessment Report

Lung test gas CO/He AGA (Carbon monoxide (CO), helium (He))

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(Carbon monoxide (CO), helium (He))

Medicinal gas, compressed; 0.28% and 9.3%

This is a summary of the public assessment report (PAR) for Lung test gas CO/He AGA. It explains how Lung test gas CO/He AGA was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Lung test gas CO/He AGA.

For practical information about using Lung test gas CO/He AGA, patients should read the package leaflet or contact their doctor or pharmacist.

What is Lung test gas CO/He AGA and what is it used for?

Lung test gas CO/He AGA is a medicine with 'well-established use'. This means that the medicinal use of the active substances of Lung test gas CO/He AGA is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

This medicine is for lung function diagnostic use only. Lung test gas CO/He AGA may be used in patients capable of following the instructions needed to perform the test, irrespective of age.

How does Lung test gas CO/He AGA work?

This medicine is for lung function diagnostic use only.

How is Lung test gas CO/He AGA used?

The pharmaceutical form of Lung test gas CO/He AGA is medicinal gas and is only for use for performing lung function tests. You should follow the instructions the personnel performing the test give you.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Lung test gas CO/He AGA have been shown in studies?

As the active substances of Lung test gas CO/He AGA are well-known substances, and its use in the performing lung function tests is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of the active substances of Lung test gas CO/He AGA in performing lung function tests.

What are the possible side effects of Lung test gas CO/He AGA?

For the full list of all side effects reported with Lung test gas CO/He AGA, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Lung test gas CO/He AGA approved?

The use of Lung test gas CO/He AGA in the performing lung function tests is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that Lung test gas CO/He AGA's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Lung test gas CO/He AGA?

A risk management plan has been developed to ensure that Lung test gas CO/He AGA is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Lung test gas CO/He AGA, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Lung test gas CO/He AGA

The marketing authorisation for Lung test gas CO/He AGA was granted on 2009-08-21 in Sweden.

The full PAR for Lung test gas CO/He AGA can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Lung test gas CO/He AGA, please read the [\[package leaflet\]](#) or contact your doctor or pharmacist.

This summary was last updated in 2018-02.