

SUMMARY OF RISK MANAGEMENT PLAN FOR OSSIGENO AIR LIQUIDE SANITÀ 300 BAR GAS MEDICINALE COMPRESSO

This is a summary of the risk management plan (RMP) for OSSIGENO AIR LIQUIDE SANITÀ 300 BAR GAS MEDICINALE COMPRESSO. The RMP details important risks of OSSIGENO AIR LIQUIDE SANITÀ 300 BAR GAS MEDICINALE COMPRESSO, how these risks can be minimised, and how more information will be obtained about OSSIGENO AIR LIQUIDE SANITÀ 300 BAR GAS MEDICINALE COMPRESSO's risks and uncertainties (missing information).

OSSIGENO AIR LIQUIDE SANITÀ 300 BAR GAS MEDICINALE COMPRESSO's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how OSSIGENO AIR LIQUIDE SANITÀ 300 BAR GAS MEDICINALE COMPRESSO should be used.

I. THE MEDICINE AND WHAT IT IS USED FOR

OSSIGENO AIR LIQUIDE SANITÀ 300 BAR GAS MEDICINALE COMPRESSO is authorised for :

- Treatment of acute and chronic respiratory failure
- Treatment under anaesthesia, in intensive care, in a hyperbaric chamber

It contains OXYGEN as the active substance and it is given by inhalation route.

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISK

Important risks of OSSIGENO AIR LIQUIDE SANITÀ 300 BAR GAS MEDICINALE COMPRESSO, together with measures to minimise such risks and the proposed studies for learning more about OSSIGENO AIR LIQUIDE SANITÀ 300 BAR GAS MEDICINALE COMPRESSO's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;

Together, these measures constitute routine risk minimisation measures.

II.A LIST OF IMPORTANT RISKS AND MISSING INFORMATION

Important risks of OSSIGENO AIR LIQUIDE SANITÀ 300 BAR GAS MEDICINALE COMPRESSO are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of OSSIGENO AIR LIQUIDE SANITÀ 300 BAR GAS MEDICINALE COMPRESSO. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B SUMMARY OF IMPORTANT RISKS

THE SAFETY INFORMATION IN THE PROPOSED PRODUCT INFORMATION IS ALIGNED TO THE REFERENCE MEDICINAL PRODUCT.

II.C POST-AUTHORISATION DEVELOPMENT PLAN

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of OSSIGENO AIR LIQUIDE SANITÀ 300 BAR GAS MEDICINALE COMPRESSO.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for OSSIGENO AIR LIQUIDE SANITÀ 300 BAR GAS MEDICINALE COMPRESSO.