

Summary Public Assessment Report

Livopan (nitrous oxide and oxygen)

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(nitrous oxide, oxygen)

medicinal gas, compressed; 50%/50%

This is a summary of the public assessment report (PAR) for Livopan. It explains how Livopan 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 Livopan.

For practical information about using Livopan, patients should read the package leaflet or contact their doctor or pharmacist.

What is Livopan and what is it used for?

Livopan is a medicine with ‘well-established use’. This means that the medicinal use of the active substance of Livopan is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Livopan should be used when painkilling effects, of rapid onset and rapid resolution are desired and when the treated pain state is of mild to moderate intensity and of limited duration. Livopan can be used in adults and children from 1 month old.

How does Livopan work?

Livopan produces painkilling effects after just a few breaths and the painkilling effects subside within minutes after use is ceased. Nitrous oxide has a painkilling effect, reduces the sensation of pain, and raises the pain threshold. Nitrous oxide also has a relaxing and slightly calming effect. These effects are produced by the effects of nitrous oxide on signal substances in your nervous system. The 50-percent concentration of oxygen (around double that in ambient air) guarantees safe oxygen content in the inspired gas.

How is Livopan used?

The pharmaceutical form of Livopan is medicinal gas, compressed, administered via inhalation in spontaneously breathing patients via a face mask.

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 Livopan have been shown in studies?

As nitrous oxide and oxygen are well-known substances, and their use in the treatment of short-term pain conditions of mild to moderate intensity is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of nitrous oxide and oxygen in the treatment of short-term pain conditions of mild to moderate intensity when rapid analgesic onset and offset effects are wanted.

What are the possible side effects of Livopan?

For the full list of all side effects reported with Livopan, see section 4 of the package leaflet.

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

Why is Livopan approved?

The use of Livopan in the treatment of short-term pain conditions of mild to moderate intensity when rapid analgesic onset and offset effects are wanted, 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 Livopan'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 Livopan?

A risk management plan has been developed to ensure that Livopan 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 Livopan, 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 Livopan

The marketing authorisation for Livopan was granted on 2007-12-07 in Sweden.

The full PAR for Livopan can be found on the following website:

<http://mri.medagencies.org/Human/>. For more information about treatment with Livopan, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2015-01.