

Ultrasound-Gel – Technical Specification

Product Description

PRIMAX Ultrasound-Gel is a coupling agent for ultrasound therapy and diagnosis.

Applications

- Application in the medical diagnostic and therapy.
- Only for external application.

Patient Contact

- non-invasive
- surface contact with intact skin (DIN EN ISO 10993)

Duration of Contact

- transient: less than 60 minutes
- limited exposure: up to 24 hours (DIN EN ISO 10993)

Handling

- Apply ultrasound gel evenly. Remove the gel with a paper towel after the examination. Clean the transducer with a special cleaning spray for transducers.

Classification

- According to Regulation (EU) 2017/745, annex VII, chapter II, section 4f, rule 1, a non-invasive medical product and belongs to class I

Specification

- contact agent for ultrasound diagnosis and therapy
- dermatologically tested
- produced on water basis
- produced under vacuum conditions, therefore absolutely free of bubbles and acoustically precise
- harmless to skin and transducers
- free from formaldehyde, perfume additives, dyes or UV stabilizers, therefore minimal allergenic potency
- clear or blue viscous gel

Ingredients

- Aqua, Carbomer, Sodium Hydroxide, Propylene Glycol, Phenoxyethanol, Methylparaben, Ethylparaben

Product sizes

- Dispenser 250 ml, 1 l
- Cubitainer 5 l

Storage

- The ultrasound gel has high storage stability, but should be protected from sunlight and stored in frost-free conditions.

Shelf life

- 30 months in accordance of the transport and storage regulation.
- A product life of 6 months from the time of opening is guaranteed, or the expiry date which is printed on the product, whichever is sooner.

Disposal

- Dispose of contents / container in accordance with local / regional / national / international regulations.

First aid measures in case of accidental swallowing

- Smooth Rinse mouth. Do not induce vomiting. If discomfort occurs, seek medical advice/ medical attention.

Standards and Certification

PRIMAX Berlin GmbH is certified according to ISO 13485 : 2016.