

# Atrauman® Ag

## General Product Description/Intended Purpose

### Atrauman® Ag

Atrauman Ag is a non-adherent wound contact layer suitable for the treatment of chronic wounds such as ulcus cruris, diabetic leg ulcer and decubitus. It is also suitable for the treatment of acute burns up to 2nd degree. Atrauman Ag is suitable for the treatment on the human skin by professional users.

Atrauman Ag carries the CE mark according to EU directive 93/42/EEC for medical devices.

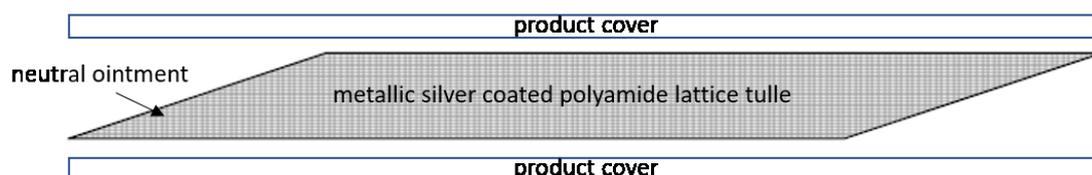
The product is classified as a class III medical device. A conformity assessment has been performed for Atrauman Ag and it has been shown to be in compliance with all applicable requirements of the above mentioned directive. The safe use and effectiveness of Atrauman Ag, therefore, is ensured if the product is used in line with the intended purpose.

## Composition

### Atrauman® Ag

fabric:	Metallic silver coated polyamide lattice tulle
impregnation:	soft and non-adhering ointment the ointment contains (INCI): Caprylic/Capric/Stearic Triglyceride, Bis-diglyceryl-polyacyladipate-2, Macrogol 2000
Product cover:	Glassine paper on both sides

## Product drawing:



## Application/Indication

The soft, thin support fabric drapes easily and ensures close contact with the wound base. The fabric's surface and the impregnation counteract adhesion to the wound; as a result, the dressing supports atraumatic dressing changes. Atrauman Ag acts as a silver containing-barrier dressing. The impregnation protects the wound edges helping to prevent maceration, it is non-medicated, contains no paraffin.

For the treatment of chronic ulcus cruris, diabetic leg ulcer and decubitus. It is also suitable for the treatment of acute burns up to 2nd degree.

# Atrauman® Ag

## Reference Numbers

Packaging	Type	Dimensions (cm)	REF
P3	Atrauman® Ag	5 x 5	499570/7
P10	Atrauman® Ag	5 x 5	499571/7
P3	Atrauman® Ag	10 x 10	499572/7
P10	Atrauman® Ag	10 x 10	499573/7
P3	Atrauman® Ag	10 x 20	499574/7
P10	Atrauman® Ag	10 x 20	499575/7

## Contraindications

Do not use Atrauman Ag on patients who may be allergic to any of its ingredients. Do not use on dry wounds.

## Special precautions

Treatment with Atrauman Ag does not replace a requisite antibiotic therapy. In the absence of available data supporting the use of this dressing on sensitive population groups such as infants, children, pregnant or nursing women, and in the absence of data to the contrary, on these population groups this dressing should be used with caution following a clinician's recommendation. In the absence of available data supporting the use of this dressing during Magnetic Resonance Imaging (MRI), it should be used with caution following a clinician's recommendation

## Side effects

In very rare cases Atrauman Ag might adhere to the wound, causing pain and bleeding upon removal. In very rare cases Atrauman Ag might cause allergic reactions. As found with other silver-containing dressings, Atrauman Ag may commonly cause temporary discoloration of the wound or wound margin.

## Warnings

Do not use Atrauman Ag in combination with iodine- or paraffin-containing dressings or ointments.

## Sterile Device

Atrauman® Ag is a sterile device, sterilized by radiation sterilization. Do not use if sterile packaging is damaged.

## Single Use Device

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

## Product disposal

In order to minimize the risk of potential infection hazards, or environmental pollution, disposable components of Atrauman Ag should follow disposal procedures according to the local regulations and infection prevention standards. Dispose medical device together with regular hospital garbage.

# Atrauman® Ag

## Product Performance Characteristics Atrauman® Ag

### Finished product\*

Test parameter	Test method	Unit	Acceptance criteria
Sealing strength primary packaging (single values)	TM00 0052-01	N/15mm	0,7 - 4,0
Dropping point	TM00 0020	°C	35 - 45
Ointment weight	TM00 0230	g/m <sup>2</sup>	Min. 157
Total weight with product cover	TM00 0009	g	5x5 cm: 0,72 – 0,86 10x10 cm: 2,80 – 3,36 10x20 cm: 5,52 – 6,64
Silver content	ATM 106 (UKAS)	Wt-%	Min. 8,4

\*All data refers to sterile products.

### Labelling

#### Lot-No. with 8-Digit Code

e.g.:



0

year

003

Number of production order of reference within a year

12

week of production

of

XX

for internal purposes only

#### Manufacturing Date

e.g.:



2015  
year

04  
month

07  
day

#### Use-by-Date

e.g.:



2015  
year

04  
month

07  
day

Shelf Life: 3 years

#### Unique Device Identification (UDI)



## Technical Data Sheet

# Atrauman® Ag

CE-mark



Single-Use device



Do not resterilize



Keep dry



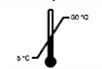
Consult instruction for use



Attention



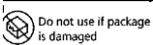
Temperature limit



Sterilized using irradiation



Do not use if package is damaged



Store flat



**Latest Date of Revision: 2021-01-13**