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Morphine Tranquilizer Autoinjector



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I. GENERAL DESCRIPTION

1. Subject of the Technical Specification

Subject of this Technical Specification are "Morphine Tranquilizer Autoinjector "

2. Identification of the product.

Name	Contents	NSN
MORPHINE	20 mg of morphine sulphate (2 ml)	6505-43-000-2805
Training device	No needle, no medical substances	6515-43-0012459

3. Classification.

Classification of Auto injectors according to Polish Military Standard NO-06-A108:2005 is:
 N.14-UZ-II-C

Classification of Auto injectors according to STANAG terminology is: self-injection device

4. Standards and related documents.

"Morphine Tranquilizer Autoinjector " meet requirements of the following standards and documents:

- Polish Military Standard NO-06-A108:2005
- FP (Polish Pharmacopoeia)
- USP (United States Pharmacopoeia)
- EP (European Pharmacopoeia)
- PN-ISO 2859-1+AC1 (International Standard)
- STANAG 2128 MED Edition 4 Medical and Dental Supply Procedures
- STANAG 2871(NBC/MED) Edition 3 First Aid Material For Chemical Injuries
- STANAG 4281 MMS Edition 1 NATO Standard Marking for Shipment and Storage
- STANAG 2350 MED Edition 3 Morphine Dosage and Casualty Markings
- Mil-STD810E Environmental Test Methods and Engineering Guidelines

5. General characteristics and scope of application.

5.1. INDIVIDUAL PACKAGE

The plastic tube with sealed screwed cap, resistant to mechanical impacts and atmospheric conditions, constitutes an external package designed for use in field conditions (shocks, dust, frost, atmospheric downfall, transportation with military means of transport, etc.). Exploitation of Auto injector in individual package, including usage and storage, is possible without any maintenance or protection procedures.

5.2. TRAINING DEVICE

The training device consists no needle and no drugs. Enables to familiarize user (soldier) with shape and methods of administration of drugs with Ravimed's Auto injectors.

6. Exploitation.

Morphine Tranquilizer Autoinjector enable effective life saving and treatment of strong post-traumatic pain. Autoinjector delivers its entire contents automatically upon activation

Training device enables effective cost saving training of Auto injector user

7. Basic functions.

7.1 Auto injector provides intramuscular application of a contained substance by a user (soldier) himself/herself according to existing needs. One chamber Auto injector (Morphine) – containing a pain-killer for relief of a strong post-traumatic pain.

7.3 Training device – no drug, no needle – one use

8. Contents

- **Morphine Sulphate (*Morphini sulfas, solution for injection 20mg/2ml*)** - substance supplied by Warsaw Pharmaceutical Works POLFA SA

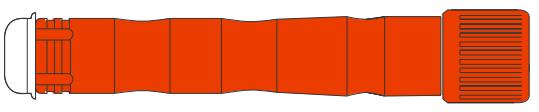
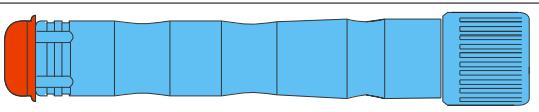
II. REQUIREMENTS

1. Technical description

Auto injector provides injection due to the action of a spring mounted inside. Total injection time does not exceed 5-6 seconds.

1.1. Contents – see point I.2

1.2. Weight and Colors of Auto injectors

		COLOR	Weight ¹ in protective container
1	single chamber	bright red MORPHINE	
2	training	light blue NO NEEDLE NO DRUG	



1 Weight ± 1 g

1.3. **Single-chamber Auto injector** – length of 115 mm (in tube), consisting of a body with screwed cap, and a white safety tip (for Training Device – red tip). Contains an injection needle, a plunger with a catch, a spring, and a single-chamber ampule with adequate substances.

1.4. **Container** – for the Auto injectors – PP transparent tube with a sealed screwed cap. Tube dimensions: Ø23 mm, length² = 115 mm. The container is specially marked³ what enables the the Auto injector to be simple and rapid in use even in the dark.

Marking type	Drawing	Photo
No marks - MORPHINE		

2. **Exploitation conditions.**

Injection conditions

The Auto injector is a single use device serving for automatic intramuscular injection of one liquid substance. The tip of the needle is specially designed to ensure strength due to the necessity of penetration through layers of clothing. Total injection time is up to 5-6 seconds.

Requirements regarding usage safety.

- Because Auto injector contain substances of a very potent influence on the human organism, it is necessary to maintain strict precaution measures and to follow provisions and recommendations of their use.
- Use according to instructions only.

Service and repair.

- Usage of an individual kit of spare parts and/or of a repair kit that could be carried together with Auto injectors is not anticipated.
- Auto injectors do not require any special maintenance procedures.

Storage and transport conditions.

- Auto injectors are designed to be stored, transported, and carried in field conditions and temporary accommodations (tent, shelter, hiding places, etc.).

2 ±0,1 mm

3 Markings only for combat Auto injectors

- Auto injectors may be transported by any means of transport.
- Auto injectors should be stored in rooms protected against direct solar radiation and at room temperature (2°C - 25°C).

III. PACKAGE

1. Individual Packing

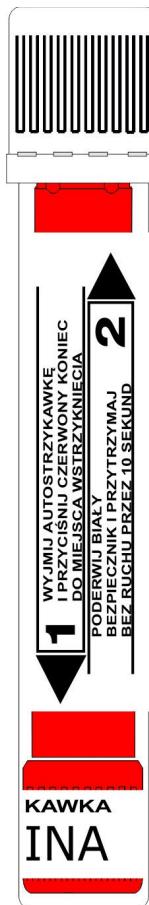
- Package for single Auto injector – translucent tube made of plastic and equipped with sealed screwed cap.

2. Collective Packing

- Collective package of single-chamber Auto injector in the form of carton boxes size = 285 x 200 x 120 mm for 70 Auto injectors in individual packing. (SMALL BOX)

IV. LABELING





**AUTOSTRZYKAWKA MORFINA
PRZECIWKO BÓLOWI, 20mg/2ml**
Roztwór do wstrzykiwań
Morphini sulfas Podanie domięśniowe
WSKAZANIA: uśmierzanie silnego bólu spowodowanego
rozległym urazami, Nie używać w zatruciu środkami
paralityczno-drgawkowymi / Do not use in nerve agent poisoning
1. WYJMIJ AUTOSTRZYKAWĘ I PRZYCIŚNIJ CZERWONY
KONIEC DO MIEJSCA WSTRZYKNIĘCIA / Take out
Auto-injector and press red end to the place of injection
2. PODERWIJ BIAŁY BEZPIECZNIK I TRZYMAJ DOCIŚNIĘTA
DO CIAŁA BEZ RUCHU PRZYNAJMNIEJ PRZEZ 10 SEKUND /
Pull the white safety tip and keep pressed the auto-injector to
your body without move at least 10 seconds
Rpw - Lek wydawany na receptę
Zawartość / Contains :
Morfiny siarczan (*morphine sulphate*) - 20 mg
Lek zawiera sodu pirosiarczyn – patrz ulotka
Przechowywać w temperaturze poniżej 25°C.
Chronić przed zamarzaniem. Lek przechowywać w
miejscu niewidocznym i niedostępnym dla dzieci.
Należy zapoznać się z treścią ulotki przed
zastosowaniem leku. **Podmiot odpowiedzialny:**
Pozwolenie nr: ZPSM Ravimed Sp. z o.o.
EXP: XX-XXXX ul. Polna 54; 05-119 Łajski
LOT XXXXXX

◀◀◀ **ravimed** ▶▶▶

VI. STORAGE

Atmospheric conditions.

Auto injectors in collective packing or individual packing should be stored without any maintenance procedures in the following conditions:

- protected against direct solar radiation and at room temperature (2°C - 25°C)
- relative humidity below 98 %

Protection against damage

Auto injectors should not be stored in areas exposed to mechanical impacts and aggressive chemical substances.

VII. TRANSPORTATION

Protection of cargo.

Carton boxes containing Auto injectors may be transported by any means of transport which meets the following requirements:

- protection against cargo displacement
- protection against cargo mechanical damage
- protection against humidity and water
- compliance with GDP

VIII. GUARANTEE REQUIREMENTS

Guarantee period for Auto injectors stored in intact original packages is stated by the expiry date (two years) on the label.