



### 4.4. SINGLEPEN M

Morphine sulfate 10 mg in water for injection 1 ml.

One-chamber autoinjector for first aid (self-aid/buddy aid) in case of a strong post-traumatic pain. This single use device provides automatic intramuscular administration of morphine sulfate solution. The SINGLEPEN M autoinjector delivers a fixed dose of 10 mg morphine sulfate. Morphine is a narcotic analgesic, which is completely absorbed after intramuscular application. One autoinjector will generally provide adequate analgesia for a 70 kg (154 pounds) adult. Onset of analgesic action is usually within 7-20 minutes following the application with maximal effects observed in 1 hour. If symptoms of pain are not relieved after 30 minutes, second SINGLEPEN M may be applied. The autoinjector is not designated for repeated or long term treatment of pain. When repeated administration is necessary, one autoinjector may be applied every 4 hours as needed.

#### 4.4.1. CONTENT OF THE ONE-CHAMBER AUTOINJECTOR

One chamber	Morphine	10 mg in 1 ml
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Autoinjector is composed of the body, injecting mechanism and an ampule (bullet) with morphine which contains the injection needle. The autoinjector body is black with a stripe sign for morphine (red). Autoinjector has no ring extensions for easy recognition in case of application at night. All autoinjector signs are according to STANAG requirements.

#### 4.4.2. PICTURES OF SINGLEPEN M





### 4.4.3. TECHNICAL DATA

Autoinjector length:	140 mm
Maximum autoinjector diameter:	24 mm
Bullet length (filled with morphine):	45 mm
Maximum bullet diameter with closure:	20 mm
Autoinjector weight:	70 g
Needle length:	20 mm
Application time:	10 s

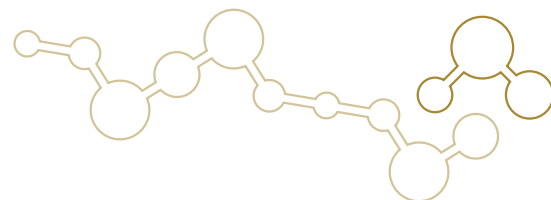
### 4.4.4. LABELLING



### 4.4.5. USAGE

1. Remove metal safety pin, place autoinjector against thigh muscle
2. Push safety fuse for antidote application and hold 10 seconds
3. Remove the autoinjector from the muscle





### 4.4.6. PACKAGE LEAFLET

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**PACKAGE LEAFLET – SUMMARY OF PRODUCT CHARACTERISTICS**  
**SINGLEPEN M | MORPHINE AUTO-INJECTOR**

One-chambered auto-injector (SINGLEPEN M) containing MORPHINE sulfate pentahydrate (10 mg). Sterile solutions for intramuscular use only.

**COMPOSITION:**  
 One auto-injector delivers morphine sulfate pentahydrate 10 mg in water for injection (1 ml). The product is pyrogen free and contains excipients (sodium chloride, glycine, disodium edetate dihydrate) to improve the stability of solution.

$\cdot \text{HO}-\text{S}(=\text{O})_2-\text{OH}$   
 $\cdot 5\text{H}_2\text{O}$

**DESCRIPTION:**  
 Prefilled one-chambered auto-injector for first aid (self- or buddy-aid) in the case of a strong acute post-traumatic pain after severe injuries or burns. This single use device provides automatic intramuscular administration of morphine.

**Indication groups:**  
 Analgesic, anodyne.

**CHARACTERISTIC:**  
 Morphine is naturally occurring alkaloid in the opium poppy (*Papaver somniferum* L.). The strong analgesic effect of morphine is conditioned by agonistic effect on opioid receptors in cerebral cortex, thalamus, formatio reticularis, limbic-hypothalamus system, periaqueductal grey matter and in substantia gelatinosa. Morphine by influence on CNS expressively attenuates acute and chronic pains, causes psychomotor attenuation, total relaxation and euphoria. Morphine attenuates the respiratory volume and frequency, reduces the sensitivity of respiratory centre to carbon dioxide.

**PHARMACOKINETICS:**  
 After application of an auto-injector, morphine is quickly re-sorbed. The absorption is retarded in circulatory shock. Onset of analgesic action is usually within 7-20 minutes following the application, the maximal effect is reached in 30-60 minutes. Plasma biological half-life is 2 hours; duration of the effect is 4-5 hours. The binding to plasma proteins is 25-35%. Morphine is bio-transformed in the liver. Less than 10% of morphine is excreted in unchanged form. The elimination half-life is about 1.9 hours. Drugs with inductive effect on hepatic enzymes have not an expressive influence on morphine metabolism. Decrease of creatinine clearance below 2 ml/min prolongs the plasma half-life more than 10 times.

**INDICATION:**  
 First aid in the case of a strong acute post-traumatic pain after severe injuries or burns. The auto-injector is not designated for long term treatment of pain. It is not to be used for prophylaxis.

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**CONTRAINDICATIONS:**  
 Administration is contraindicated in hypersensitivity to the morphine or excipients, damage of lungs function with depression of respiratory centre, chronic obstructive pulmonary disease, paralytic ileus and head injuries with elevated intracranial pressure. Morphine potentiates the effects of other CNS depressants, including alcohol. Auto-injector is not suitable for children and pregnant or lactating women.

**SIDE EFFECTS:**  
 In normal doses adverse events occur in about 7% of people, most frequently nausea, vomiting and constipation (3-4%). Respiratory depression, drowsiness and confusion occur in approximately 2%, drop in blood pressure in about 0.5% of patients. Morphine can cause biliary and urethral spasms, dry mouth, sweating, facial flushing, dizziness, bradycardia, tachycardia, palpitations, hypothermia, mood changes (euphoria, dysphoria), asthenia, headache, sleep disturbances, blurred vision, miosis, taste disturbance, decreased appetite, allergic reactions at the injection site (pruritus, urticaria) and total (bronchoconstriction). Higher doses may result in significant respiratory depression. In patients with asthma bronchiale, morphine may induce bronchospasm. Among other serious adverse reactions belongs the occurrence of psychic and somatic dependence. The specific antagonist of morphine is naloxone, which can quickly remove the side effects/intoxication symptoms.

**DOSAGE:**  
 One auto-injector should be administered intramuscularly in the case of a strong acute post-traumatic pain. If symptoms of pain are not relieved after 30 minutes, second SINGLEPEN M may be applied. The auto-injector is not designated for repeated or long term treatment of pain. When repeated administration is necessary, one auto-injector may be applied every 4 hours as needed.

**Instructions for application**

1. Remove cotter pin, place auto-injector against thigh muscle.
2. Push safety fuse for antidote application and hold 10 seconds.
3. Remove auto-injector from muscle.

**STORAGE:**  
 Store in a dry and dark place, at temperature 5-25°C, do not refrigerate or freeze.

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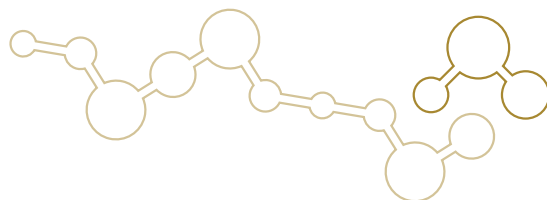
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### 4.4.7. STORAGE CONDITIONS

5–25°C (41–77°F)

### 4.4.8. WARRANTY

3 years

### 4.4.9. PACKAGING

Carton with 50 pcs



Photo for example of packaging only.