

### 4.3. SINGLEPEN D

Autoinjector is a semiautomatic injection device for the first aid in case of nerve agent (G or V) or organophosphorus pesticide intoxication designed for self application or mutual application (buddy aid), after donning protective mask and prior to the decontamination and delivery of medical care. The autoinjector is a part of regular health equipment of each soldier. Autoinjector delivers diazepam intramuscularly to the back muscles of thigh and is able to penetrate several layers of clothing. Autoinjector is a disposable device, intended for single dose delivery. Diazepam may prevent damage of the brain, convulsions (or reduce their duration) and is also useful as an anxiolytic drug during poisoning. Diazepam is a centrally acting anticonvulsive drug. It is applied after application of DOUBLEPEN (OA or PA) autoinjector.

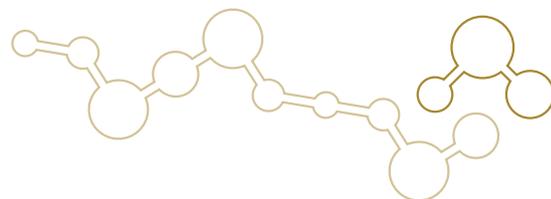
#### 4.3.1. CONTENT OF THE ONE-CHAMBER AUTOINJECTOR

<b>One chamber</b>	Diazepam	10 mg in 2 ml
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Autoinjector is composed of the body, injecting mechanism and an ampule (bullet) with diazepam which contains the injection needle. The autoinjector body is black with a stripe sign for diazepam (grey). Autoinjector has three ring extensions for easy recognition in case of application at night. All autoinjector signs are according to STANAG requirements.

#### 4.3.2. PICTURES OF SINGLEPEN D





### 4.3.3. TECHNICAL DATA

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

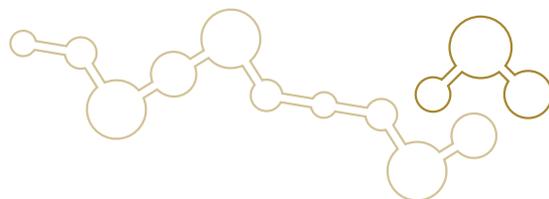
### 4.3.4. LABELLING



### 4.3.5. 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





### 4.3.6. PACKAGE LEAFLET

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**PACKAGE LEAFLET – SUMMARY OF PRODUCT CHARACTERISTICS**  
**SINGLEPEN D | DIAZEPAM AUTO-INJECTOR**

One-chambered auto-injector (SINGLEPEN D) containing DIAZEPAM (10 mg). Sterile solutions for intramuscular use only.

**COMPOSITION:**  
 One auto-injector delivers diazepam 10 mg in water for injection (2 ml). The product is pyrogen free and contains excipients (propylene glycol, ethyl alcohol, sodium benzoate, benzoic acid, benzyl alcohol, sodium chloride) to improve the stability of solution.

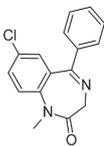
**DESCRIPTION:**  
 Prefilled one-chambered auto-injector for first aid (self- or buddy-aid) in the case of convulsions, seizures and for relief of skeletal muscle spasms during intoxication with nerve agents or organophosphate pesticides.

**Indication groups:**  
 Anticonvulsive, anxiolytic.

**CHARACTERISTIC:**  
 Diazepam is a benzodiazepine. It binds to the benzodiazepine site of the  $\gamma$ -aminobutyric acid (GABA) receptor, leading to central nervous system depression. Its action enhances the effects of the neurotransmitter GABA. Diazepam is a centrally acting anticonvulsive drug. It may prevent the damage of the brain, convulsions (or reduce their duration) and is also useful as an anxiolytic drug during poisoning with highly toxic organophosphorus compounds - nerve agents or organophosphate pesticides.

**PHARMACOKINETICS:**  
 After application of an auto-injector, the site of injection is usually painful and diazepam is erratically absorbed. The absorption is retarded in circulatory shock. Onset of anticonvulsive action is usually within 15-30 minutes following the application, the maximal effect is reached in 60-90 minutes. Plasma biological half-life is 20-70 hours; duration of the effect is approximately 3 hours. Diazepam is metabolised in the liver. Its metabolites are excreted mainly in the urine and faeces as glucuronides.

**INDICATION:**  
 First aid in the case of convulsions, seizures and for relief of muscle spasms during poisoning with highly toxic organophosphorus compounds. The auto-injector is not designated for long term treatment. It is not to be used for prophylaxis.



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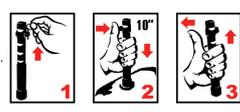
**CONTRAINDICATIONS:**  
 Administration is contraindicated in hypersensitivity to the diazepam or used excipients, in people with breathing problems (e.g. chronic obstructive airways disease, sleeping apnea), depression/hyperactivity, porphyria, liver disorders, acute narrow angle glaucoma, open angle glaucoma glaucoma and myasthenia gravis. Diazepam potentiates the effects of other CNS depressants, including alcohol. Auto-injector is not suitable for children and pregnant or lactating women.

**SIDE EFFECTS:**  
 Most commonly reported side effects are drowsiness, fatigue, weakness, ataxia, tremor, problems with coordination, confusion, dizziness, dry mouth, nausea, diarrhea and ataxia, venous thrombosis and phlebitis (at the site of application). Reactions reported less frequently include confusion, depression, hypoactivity, dysarthria, headache, slurred speech, syncope, tremor, vertigo, constipation, incontinence/urinary retention, cardiovascular collapse, hypotension, bradycardia, diplopia, blurred vision, nystagmus, skin allergic reactions, changes in salivation, icterus; in some people paradoxical reactions such as stimulation, hallucinations, restlessness, anxiety, aggressiveness, increased muscle spasticity and sleep disturbances have been reported. Among other serious adverse reactions belongs the occurrence of psychic and somatic dependence. The specific antagonist of diazepam is flumazenil (flumazepil), which can quickly remove the side effects/intoxication symptoms.

**DOSAGE:**  
 A dose of diazepam in case of acute muscle seizures is 10 – 20 mg administered intramuscularly. Therefore, one or two auto-injectors should be administered intramuscularly in the case of severe convulsions. The auto-injector is not designated for repeated or long term treatment of convulsions. When repeated administration is necessary, one auto-injector may be applied every 4 hours as needed, under medical supervision.

**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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 for ChemProtect.SK s.r.o., Jasenie 414, 976 75, Slovak Republic, ID number: 44 397 526  
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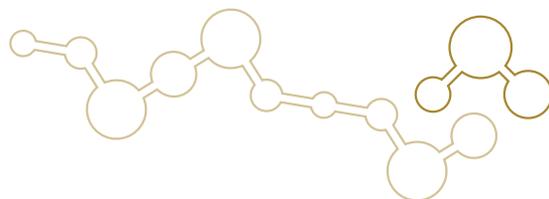
Last revision: May 2015

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### 4.3.7. STORAGE CONDITIONS

5–25°C (41–77°F)

### 4.3.8. WARRANTY

3 years

### 4.3.9. PACKAGING

Carton with 50 pcs

