

## User Guide







**GensuPen<sup>2</sup>**  
AN AUTOMATIC GENSULIN  
PEN INJECTOR

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GensuPen®2 is an easy to use reusable automatic pen injector intended for self-administration of insulin by diabetes patients and by third parties to patients requiring insulin treatment. It provides the patient with a precise, safe and convenient way to administer the insulin dose recommended by a healthcare professional, in the range of 1 to 60 units in 1-unit increments.

GensuPen®2 is intended for use exclusively with standard GENSULIN® 3ml cartridges manufactured by BIOTON S.A. GensuPen®2 is designed for use with disposable 4 mm, 5 mm, 6 mm and 8 mm needles.

Do not use GensuPen®2 if it is not working properly or looks damaged. In such case, exchange the pen for a new one via your healthcare provider.

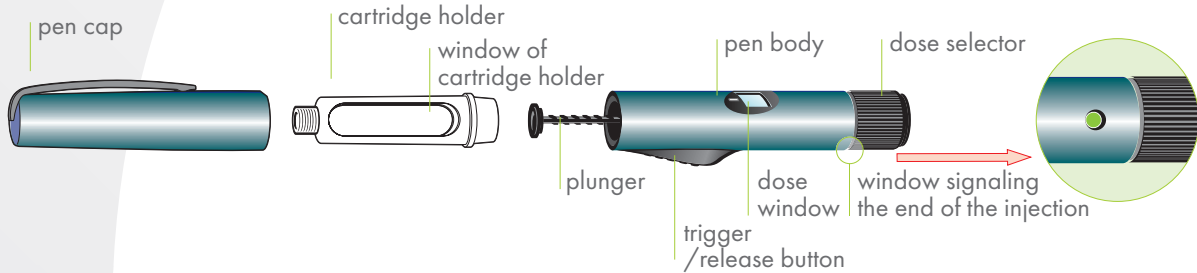
GensuPen®2 is designed for single patient use. Do not share it with others.

People who are blind or have vision problems should not use GensuPen®2 without help from a person trained in its use.

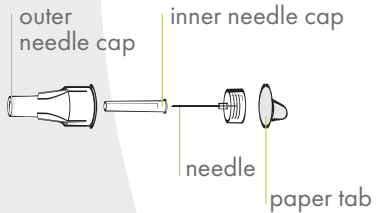


**important information**

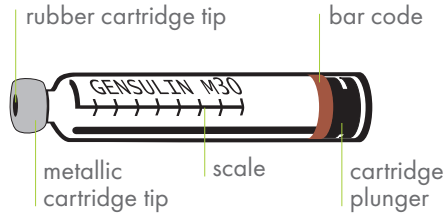
## CONSTRUCTION OF THE PEN INJECTOR



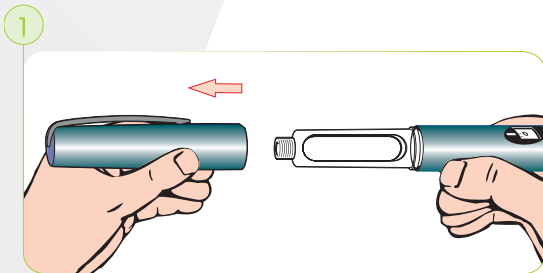
## PEN NEEDLE SET



## INSULIN CARTRIDGE



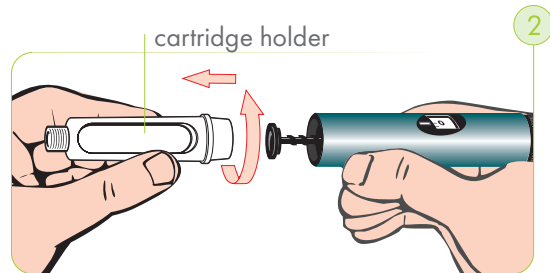
**overview of pen parts**



Remove **the pen cap**.

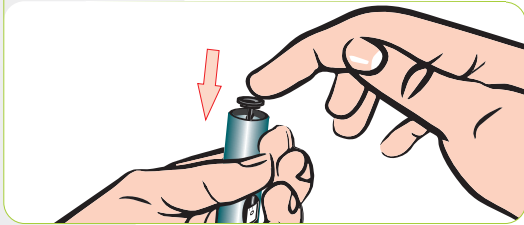


Twist off **the cartridge holder** by turning it **counterclockwise**.



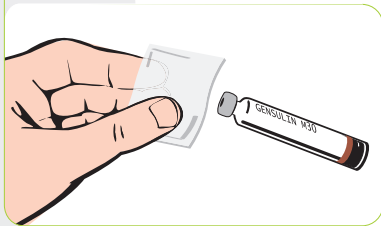
**preparing the pen for use**

3



Push the plunger into the pen body until it stops as shown in the picture. Do not tilt the plunger sideways. The plunger should slide into the body of the pen.

4



Disinfect the rubber tip of the cartridge with an alcohol swab.

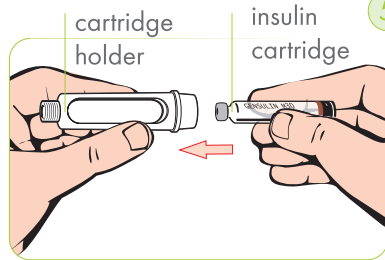
Insert **the insulin cartridge into the cartridge holder**, with narrower rubber tip first.

**WARNING**

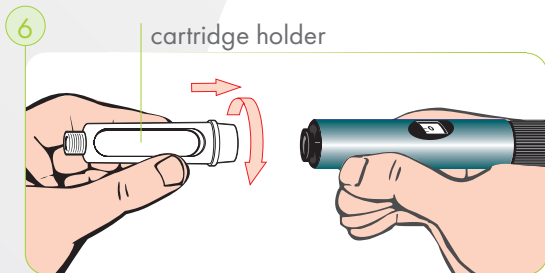
⚠ There are two rubber tips on the cartridge: narrower at the front and wider at the back.



5

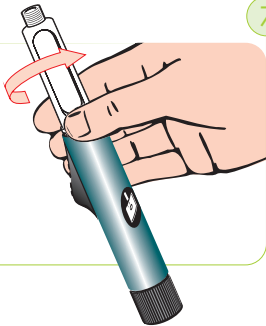
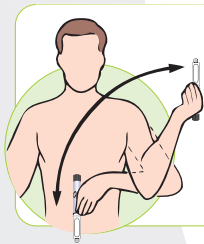


**preparing the pen for use**



Check if the right type of insulin is inside the cartridge holder.

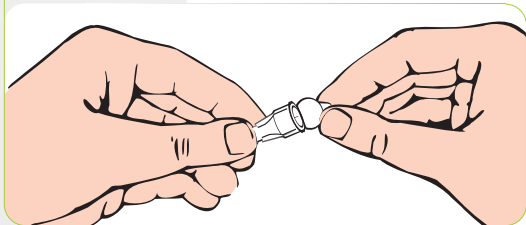
Twist **the cartridge holder** back on to **the pen body** in a clockwise direction until you hear a click.



**If you use intermediate-acting insulin (Gensulin<sup>®</sup> N) or premixed insulin (Gensulin<sup>®</sup> M30, M40 or M50),** you should mix the insulin. Roll the insulin pen in your hands 10 times, before turning it over 10 times by 180 degrees to obtain a homogenous turbidity or milky appearance. Repeat the steps until the insulin appears to be uniformly mixed.

**preparing the pen for use**

8



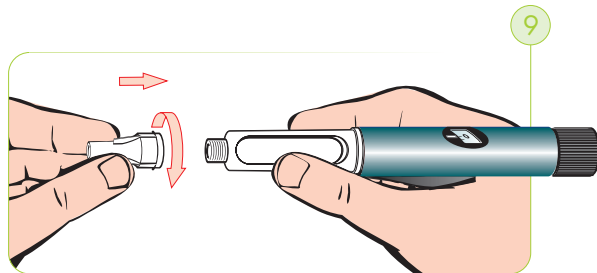
Take a new needle and tear off the paper tab.

**IMPORTANT**

⚠ For each injection, use a new needle. Do not use needles with damaged packaging.

Reusing the same needles or needles with damaged packaging would increase the risk of infectious disease transmission. Reusing the same needles could increase the risk of lipohypertrophy.

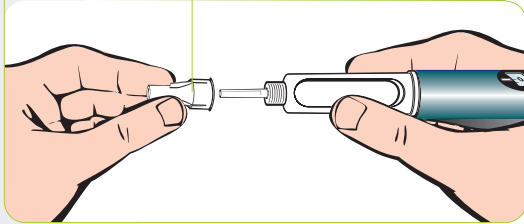
**Push the needle straight onto the pen,**  
and tighten it **by turning it clockwise.**



**preparing the pen for use**

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outer needle cap



Remove **the outer needle cap**. Save it as you will need it after the injection to safely remove the needle from the pen.

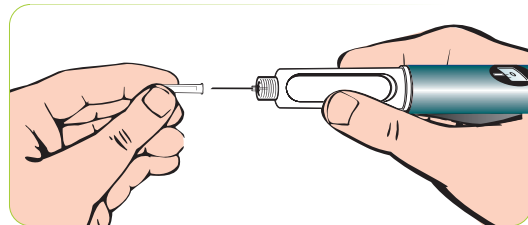


**IMPORTANT**

⚠ If you accidentally prick yourself with a needle, use a skin disinfectant.



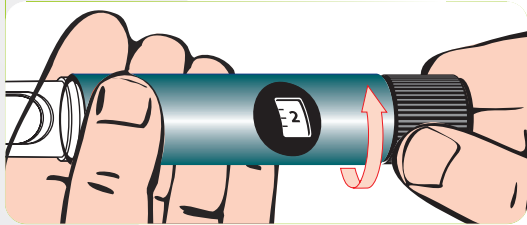
Remove **the inner needle cap**.



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**preparing the pen for use**

12



Turn the dose selector to choose **2 testing units**.

How to select the dose:

- Turn the dose selector clockwise.
- Numbers or marks corresponding to the insulin units will appear in the dose window. Turn the dose selector till the desired dose appears on the dose window.

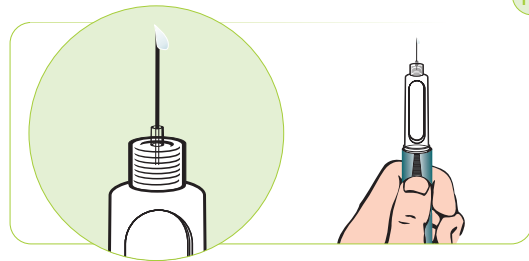
Hold the pen with the needle facing upwards. Using your thumb, slide **the trigger** in the direction of the needle. Hold the trigger until a green dot appears in **the window signaling the end of the injection.**

**WARNING**

⚠ A drop of insulin should appear at the tip of the needle. If no insulin appears, repeat steps 12 and 13 until insulin squirts from the needle tip. If no insulin appears after several attempts, change the needle, and repeat steps 8 to 13.

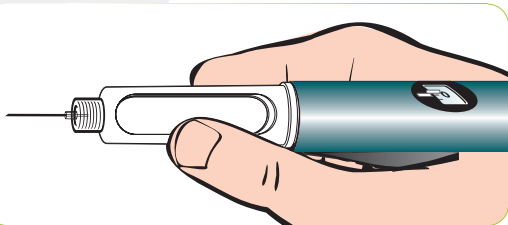


13



**preparing the pen for injection**

14



**If you use several types of insulin, check if the cartridge in the pen corresponds with the insulin type you should inject.**

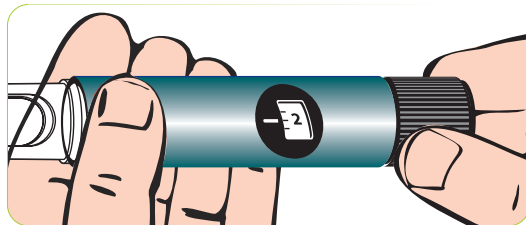
**WARNING**

If you have chosen a dose that is too high, you can reduce it easily by rotating the dose selector counterclockwise until the desired dose is displayed in the dose window. These clicks have a different sound.

In order to select the dose of insulin you want to inject, turn the dose selector clockwise until the correct number of insulin units is visible in the dose window.

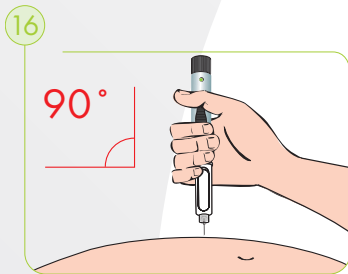
IMPORTANT

**⚠ If you accidentally inject a dose that is higher than the prescribed one, contact your attending physician immediately.**



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**preparing the pen for injection**



Place the GensuPen<sup>®</sup>2 firmly in your hand. Your thumb should rest comfortably on the trigger and other fingers should grip the pen. Insert the needle into the subcutaneous tissue. Use your thumb to push the trigger towards the needle. The correct techniques of insulin administration are described on page 16.

The recommended method of administration for most adults is at 90°.

**Hold the trigger until a green dot appears** signalling the end of injection.

**IMPORTANT**

⚠ To avoid complications at the injection site, never change the angle of the needle during the injection and needle removal.

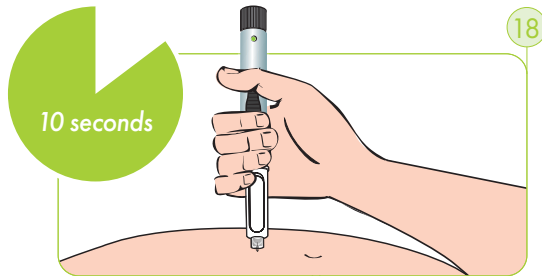


**injecting a dose**

**IMPORTANT**

⚠ If the green dot does not appear, it means that insulin in the cartridge has finished. Remember the number of insulin units visible in the dose window of GensuPen®2. It corresponds to the number of units of insulin that you still need to complete the injection. Change the insulin cartridge and refill the needed dose by proceeding in accordance with steps 1-18.

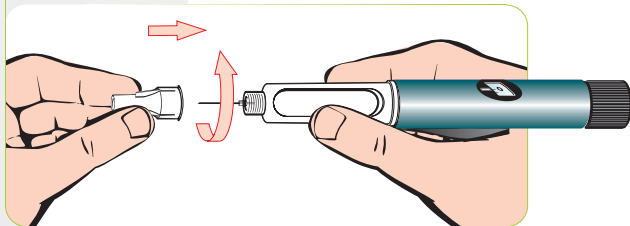




Count to ten and then remove the needle at the same angle as it was inserted.

**injecting a dose**

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After the injection, put the outer cap back onto the needle and rotate it counterclockwise to dislodge the needle. Remove the used needle in accordance with information provided by the needle manufacturer. Insulin injection has been completed.

**IMPORTANT**

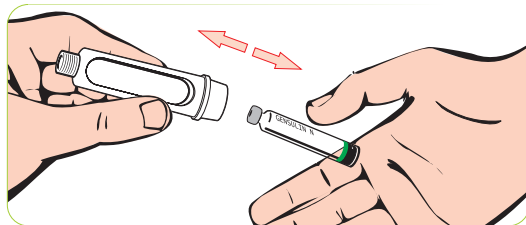
⚠ Used needles and empty insulin cartridges are classified as hazardous waste. Keep them away from children. To avoid injury, do not attempt putting the inner cap back on.

## HOW TO REPLACE A USED INSULIN CARTRIDGE?

Perform the action described in steps ①-②. Shake the empty cartridge from its holder and remove it according to the information supplied by the manufacturer of insulin. Set the dose selector at position "0" by turning it counterclockwise. Follow steps ③-⑦.

## HOW TO REPLACE A USED NEEDLE?

Follow the guidelines described in step ⑱. Then perform procedures described in steps ⑧-⑪.



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**replacing a used cartridge and a used needle**

## INSULIN ADMINISTRATION SITES

For short-acting insulin (GENSULIN<sup>®</sup>R), intermediate-acting insulin (GENSULIN<sup>®</sup>N) and premixed insulin (GENSULIN<sup>®</sup>M30, M40, M50), the recommended injection sites are:

- ① **ABDOMEN**    ② **THIGHS**    ③ **BUTTOCKS**

### WARNING

⚠ If there is a risk of nocturnal hypoglycaemia, the intermediate-acting insulin (GENSULIN<sup>®</sup>N) and premixed insulin (GENSULIN<sup>®</sup>M30, M40, M50) should be administered in the thighs or in the buttocks due to slower absorption of insulin from these sites.

To reduce the risk of damaging skin tissue:

- divide each site into four parts;
- rotate the injection site every one to two weeks;
- keep at least 1 cm distance (approximately one finger thickness) between the new injection site and the previous one.

**IMPORTANT**

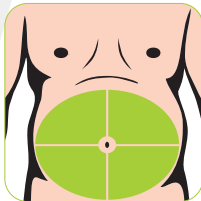
⚠ Remember that the injection site must be changed regularly.



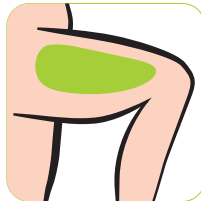
**proper injection sites and techniques**

## INSULIN ADMINISTRATION SITES

### ① ABDOMEN

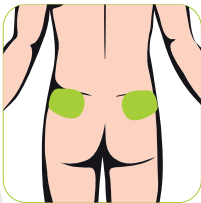


### ② THIGHS

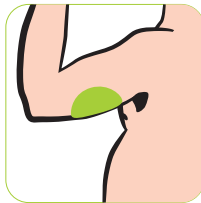


- do not flex your muscles;
- do not inject insulin in the thigh before a planned physical activity (due to faster absorption).

### ③ BUTTOCKS



### ④ ARMS

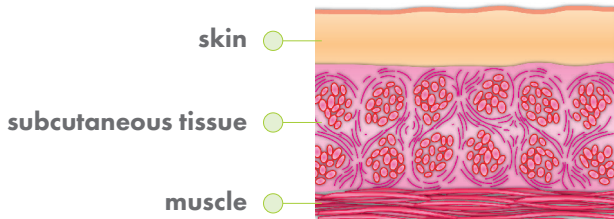


**The arms are not recommended for self-injection due to difficulty accessing the site.** Caregivers who have been properly instructed in insulin injection technique may choose the back of the arm as the optional injection site.

## INSULIN ADMINISTRATION TECHNIQUE

To ensure proper insulin absorption, administer the injection into the subcutaneous tissue. If the injection site is dirty or the patient is in an environment conducive to infection, the site should be disinfected. If alcohol has been used for disinfection, allow the skin to dry completely before injection.

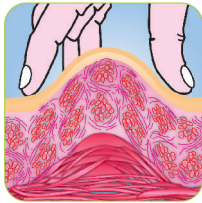
You can administer GENSULIN® by folding the skin when the estimated distance between the skin surface and the muscle is the same or less than the length of the needle.







✓ correct skin lift



✗ incorrect skin lift

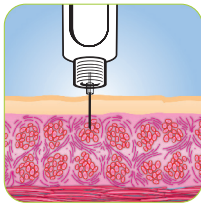
## PROPER TECHNIQUES OF SKIN LIFT

Delicately lift the skin and subcutaneous tissue, or fatty layer, between your thumb and index finger, leaving the muscle behind. Administer insulin.

**proper injection sites and techniques**

## **INSULIN ADMINISTRATION TECHNIQUE - INJECTION**

Insert the needle into the subcutaneous tissue. Using your thumb, push the trigger button and hold it till the green dot appears, signaling the end of the injection. Count to ten before removing the needle at the same angle as it was inserted.



**Adults**

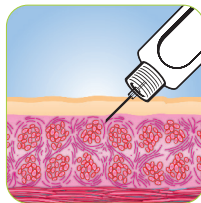
4 mm, 5 mm, 6 mm

**Adults (slim)**

4 mm, 5 mm

**Children (>6 years)  
and adolescents**

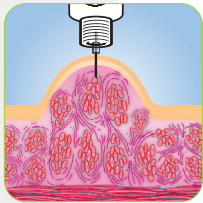
4 mm, 5 mm



**Adults (slim)**

6 mm

**proper injection sites and techniques**



**Adults (slim)**

4 mm, 5 mm, 6 mm

**Adults**

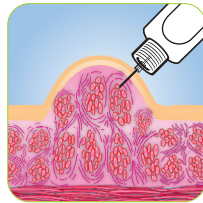
8 mm

**Children (>6 years) and adolescents**

5 mm

**Children (slim, >6 years)  
and adolescents  
Children 2-6 years**

4 mm



**Adults (slim)**

8 mm

**Children (>6 years) and adolescents**

6 mm

**Children (slim, > 6 years)  
and adolescents**

**Children 2-6 years**

5 mm, 6 mm

**IMPORTANT**

⚠ Release the skin lift after the injection.

Establish the following with your healthcare provider:

- thickness of your subcutaneous tissue,
- appropriate needle sizes (4 mm, 5 mm, 6 mm, 8 mm) selected for the specific insulin administration sites,
- angle of needle insertion when making the injection.

## STORAGE AND CLEANING

- ① GensuPen<sup>®</sup>2 injector should always be stored and carried with the pen cap on, without the needle.
- ② GensuPen<sup>®</sup>2 with the insulin cartridge should be stored at the temperature recommended in the Package Leaflet of GENSULIN<sup>®</sup> manufactured by BIOTON S.A.
- ③ GensuPen<sup>®</sup>2 with the insulin cartridge should be stored at temperature of 25°C for a maximum period of 28 days.
- ④ GensuPen<sup>®</sup>2 should be stored in its case.

⚠ Do not put GensuPen<sup>®</sup>2 into water.



- ⑤ Clean GensuPen®2 daily. Use only a damp cloth for cleaning. Do not immerse GensuPen®2 in water. Do not use alcohol, hydrogen peroxide, disinfectants or lubricants to clean the pen injector.
- ⑥ GensuPen®2 without the insulin cartridge should not be stored at temperatures higher than 70°C or below -40°C. Store the pen injector far from humidity and dust and protect it from direct sun exposure.
- ⑦ GensuPen®2 should be protected against major forces.

**AFTER****After each injection:**

- remove and discard the needle, abiding by the safety rules.

**NEVER****Never use:**

- any insulin that is not prescribed to you by your healthcare professional,
- insulin after the expiry date,
- needles that are not recommended.

**NOTE!**

- GensuPen®2 cannot be used without the insulin cartridge as it may cause its defective operation,
- The usage of cartridge other than Gensulin® is associated with dangers of inaccurate insulin dosing.

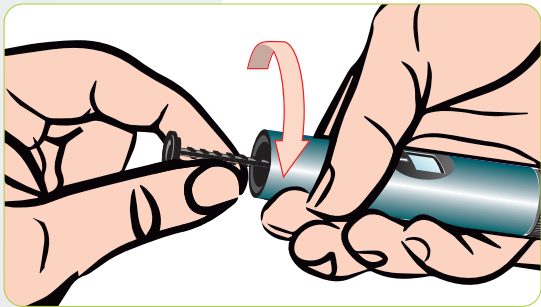


### **Why does the green dot not appear after the end of insulin injection?**

**A:** If the green dot does not appear after the injection is made, it means that there is not sufficient insulin in the cartridge to administer the whole dose. In such instances, please follow IMPORTANT steps listed on page 12.



**frequently asked questions**



**What should I do if I cannot press the plunger into the pen body when replacing the cartridge?**

**A:** You should screw the plunger clockwise into the pen body. Then push the end of the plunger into the pen body until it comes to the first moment of resistance. In case of further problems, stop using the pen and contact the pen manufacturer.

### **The pen injector fell on the floor; how to check if it operates correctly?**

**A:** Check to ensure the cartridge is not damaged or leaking. Make sure that all parts of the injector are intact and correctly connected. Replace the needle and prepare the pen injector, following steps 10-13. If insulin drop appears at the needle tip, it means that the pen injector operates correctly.

### **What should I do if I cannot put the cartridge into the pen body?**

**A:** Check if the plunger is fully inserted and if the cartridge is correctly mounted.

**Why is priming of GensuPen®2 before the injection so important?**

**A:** Priming of GensuPen®2 helps to ensure that pen is working correctly, delivering the right amount of insulin.

**What to do if air is still present in the cartridge after the pen injector is primed?**

**A:** Tap the cartridge gently with your finger to remove the air from the needle and re-check insulin flow as shown on page 9.

**How can I find out how much insulin is left in the cartridge?**

**A:** The scale on the cartridge gives an approximate indication of the amount of insulin left. This can be seen through the dose window.

### **Can I administer insulin each time at the same site?**

**A:** No, the injection site should be rotated every day to prevent lipodystrophy (pitted or thickened skin). Injection should be done into the subcutaneous tissue of abdomen, buttocks and thighs. Change injection sites in one anatomical area, so that each site is not used more than once a month. If you notice thickening or atrophy of subcutaneous tissue, you should stop administering insulin at this site and contact your healthcare professional immediately.

### **What should be avoided after insulin injection?**

**A:** Exercising (running, jogging and cycling) and taking hot showers should be avoided after insulin injection, as it may accelerate the rate of insulin absorption.



**frequently asked questions**

**What may be the consequences of accelerated insulin absorption from the subcutaneous tissue?**

**A:** Accelerated absorption may cause earlier hypoglycaemia or later hyperglycaemia. Therefore, you should always consult the range of dose modification with your physician whenever it is possible that the insulin absorption rate may be modified.

**Can insulin be injected through clothes?**

**A:** Insulin injection through clothes is not recommended as it is impossible to check if there is any leakage of insulin or bleeding from the injection site.

## **Why did the drop of insulin not appear at the needle tip despite repeated priming?**

**A:**

- a) There may be a gap between the pen plunger and the cartridge plunger. Check if the cartridge is correctly placed, and if the plunger is pushing the cartridge. If the end of the plunger pushes the cartridge, insulin should flow out.
- b) The needle might be blocked. You may need to replace the needle with a new one.

### **Why does the dose selector turn slowly when I administer the injection?**

**A:** One of the possible causes is a clogged needle - replace the needle with a new one. Check for dirt accumulation in the interior of the pen. Do not accelerate the dose selector manually. This may cause modification of the set dose to a lower one. Another reason may be choosing the wrong administration site with traumatized tissue, too often used to inject insulin. In this case, the insulin injection site should be changed.

### **Do all insulin need to be mixed before injection?**

**A:** Each insulin except for **GENSULIN®R (short-acting insulin)** should be mixed before injection.





If you need assistance, contact your local healthcare provider or write to:  
**bioinfo@bioton.com**

Go to **www.bioton.com** for additional information or view „How to use GensuPen®2“ video for more guidance.

**frequently asked questions**

Package content:

GensuPen<sup>®</sup>2 automatic pen injector, case, User Guide.

GensuPen<sup>®</sup>2 meets the standard and general requirement of dosing accuracy and robustness of PN-EN ISO 11608-1.

GensuPen<sup>®</sup>2 is intended for use with disposable 4 mm, 5 mm, 6 mm, 8 mm needles according to EN ISO 11608-2.

GensuPen<sup>®</sup>2 should be replaced with a new one after about 2 years of use, when decided by the physician or in any case when there are doubts as to its functionality.

**Manufacturer:**

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**fax:** +48 22 721 13 33

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www.bioton.com

**Distributor:**



**information from the manufacturer**





**notes**





**notes**

Read the instruction carefully  
before using GensuPen®2.

Failure to follow the  
recommendations may lead to  
serious consequences.



Using the device  
differently from the one  
described in this manual is not  
recommended.

GEN.UL.004.17-EN-v.3  
Revision date: February 2022