



Фотографические изображения медицинского изделия
Шприц-ручка «ОлСтар» (AllStar) для многократного использования
с принадлежностями,
производства "Sanofi-Aventis Deutschland GmbH", Germany

ЗАО «Санофи Россия»

Адрес: 125009, Москва, ул. Тверская, 22. Тел.: (495) 721-1400. Факс: (495) 721-1411. www.sanofi.ru

ЭЛЕКТРОННАЯ КОПИЯ ОФОРМЛЕНА ЦЕНТРОМ ИСПЫТАНИЙ И РЕГИСТРАЦИИ МЕДИЦИНСКИХ ИЗДЕЛИЙ

ручка «ОлСтар» (AllStar) для многократного использования.



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Чехол;



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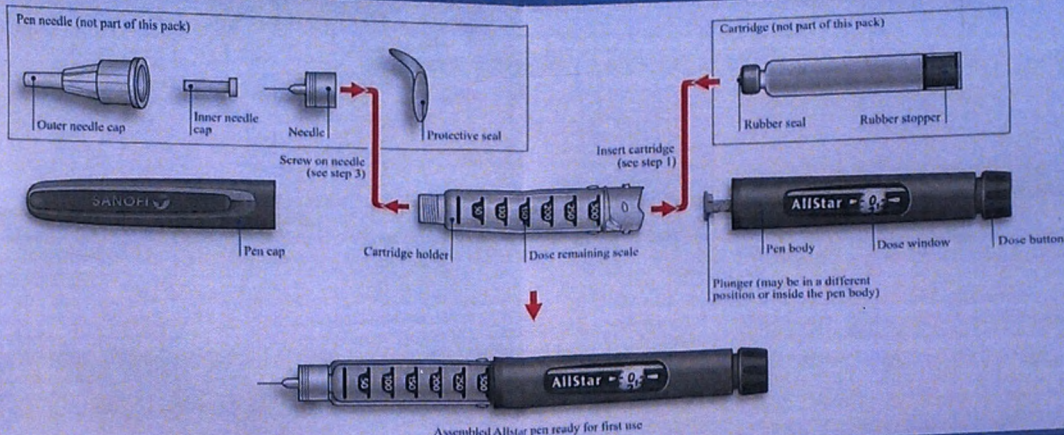
3. Инструкция по использованию для пациентов;

AllStar™: Read this leaflet carefully

Instruction for use
AllStar™
Reusable insulin delivery device

SANOFI

The AllStar components



Before you start

Read these instructions and follow them completely each time you use AllStar to ensure that you get the right dose.

If you do not follow these instructions completely, you may get too much or too little insulin, which may affect your blood glucose levels.

- If you are not able to follow all the instructions completely on your own, are blind or have severe vision problems, use AllStar only if you have help from a person who is able to follow the instructions.
- AllStar is a re-usable pen for the injection of insulin.

Talk with your healthcare professional about proper injection technique before using AllStar.

AllStar is a re-usable pen for the injection of insulin.

- You can set doses from 1 to 80 units in steps of 1 unit.
- AllStar can only be used with 3 ml (300 units) insulin cartridges (U-100) from Sanofi Group.
- Each insulin cartridge contains 300 units and can be used for multiple injections until it is empty or 28 days have passed since its first use (whichever comes first).
- The rubber stopper will only move to the end of the cartridge when all 300 units have been given. AllStar has been designed to be used for up to 3 years after first use.

Record the date your pen was first used here:

DD / MM / YYYY

Contact your healthcare professional to get a new AllStar when your pen has been used for 3 years. If you have any questions about AllStar, ask your healthcare professional.

Reading the dose remaining scale

The approximate number of units remaining in the cartridge is shown on the scale by the end of the rubber stopper nearest to the needle.

Example 1
Approximately 250 units remaining.



Example 2
Between 50 and 100 units remaining.



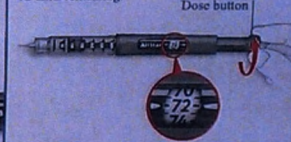
You cannot select more units than what is remaining in the cartridge.

- If less than 80 units are left, the exact number can be found by:

- turning the dose button as far as it will turn easily

- reading the number in the dose window.

Example
72 units remaining.



Important information for use of AllStar:

IMPORTANT

- Always check the label on your cartridge for the type of insulin and expiry date before each injection.
- Always attach a new needle before each injection. Use needles from Becton Dickinson and Company, Ypsomed and Owen Mumford. These are the manufacturers that have been approved for use with AllStar. The needle is not part of this pack.
- Always perform the safety test before each injection (see Step 4).
- If you use different types of insulin, you should use a different color AllStar or another Sanofi Group pen for each insulin. You should ensure to differentiate your pens containing different types of insulin.

- If you are giving an injection to another person or if your injection is given by another person, take special care not to touch the needle tip to avoid accidental needle injury and passing infection.
- For use in a multi-patient environment, e.g. hospital or nursing home, special caution must be taken to ensure identification of the correct pen for each patient.
- Each AllStar, each needle and each cartridge are only for one person's use. Do not share with anyone else.
- Never use AllStar if it is damaged or if you are not sure that it is working properly.
- Never use an insulin cartridge if it is damaged.
- Always have a back-up method for delivering your insulin available (e.g. a spare insulin cartridge and a spare AllStar or a U-100 insulin syringe).
- AllStar should not be stored in the refrigerator.

Storage and maintenance of AllStar

Storage Instructions

- Keep AllStar out of the reach and sight of children.
- It is recommended to store AllStar in carry case provided.
- Do not store AllStar in the refrigerator between injections.
- Do not store AllStar with a needle attached.
- If your insulin cartridge is in cool storage (e.g. refrigerator), take it out 1 to 2 hours before you inject to allow it to warm up. Cold insulin is more painful to inject.
- The insulin cartridge can be used for multiple injections – do not remove it from AllStar between injections unless cartridge is empty.
- From when the cartridge is first used, it can be used for up to 28 days under normal carrying or storage conditions.
- Protect AllStar from direct sunlight and from high storage temperatures (e.g. do not store AllStar in a hot car).

- See patient insert / leaflet supplied with the 3 ml insulin cartridge for further cartridge storage information.
 - After the 3 years of using the pen, dispose of the pen safely as instructed by your healthcare provider.
- ##### Maintenance
- Protect your AllStar from dust and dirt.
 - You can clean the outside of your AllStar by wiping it with a damp cloth.
 - Do not soak, wash or lubricate AllStar as this may damage it.
 - Your AllStar is designed to work accurately and safely. It should be handled with care.
 - Avoid situations where AllStar might be damaged.
 - Do not use excessive force when turning or pressing the dose button or when pushing the plunger back in.
 - If your AllStar is damaged then it is no longer safe to use.
 - If you are not sure whether or not your AllStar is damaged, contact your healthcare professional.

AllStar is a trademark of the Sanofi Group.
AllStar meets the current dose accuracy and functional requirements of ISO 11608-1:2000 with Sanofi Group 3 ml (300 units) insulin cartridges (100 units per ml).
Revision date: February 2013

Manufacturer
Sanofi-Aventis Deutschland GmbH
Industriepark Höchst
D-65926 Frankfurt am Main
Germany.
www.sanofi.com



Consult instructions for use



Batch code



Keep away from sunlight



Manufacturer



SIL-A-0132113-1 (256885)

There are important instructions on the other side of the page.

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ALLSTAR: GIVING INJECTIONS WITH YOUR REUSABLE INSULIN DELIVERY DEVICE

ENSURE THAT YOU READ THE FULL INSTRUCTIONS FOR USE BEFORE USING ALLSTAR.

There are important instructions on the other side of the page.

What you need for your injection:

- Your AllStar reusable insulin injection pen
- One Sanofi Group 3 ml (300 units) insulin cartridge (100 units per ml) (not part of this pack)

Pen needle (not part of this pack)

Outer needle cap
Inner needle cap
Needle

Protective seal

Screw on needle (see step 3)

Pen cap

Cartridge holder

Dose remaining scale

Insert cartridge (see step 1)

Cartridge (not part of this pack)

Rubber seal
Rubber stopper

Plunger

Pen body

Dose window

Dose button

Step 1: Insert a new insulin cartridge

Follow the first time you use AllStar or when replacing an insulin cartridge.

A. Pull off the pen-cap from AllStar.

B. Unscrew the insulin cartridge holder from the pen body.

C. Check the label of your insulin cartridge for insulin type and expiry date.

D. Align the insulin cartridge holder straight with the pen body and use the cartridge's rubber stopper to push the plunger back.

E. Screw the cartridge holder firmly back on to the pen body until it clicks into place.

CHECK: The alignment marks on the cartridge holder and the pen body must line up as shown.

• If the features are not aligned, unscrew the cartridge holder and try again.

Pen cap

Pen body

Cartridge holder

Insulin cartridge

Plunger may be in a different position as shown or may be inside the pen body.

Cartridge holder (with cartridge inside)

Cartridge holder

Pen body

Cartridge holder

Pen body

Cartridge holder

Pen body

Cartridge holder

Pen body

Cartridge holder

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Pen body

Step 2: Check your insulin before each injection

A. Check your insulin cartridge label.

B. Check the insulin.

C. After mixing, check your insulin.

D. Turn the pen gently up and down at least 10 times to mix the insulin.

E. Turn the pen gently up and down at least 10 times to mix the insulin.

F. Turn the pen gently up and down at least 10 times to mix the insulin.

G. Turn the pen gently up and down at least 10 times to mix the insulin.

H. Turn the pen gently up and down at least 10 times to mix the insulin.

I. Turn the pen gently up and down at least 10 times to mix the insulin.

J. Turn the pen gently up and down at least 10 times to mix the insulin.

K. Turn the pen gently up and down at least 10 times to mix the insulin.

L. Turn the pen gently up and down at least 10 times to mix the insulin.

M. Turn the pen gently up and down at least 10 times to mix the insulin.

N. Turn the pen gently up and down at least 10 times to mix the insulin.

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BG. Turn the pen gently up and down at least 10 times to mix the insulin.

BH. Turn the pen gently up and down at least 10 times to mix the insulin.

BI. Turn the pen gently up and down at least 10 times to mix the insulin.

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BK. Turn the pen gently up and down at least 10 times to mix the insulin.

BL. Turn the pen gently up and down at least 10 times to mix the insulin.

BM. Turn the pen gently up and down at least 10 times to mix the insulin.

BN. Turn the pen gently up and down at least 10 times to mix the insulin.

BO. Turn the pen gently up and down at least 10 times to mix the insulin.

BP. Turn the pen gently up and down at least 10 times to mix the insulin.

BQ. Turn the pen gently up and down at least 10 times to mix the insulin.

BR. Turn the pen gently up and down at least 10 times to mix the insulin.

BS. Turn the pen gently up and down at least 10 times to mix the insulin.

BT. Turn the pen gently up and down at least 10 times to mix the insulin.

BU. Turn the pen gently up and down at least 10 times to mix the insulin.

BV. Turn the pen gently up and down at least 10 times to mix the insulin.

BW. Turn the pen gently up and down at least 10 times to mix the insulin.

BX. Turn the pen gently up and down at least 10 times to mix the insulin.

BY. Turn the pen gently up and down at least 10 times to mix the insulin.

BZ. Turn the pen gently up and down at least 10 times to mix the insulin.

CA. Turn the pen gently up and down at least 10 times to mix the insulin.

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CI. Turn the pen gently up and down at least 10 times to mix the insulin.

CJ. Turn the pen gently up and down at least 10 times to mix the insulin.

CK. Turn the pen gently up and down at least 10 times to mix the insulin.

CL. Turn the pen gently up and down at least 10 times to mix the insulin.

CM. Turn the pen gently up and down at least 10 times to mix the insulin.

CN. Turn the pen gently up and down at least 10 times to mix the insulin.

CO. Turn the pen gently up and down at least 10 times to mix the insulin.

Step 3: Attach a new needle before every injection

IMPORTANT

Always use a new sterile needle for every injection. This helps prevent contamination, inaccurate dosing and needle blocks.

Always attach a new needle before each injection. Use needles from Artason, Becton Dickinson and Company, Ypsomed and Owen-Mumford. These are the manufacturers that have been approved for use with AllStar.

Please note: The needles shown are only an example – your needles might look different.

A. Remove the protective seal from a new pen needle.

B. Line up the needle with the pen, and keep it straight as you attach it. Screw or push the needle on, depending on your needle type.

C. Take off the outer needle cap, and keep it safe to unscrew the needle after the injection.

D. Take off the inner needle cap and discard it.

E. Take off the inner needle cap and discard it.

F. Take off the inner needle cap and discard it.

G. Take off the inner needle cap and discard it.

H. Take off the inner needle cap and discard it.

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AE. Take off the inner needle cap and discard it.

AF. Take off the inner needle cap and discard it.



Warranty Card

Thank you for purchasing Allstar™. Allstar™ has undergone rigorous quality checks and we have taken utmost care in providing you with a high quality insulin delivery device.

Allstar™ is warranted for 3 years from the date of purchase provided it has been used as per details provided in the instruction manual.

Do not use your Allstar™ for more than 3 years from the date of purchase.

After 3 years contact your healthcare provider or pharmacist to purchase a new Allstar™

This warranty is limited to the purchaser and is not transferable.

Kindly fill the following details and retain this card for future reference/ communication:

Patient details:

Name: _____

Address: _____

City: _____ State: _____

Pin No.: _____

Tel. No.: _____ Mobile No.: _____

Product details (please refer to the carton for details):

Batch No.: _____

Date of Manufacturing: _____

For any complaints/ queries contact:

Санофи-Авентис Дойчланд ГмбХ,
Германия

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SLA-0114012-2H [52-0005]

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