

INSULINAGYPT R CARTRIDGE

Insulin Regular/Soluble 100 IU/mL (rDNA origin)

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What InsulinagypT R is used for

InsulinagypT R (Regular Insulin) cartridge is indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus.

How InsulinagypT R works

InsulinagypT R (Regular Insulin) cartridge is a fast-acting human insulin that helps lower blood sugar levels. It works by facilitating the entry of glucose into the cells, where it is either used for energy or stored. It typically begins to act within 30 minutes, reaches its peak effect between 2 to 4 hours, and remains active for up to 8 hours. It is administered before meals to control postprandial blood sugar levels.

Before you use InsulinagypT R

- When you must not use it

Do not take this medicine if:

- Do not use during episodes of hypoglycemia.
- Do not use in patients with hypersensitivity to InsulinagypT R or any of its excipients.

- Before you start to use it

Before using insulin, it is important to carefully read and follow your healthcare provider's instructions. Inform your doctor about any medical conditions you may have, particularly if you experience frequent episodes of hypoglycemia, have kidney or liver disorders, or if you are pregnant or planning to become pregnant.

Make sure to check the appearance of the insulin solution before each injection. Use only if the solution is clear, colorless, and free of visible particles. Do not use the product if it appears cloudy, thickened, or contains precipitates.

Discuss with your doctor or pharmacist all the medications you are currently taking, including over-the-counter drugs and herbal supplements, as some medications can alter the way insulin works.

You should also be aware of the importance of adjusting your insulin dose based on factors such as physical activity, changes in diet, illness, or stress, as these can significantly affect blood glucose levels.

Finally, ensure that you are properly trained in the correct injection techniques, rotation of injection sites, and safe handling and storage of insulin to maintain its effectiveness and reduce the risk of adverse reactions.

Pregnancy and lactation

• Pregnancy

It is essential to maintain good control of the insulin treated (insulin-dependent or gestational diabetes) patient throughout pregnancy. Insulin requirement usually decreases during the first trimester of pregnancy and increases during the second and third trimester.

Women with diabetes should be advised to inform their doctors if they are pregnant or are contemplating pregnancy.

Careful monitoring of glucose control, as well as general health, is essential in pregnant patients with diabetes.

• Breast-feeding

Women with diabetes who are lactating may require adjustments in insulin dose and/or diet

Taking other medicines

If you are taking, have recently taken, or might take any other medicines, please inform your doctor or pharmacist before starting regular insulin. Other medicines can interfere with the effect of insulin and may require adjustments in your dosage to maintain appropriate blood glucose control.

Some medicines may increase the blood-glucose-lowering effect of insulin and raise the risk of hypoglycemia. These include oral antidiabetics, monoamine oxidase inhibitors (MAOIs), beta-blockers, angiotensin-converting enzyme (ACE) inhibitors, and salicylates (such as aspirin).

Other medicines may reduce the blood-glucose-lowering effect of insulin, potentially leading to hyperglycemia. Examples include corticosteroids, certain diuretics, thyroid hormones, oral contraceptives, and sympathomimetic agents.

In addition, beta-blockers and other similar agents may mask the symptoms of hypoglycemia, such as increased heart rate or tremors, making it more difficult to recognize a low blood sugar episode.

Always seek medical advice before starting, stopping, or changing any medication while using insulin to ensure your treatment remains safe and effective.

How to use InsulinagypT R

Do not reuse needles. Dispose of the needle in a responsible manner. Needles must not be shared.

Cartridges can be used until empty, then properly discard. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Instructions for use and handling:

A solution for injection in a 3mL cartridge to be used in conjunction with

reusable pen only. Please refer to the User Manual of the reusable pen for more information.

Preparing the Dose:

A solution for injection in a 3mL cartridge to be used in conjunction with reusable pen only.

Please refer to the User Manual of the reusable pen for more information.

a. Preparing a dose

Before using the reusable pen, the user manual must be read carefully. The reusable pen must be used as recommended in the user manual. Pens should not be used if any part looks broken or damaged.

The cartridges should be examined frequently and should not be used if clumps of material are present or if solid white particles stick to the bottom or wall of the cartridge, giving a frosted appearance.

b. Injecting a dose

Refer to the detailed instructions for preparing the pen and injecting the dose, the following is a general description.

1. Wash your hands.
2. Choose a site for injection.
3. Clean the skin as instructed.
4. Stabilise the skin by spreading it or pinching up a large area. Insert the needle and inject as instructed.
5. Pull the needle out and apply gentle pressure over the injection site for several seconds. Do not rub the area.
6. For an injection device use the outer needle cap, unscrew the needle and dispose of it safely.
7. Use of the injection sites should be rotated so that the same is not used more than approximately once a month.

- How much to use

The dosage should be determined by the physician, according to the requirements of the patient.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Insulinagyp R for as long your doctor recommends

- If you forget to use it

If you take less Insulinagyp R than you need, your blood sugar levels may increase. Check your blood sugar.

- If you use too much (overdose)

If you take more Insulinagyp R than you need, your blood sugar levels may become low. Check your blood sugar.

While you are using Insulinagyp R

- Things you must do

Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists treating you that you are taking of Insulinagyp R. Tell your doctor immediately if you become pregnant while taking this medication.

If you experience hypoglycemia (low blood sugar), eat glucose tablets, sugar or drink a sugary drink. Then eat fruit, biscuits, or a sandwich, as your doctor has advised you and have some rest. This will often get you over mild hypoglycemia or a minor insulin overdose.

If you get worse and your breathing is shallow and your skin gets pale, tell your doctor at once.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Insulinagyp R to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines: your ability to concentrate and react may be reduced if you have hypoglycemia (low blood sugar). Please remember this in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery).

You should contact your diabetes specialist nurse or doctor about the advisability of driving if you have:

- frequent episodes

of hypoglycaemia

- reduced or absent warning signs of hypoglycaemia.

Side effects

Like all medicines Insulinagyp R can cause side effects although not everybody gets them.

Possible side effects are:

- Hypoglycaemia is the most frequent undesirable effect of insulin therapy that a patient with diabetes may suffer.
- Severe hypoglycaemia may lead to loss of consciousness, and in extreme cases, death. No specific frequency for hypoglycaemia is presented, since hypoglycaemia is a result of both the insulin dose and other factors e.g. a patient's level of diet and exercise. Local allergy in patients is common ($\geq 1/100$ to $< 1/10$).
- Redness, swelling, and itching can occur at the site of insulin injection. This condition usually resolves in a few days to a few weeks. In some instances, local reactions may be related to factors other than insulin, such as irritants in the skin cleansing agent or poor injection technique. Systemic allergy, which is very rare ($< 1/10,000$) but potentially more serious, is a generalised allergy to insulin. It may cause rash over the whole body, shortness of breath, wheezing, reduction in blood pressure, fast pulse, or sweating. Severe cases of generalised allergy may be life-threatening. In the rare event of a severe allergy to Gensulin, treatment is required immediately. A change of insulin or desensitisation may be required.
- Lipodystrophy at the injection site is uncommon ($\geq 1/1,000$ to $< 1/100$). Skin and subcutaneous tissue disorders: Frequency "unknown": Cutaneous amyloidosis.
- Skin and subcutaneous tissue disorders: Lipodystrophy and cutaneous amyloidosis may occur at

the injection site and delay local insulin absorption.

Continuous rotation of the injection site within the given injection area may help to reduce or prevent these reactions

Cases of oedema have been reported with insulin therapy, particularly if previous poor metabolic control is improved by intensified insulin therapy.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → [Reporting Side Effects to Medicines \(ConSERF\)](#) or [Vaccines \(AEFI\)](#)].

Storage and Disposal of Insulinagyp R

Storage

Not in use (unopened): should be stored in a refrigerator at temperature (2-8 °C), do not freeze. In-use (opened): can be kept unrefrigerated as long as it is kept as cool as possible, below (30°C), away from heat and light.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Insulinagyp R (Regular Insulin) 100 IU/mL, 3 mL cartridge solution for injection is a sterile, clear, colourless, aqueous solution and contains 100 units of human insulin in each milliliter (100 IU/ml).

Ingredients

Active ingredients

- Insulin Regular/Soluble 100 IU/mL (rDNA origin)

Inactive ingredients

- Glycerol
- M-Cresol distilled
- Water for injection
- Hydrochloric acid
- Sodium hydroxide

MAL number(s):

MALXXXXX

Manufacturer

Medical Union Pharmaceuticals (MUP), Insulin Plant, part no (1)– 2nd industrial area-6th October City-Giza-Egypt

Product Registration Holder

DMW International SDN. BHD.
No. B2-09, 2ND Floor (Lift 5),
Megan Embassy, Block B 225
Jalan Ampang 50450 Kuala Lumpur, Malaysia

Date of revision

13/05/2025

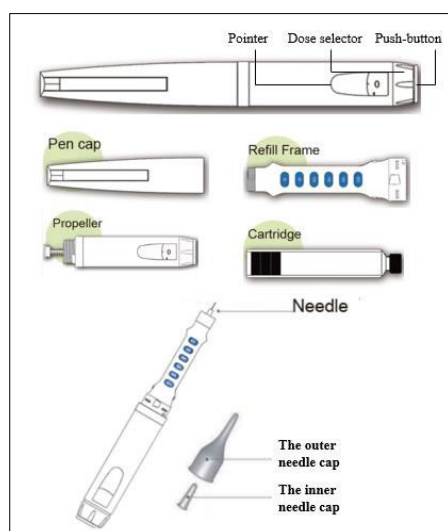
Serial Number

NPRA (R3)25/93

INSTRUCTIONS ON HOW TO USE DELFU PEN INJECTOR

Read the following instructions carefully before using your DELFU Pen Injector. If you do not follow the instructions carefully, you may get too little or too much insulin, which can lead to too high or too low blood sugar level.

Your DELFU Pen Injector is designed to be used, with disposable needles. The pen is suitable for BD needle and NOVO. As a precautionary measure, always carry a spare insulin delivery device in case your DELFU Pen Injector is lost or damaged.



Caring your DELFU Pen Injector

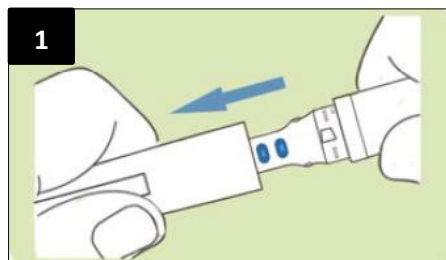
Your DELFU Pen Injector must be handled with care.

If it is dropped, damaged or crushed, there is a risk of insulin leakage. This may cause inaccurate dosing, which can lead to too high or too low blood sugar level.

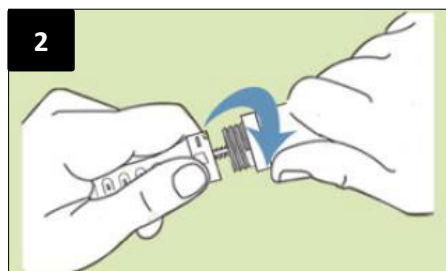
You can clean the exterior of your DELFU Pen Injector by wiping it with a medicinal swab. Do not soak it, wash or lubricate it as it may damage the pen.

Preparing DELFU Pen Injector

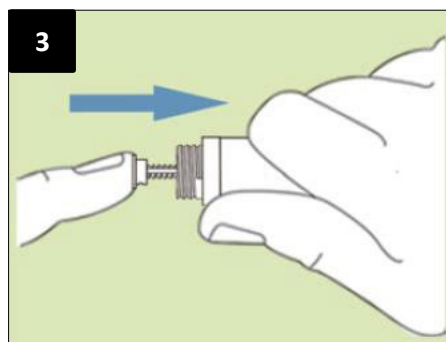
Check the name of insulin cartridge to make sure that it contains the correct type of insulin. This is especially important if you take more than one type of insulin. If you take more than one type of insulin, your blood sugar level may get too high or too low.



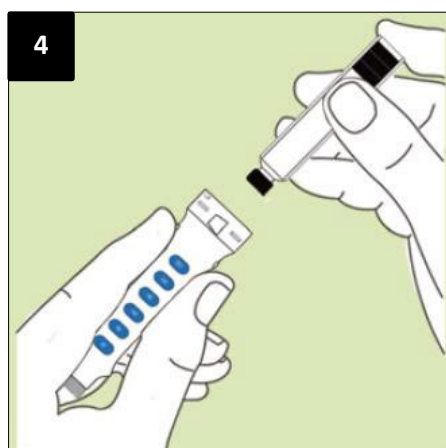
1 Get the pen from the box, unplug the cap.



2 Unscrew the cartridge holder.

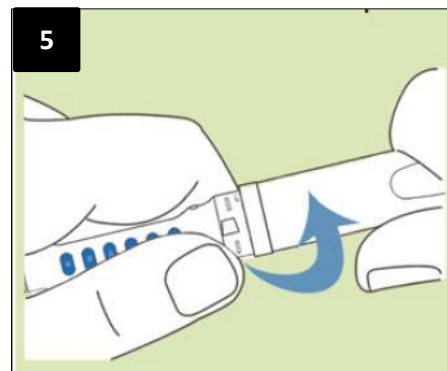


3 Push back the screw until the internal plunger fully retracted.



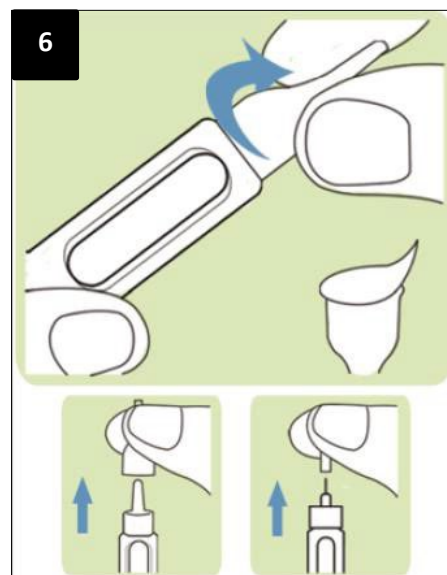
4 Insert the cartridge into the Refill Frame, putting the small end of the cartridge into the cartridge holder.

Note: Please make sure the cartridge is not broken before you install the cartridge.



5 Screw the cartridge holder back onto the pen body until it is secure.

Note: If the cartridge is not installed properly, you may be unable to screw on the cartridge holder and may not be able to inject the correct dose.



6 Remove the protective sheet, then screw the needle onto the cartridge holder, remove the needle cap and make sure the needle is not bent or damaged.

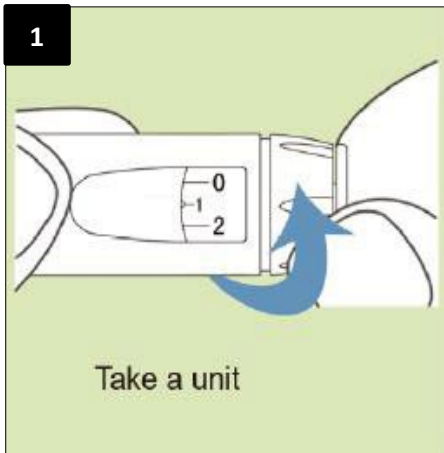
Note: Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

Be careful not to bend or damage the needle before use.

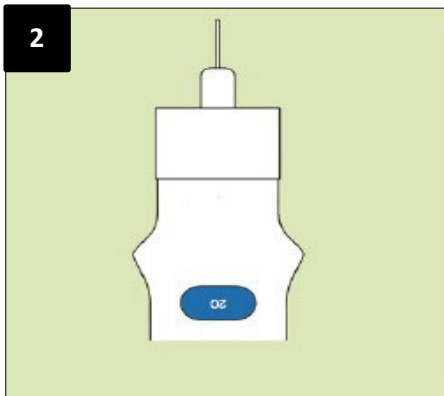
Checking the insulin flow.

Prior to each injection, small amounts of air may collect in the cartridge during normal use. To avoid injection of air and ensure proper dosing:

Before each injection it is required to install a new needle.



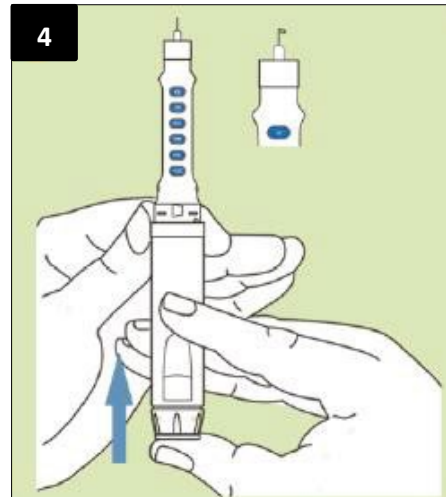
Turn the dose selector, select a dose that you want to inject.



Put the pen vertical and the pen needle upward.

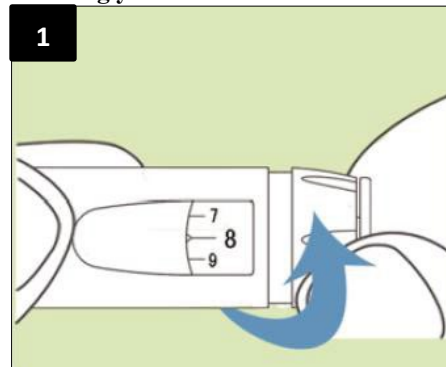


Hold your DELFU Pen Injector with the needle pointing upwards and tap the cartridge gently with your finger a few times to make any air bubbles collect at the top of the cartridge.

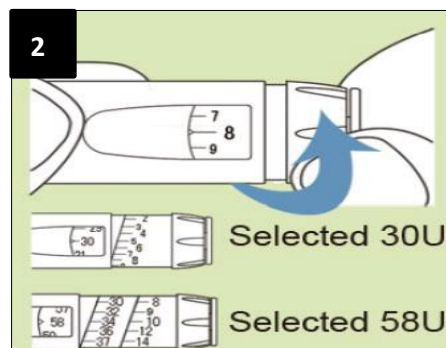


Press the injection button till you see liquid hanging on the tip. If not, change the needle and repeat the procedure. If a drop of insulin still does not appear, the pen is defective, and you must use a new one.

Selecting your dose



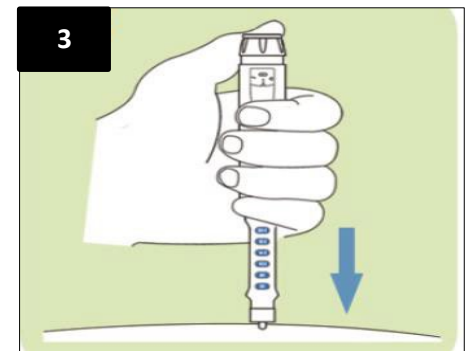
Turn the dose selector to select the number of units you need to inject.



The dose can be corrected either up or down by turning the dose selector in either direction until the correct dose lines up with the pointer. When turning the dose selector, be careful not to push the push-button as insulin will come out.

You cannot select a dose larger than the number of units left in the cartridge. The maximum dose is 0.6ml, if you dose is large than 0.6ml, you should be injected twice.

Always use the dose selector and the pointer to see how many units you have selected before injecting the insulin.

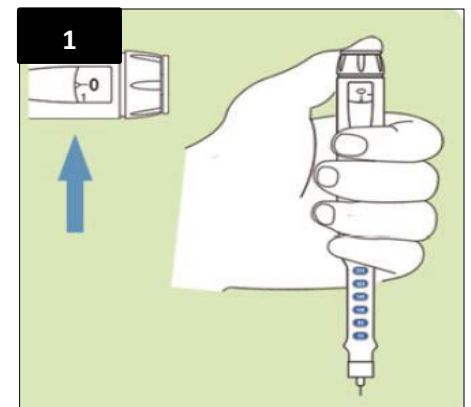


At the end of an injection, the number in the window should be "0", if it is not, this is amount of insulin you did not receive, remember this number, remove the needle and the empty cartridge.

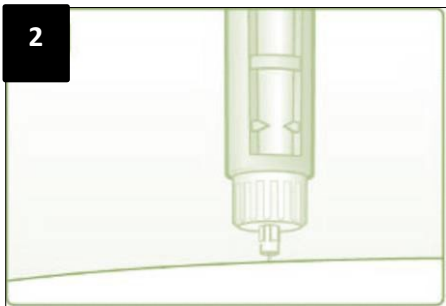
If you select and inject the wrong dose, your blood sugar level may get too high or too low. Do not use the residual scale, it only shows approximately how much insulin is left in your pen.

Making the injection

Insert the needle into your skin. Use the injection technique shown by your doctor or nurse.



Inject the dose by pressing the push-button all the way in until 0 lines up with the pointer. Be careful only to push the push-button when injecting.



Keep the push-button fully depressed and let the needle remain under the skin for at least 6 seconds. This will make sure you get the full dose.

Withdraw the needle from the skin, then release the pressure on the push-button.

Always make sure that the dose selector returns to '0' after the injection. If the dose selector stops before it returns to '0', the full dose has not been delivered, which may result in too high blood sugar level.

infection, leakage of insulin, blocked needles and inaccurate dosing.

Further important information

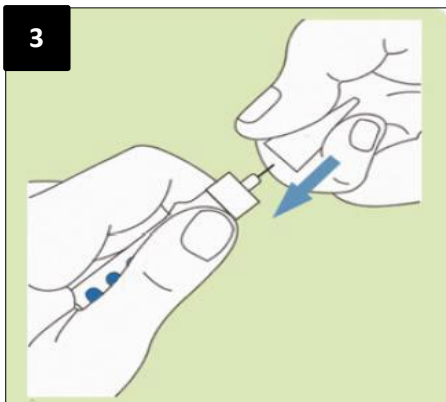
Caregivers must be very careful when handling used needles – to reduce the risk of needle sticks and cross-infection.

Dispose of your used DELFU Pen Injector carefully without the needle attached.

Never share your pen or your needles with other people. It might lead to cross-infection.

Never share your pen with other people. Your medicine might be harmful to their health.

Always keep your pen and needles out of sight and reach of others, especially children.



Lead the needle into the big outer needle cap without touching it. When the needle is covered, carefully push the big outer needle cap completely on and then unscrew the needle.

Dispose of it carefully and put the pen cap back on.

Always remove the needle after each injection and store your DELFU Pen Injector without the needle attached. This reduces the risk of contamination,