


PRODUKT PRODUCT	Ulotka Gensulin R 100IU				
ODBIORCA CUSTOMER	Bioton	HOT STAMPING	<input type="checkbox"/>		
KOD WYROBU PRODUCT'S CODE	04-UG-YEF01-2	TŁOCZENIE EMBOSS	<input type="checkbox"/>	NR PROJEKTU PROJECT NR	PG 2364/2020
NR WZORU ID MODEL	04-UG-YEF01-2	LAKIER 1 VARNISH 1	<input type="checkbox"/>	KOREKTA PROOF NR	1
WYMIARY DIMENSION	170x390 mm	LAKIER 2 VARNISH 2	<input type="checkbox"/>	DATA DATE	08-04-2020
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PATIENT INFORMATION LEAFLET:
USER INFORMATION

GENSULIN R

100 IU/ml, solution for injection

(*Insulinum humanum*)



Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Gensulin R is and what it is used for
2. What you need to know before you use Gensulin R
3. How to use Gensulin R
4. Possible side effects
5. How to store Gensulin R
6. Contents of the pack and other information

1. What Gensulin R is and what it is used for

Gensulin R contains human insulin produced by DNA recombination using bacteria *Escherichia coli*. The insulin is identical to insulin produced by human organism.

Insulin is a hormone secreted in the human pancreas. It is involved in carbohydrate, fat and protein metabolism and causes, among others, blood glucose reduction. Insulin deficiency leads to diabetes. Insulin administered in injections acts identically to the hormone produced by the human body. Gensulin R is presented in 10 ml vials used with a special syringe or in 3 ml cartridges used with an insulin administration device.

Gensulin R (solution) is a short-acting insulin. The onset (blood sugar reduction) occurs within 30 minutes from injection, the peak action – after 1-3 h and the hypoglycaemic action (reduced blood glucose) is maintained up to 8 h and depends on the dose size.

2. What you need to know before you use Gensulin R

Do not use Gensulin R:

- when symptoms indicative of hypoglycaemia (low blood glucose) occur,
- in patients with allergy (hypersensitivity) to insulin or to any of the excipients used in Gensulin R (listed in point 6).

Warnings and precautions

Talk to your doctor or pharmacist or nurse before using Gensulin R.

Gensulin R in a 3 ml cartridge is indicated only for subcutaneous injections with a multiple use pen injector. In case insulin administration by a different method is needed, a doctor must be consulted. Gensulin R in a 10 ml vial is indicated for subcutaneous injections and in exceptional cases it can be administered intravenously or intramuscularly.

While using Gensulin R, caution should be given in the following cases:

- history of allergic reactions to any insulin preparation, medicinal product, food preservatives or colorants;
- when alcohol is consumed: symptoms indicative of hypoglycaemia should be taken account of, alcohol should never be taken on empty stomach;
- when the patient does more exercises than usual or changes the diet;
- disease with high fever, severe infection, strong emotions, alimentary tract disease or disorder with vomiting, diarrhoea, delayed gastric emptying and absorption disorder. In such cases blood and urine glucose should often be controlled and all irregularities should be consulted with a doctor. If possible, the recommended insulin doses and regular meals should be taken;
- when a foreign trip is planned, a change of the time zone may result in changed insulin requirement and modification of injection timing may be required. Prior to a trip, during which at least two time zones will be crossed, the doctor should be consulted with respect to the modification of the insulin administration mode. During an air trip, insulin should be kept in the hand luggage and not in a luggage hatch (it must not be frozen).

Patients with:

- pancreatic diabetes
- pituitary, adrenal and thyroid dysfunction

should consult the doctor since it may be necessary to modify the insulin dose.

Using Gensulin R in patients with impaired renal and/or hepatic function : Insulin requirement can be significantly changed in renal and hepatic dysfunction.

Using Gensulin R in senior patients :

In senior patients the duration of insulin action is longer.

Consult your doctor even if the above-mentioned warnings refer to occurrences in the past.

Other medicines and Gensulin R

Tell your doctor if you are taking, have recently taken or might take any other medicines, even those sold without prescription (cold, catarrh, cough and fever remedies, appetite-suppressing drugs) since they can affect your insulin requirement.

Gensulin R should not be mixed with insulin of animal origin and biosynthetic insulin of other manufacturers.

Many frequently used medications (e.g. some hypertension drugs, cardiac medications, lipid-lowering drugs, thyroid medications, some antidepressants, anticonvulsants, salicylates, antibacterial agents and oral contraceptives) may affect insulin action and the efficacy of insulin therapy. Thus the doctor should always be informed about all medications administered regularly or periodically. Patient should also consult the doctor or pharmacist prior to using a non-prescription medication.

The doctor should always be consulted in case a therapy with a new drug is started. When a doctor is consulted with reasons other than diabetes, they must be informed about insulin therapy.

Drugs and substances increasing insulin action: oral hypoglycaemic (antidiabetic) agents, salicylates (e.g. acetylsalicylic acid), some antidepressants (monoamine oxidase inhibitors MAOI), some angiotensin-converting enzyme inhibitors (ACEI) (captopril, enalapril), non-selective β -adrenolytic drugs (propranolol, sotalol) and ethyl alcohol.

Drugs and substances reducing insulin action: glucocorticosteroids, thyroid hormones, growth hormone, danazol, β_2 -sympathomimetics (ritodrine, salbutamol, terbutaline), diuretic thiazides (e.g. hydrochlorothiazide) and niacin.

Insulin requirement may be changed by somatostatin analogues (octreotide, lanreotide).

Pioglitazone (oral antidiabetic drug):

For some patients with long-term type 2 diabetes treatment and a cardiac disease or a history of stroke, cases of cardiac insufficiency have been reported with concomitant administration of pioglitazone and insulin. Consult a physician immediately if you develop any cardiac insufficiency symptoms, such as shortness of breath, sudden body weight increase or local oedema.

Gensulin R with food and drink

Gensulin R should be administered within 15 min before a meal.

It is very important to consume regular and substantial meals.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy in a diabetic patient is an indication for insulin therapy. During pregnancy it is very important to maintain the right blood glucose since excessive levels of blood glucose can have teratogenic effects on the foetus. During the first trimester, insulin requirement decreases, thus the insulin dose should be reduced. Insulin requirement increases gradually during the second and third trimester, on average by 75% of the pre-pregnancy dose. Immediately after delivery insulin requirement becomes abruptly reduced.

In diabetic breastfeeding mothers it may be necessary to modify the insulin dose and/or diet since during lactation insulin requirement is below the pre-pregnancy level and comes back to the initial level after 6-9 months.

Driving and using machines

The ability to drive may be impaired as hypoglycaemia slows reaction time and dulls concentration. Initiation of insulin therapy, drug change, stress and excessive exercise – associated with significant changes in blood glucose – can result in impaired ability to drive and operate machines. The patient should refrain from driving when symptoms indicative of hypoglycaemia occur. The doctor should be consulted to determine patient's ability to drive and operate machines in case of frequent hypoglycaemia or difficulty in recognising its symptoms.

It is recommended to control blood glucose levels during long trips.

3. How to use Gensulin R

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

In clinical practice there are many human insulin therapy models. The right regimen, satisfying the individual patient needs, should be selected by the doctor. On the basis of blood glucose, the doctor defines the right dose and type of insulin product for the patient.

Dose modification, decision to mix insulin products and change into other insulin preparations can be made by the doctor only.

The patient should check blood and urine glucose levels with simple tests (e.g. strip test). When the glucose levels are not correct, inform your doctor. The doctor should be consulted regularly, especially during the first weeks of insulin therapy.

Before you use Gensulin R

- check the label on the outer package and on the cartridge or on the vial, for product name and letter-symbol compliance with the insulin recommended by your doctor,
- check the expiry date which is stated on the package.

Administration mode

Use the insulin dose recommended by the doctor or nurse in the diabetes clinic.


Change the injection site to avoid skin thickening (see point 4: Possible side effects). It is best to inject insulin in the abdominal area, buttocks, anterior thigh or arm. Abdominal insulin injection results in faster absorption than injections in other areas.

Change injection sites, do not inject insulin into the same area more frequently than once a month.

Gensulin R should be administered within 15 min before a meal.

Take insulin out of the refrigerator a dozen or so minutes before the injection to make it adjust to ambient temperature (if you start a new vial or cartridge). Used vial or cartridge can be kept at room temperature for 28 days.

Follow hygiene rules during administration: wash your hands before drug administration and disinfect the injection site.

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Before drug administration, closely examine the insulin vial or cartridge.

Gensulin R solution should be colourless and transparent with appearance and consistence of water. Do not use the product if the solution is turbid, dense or coloured.

While making an injection, special caution should be taken not to introduce the needle into vascular lumen.

Administering Gensulin R in vials using a syringe

Gensulin R in a 10 ml vial is indicated for subcutaneous injections and in exceptional cases it can be administered intravenously or intramuscularly. Insulin should be administered with special syringes marked with insulin units. It is recommended to use syringes of the same type and manufacturer. Always check whether the syringe you are using is scaled for the strength of insulin used.

The procedure

Immediately before injection:

1. Remove the protective plastic cap from the vial (do not break the cap).
2. Wipe the vial stopper with alcohol. Do not take the stopper out!
3. Draw into the syringe a volume of air equal to the insulin dose.
4. Pierce the rubber stopper with a needle placed on the syringe and inject the air into the vial.
5. Invert the vial with the syringe.
6. Make sure the needle tip is immersed in insulin solution.
7. Draw into the syringe the appropriate volume of insulin.
8. Remove air bubbles from the syringe.
9. Check the recommended dose again and withdraw the needle from the vial.
10. Disinfect the skin at the injection site.

Injecting insulin:

1. Stabilise the skin with one hand by lifting or pinching big surface to form a skin fold.
2. Take the syringe with the other hand and keep it like a pencil. Pierce the needle into the skin (at 90° angle). Make sure the needle is fully inserted and well placed in subcutaneous fat and not in deeper skin layers (in very slim patients it may be necessary to place the needle not perpendicularly but at an angle).
3. To inject insulin, push the plunger to the very end in less than 5 seconds.
4. Keep a cotton pad with alcohol close to the needle and remove the needle from the skin. For a couple of seconds press the cotton pad with alcohol to the injection site. Do not rub the skin!

To prevent tissue damage, change the injection site every time you administer the drug. The new injection site should be at least 1-2 cm away from the old one.

Mixing Gensulin R in vials with Gensulin N solution in vial

The decision on mixing Gensulin R with Gensulin N suspension can be made only by a doctor. While making the mixture, always introduce short-acting Gensulin R first into the syringe. Apply the above procedure to administer the drug.

Administering Gensulin R in pen cartridges

Gensulin R in a 3 ml cartridge is indicated only for subcutaneous injections with a multiple use pen injector. In case insulin administration by a different method is needed, a doctor must be consulted.

3 ml cartridges are administered with a pen bearing the CE mark in accordance with the manufacture's instruction.

To load the pen, place the needle and inject insulin, closely follow the instruction of the pen manufacturer attached to the pen.

Cartridge construction makes it impossible to add different insulin to the cartridge. Used cartridges cannot be refilled.

If you take more Gensulin R than you should

If you take more Gensulin R than you should, immediately consult a doctor or pharmacist.

Insulin overdose evokes hypoglycaemia (blood sugar is too low). The symptoms include: apathy, confusion, palpitation, headache, sweating and vomiting.

In moderate hypoglycaemia it will suffice to administer sweet drinks or carbohydrate-rich food. The patient should take a rest. Patients should carry sugar cubes, glucose or sweets on them.

Severe hypoglycaemia can lead to convulsions, loss of consciousness and even death. The patient can regain consciousness after glucagon injection made by a trained person. After a glucagon injection, immediately upon consciousness regaining, the patient should eat sugar or a sweet snack. If the patient does not regain consciousness after a glucagon injection, hospitalisation is required. Each time glucagon is administered, the patient should seek medical advice to determine the cause of hypoglycaemia and methods to prevent it in future.

Patient's relatives, friends and colleagues should be informed that in case of consciousness loss, they should place the patient on their side and immediately seek medical advice. The patient in such condition must not be given any drinks or food due to the risk of choking.

In case of hypoglycaemia with consciousness loss or frequent hypoglycaemic conditions, the doctor should be consulted as it may be necessary to change the insulin dose and administration timing as well as diet and physical activity.

Hypoglycaemia is caused by:

- injection of a too high insulin dose
- too small or skipped meal
- more physical exercise than usual.

If you forget to take Gensulin R

Do not take a double dose to make up for a forgotten dose.

In case you forget to take Gensulin R, blood glucose levels can be too high (this condition is hyperglycaemia). Hyperglycaemia symptoms occur gradually. The symptoms include: sleepiness, face reddening, excessive thirst, appetite loss, acetone-breath, accelerated breathing and pulse.

In case any of the above-mentioned symptoms occur, measure blood glucose and, if possible, examine ketone bodies in the urine and immediately contact your doctor.

These can be symptoms of a very serious condition – ketoacidosis. Untreated ketoacidosis may lead to insulin coma and even death.

Other reasons of hyperglycaemia, apart from skipping an insulin dose, are: infection or fever, excessive meal and reduced physical exercise.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Gensulin R can cause hypoglycaemia (low blood sugar). See point 3: How to use Gensulin R.

Frequent adverse effects (1/100 to < 1/10):

- topical allergic reaction – at insulin injection site erythema, oedema and itching may occur. The symptoms usually disappear after a couple of days or weeks. In some cases topical reactions can be caused by factors other than insulin, e.g. irritating substances included in skin disinfectants or a wrong injection technique.

Infrequent adverse effects (1/1000 to < 1/100):

- lipodystrophy (thickening) at injection site.

Very rare adverse effects (<1/10 000):

- systemic allergic reactions indicative of generalised hypersensitivity to insulin. The symptoms include: eruption all over body, dyspnoea, wheezing breath, lowered arterial pressure, accelerated pulse and sweating. In serious cases, generalised allergy symptoms can be life threatening. Rare cases of severe allergy to Gensulin R require immediate treatment. Insulin change or desensitisation can be necessary.

Following adverse reactions have been reported during post-marketing experience:

- Oedema, particularly if previous poor metabolic control is improved by intensified insulin therapy;
- Weight gain;
- Injection site reactions: discoloration, bleeding, induration, mass, nodule, pain, rash, urticaria, pustule;
- Pruritus and generalized pruritus;
- Dizziness.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Gensulin R

Store in a refrigerator (2°C - 8°C). Do not freeze.

Upon opening the package, the product is stable for 28 days at temp. up to 25°C. Gensulin R should be protected from light. Vials and cartridges that are used or intended to be used should not be kept in a refrigerator. The patient can carry them on themselves. Gensulin R should be protected from high temperature.

Keep this medicine out of the sight and reach of children.

Do not use Gensulin R after the expiry date which is stated on the label. The expiry date is the last day of the indicated month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Gensulin R contains:

- The active substance is recombinant human insulin obtained by means of biotechnological recombination. 1 ml contains 100 IU of human insulin. The vial contains 10 ml corresponding to 1000 IU of human insulin. The cartridge contains 3 ml corresponding to 300 IU of human insulin.

- The other ingredients (excipients) are: glycerol, m-cresol, hydrochloric acid (solution 0.1 M), sodium hydroxide (0.2 N), water for injections.

What Gensulin R looks like and contents of the pack

Gensulin R is sterile, transparent and colourless aqueous solution of human insulin, pH 7-7.6.

Packaging

- 1 glass vial, closed with aluminum cap with double-layered rubber disc and polypropylene cap, containing 10 ml of Gensulin R, packed in carton box.
- 5 glass cartridges for pens containing 3 ml of Gensulin R, packed in carton box.
- 10 glass cartridges containing 3 ml of Gensulin R, packed in carton box.

Marketing Authorisation Holder and Manufacturer

BIOTON S.A.
5 Staroscinska St.,
02-516 Warsaw
Poland

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