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Klient: BIOTON
Nazwa projektu: **Gensulin M30 ulotka uniwersalna, strona 1**
Wymiary zewn.: 170 × 390 mm
Indeks materiałowy: 04-UG-MYSF01-01
Nr korekty: 4
Kraj: Uniwersalny
Data: 21.07.2025
Opracowanie: Wojciech Kubina

Kolory:
100% black
wykrojnik
Rozmiar najmniejszej czcionki: 8 pkt
Zatwierdził: *Data:*

BIOTON

GENSULIN M30 (30/70)

100 IU/ml suspension for injection

Human Insulin

1. NAME OF THE MEDICINAL PRODUCT

Gensulin M30 (30/70) 100 IU/ml suspension for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of Gensulin M30 (30/70) suspension contains 100 IU of biphasic human insulin (Insulinum humanum) obtained by E. coli recombinant DNA technology process.

Each cartridge for pen contains 3 ml of suspension, corresponding to 300 IU of biphasic insulin, consisting of 30% soluble and 70% isophane insulin (Insulin, Human of recombinant DNA origin) .

The product is a white or almost white suspension which, on standing, deposits a white or almost white sediment and leaves a colourless or almost colourless supernatant; the sediment is readily resuspended by gently shaking.

Contains metacresol 1.5mg/ml and phenol 0.65mg/ml as preservatives.

Gensulin M30 is a biosimilar medicinal product of Humulin 30/70.

3. PHARMACEUTICAL FORM

Gensulin M30 (30/70): suspension for injection in a cartridge.

Gensulin M30 (30/70) is a sterile suspension of human insulin in the proportion of 30% of soluble insulin to 70% isophane insulin.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the treatment of patients with diabetes mellitus for whom diet and/or oral agents are not sufficient.

4.2. Posology and method of administration

Posology

The dosage is determined by the physician according to the requirement of the patient.

Paediatric population
No data are available.

Method of administration

Subcutaneous use

Gensulin M30 in cartridges is only suitable for subcutaneous injections from a reusable pen.

Gensulin M30 in cartridges must not be administered intravenously or intramuscularly

Subcutaneous administration should be in the upper arms, thighs, buttocks or abdomen. Use of injection sites should be rotated so that the same site is not used more than approximately once a month in order to reduce the risk of lipodystrophy and cutaneous amyloidosis (see section 4.4 and 4.8).

Care should be taken when injecting Gensulin M30 to ensure that a blood vessel has not been entered. After any insulin injection, the injection site should not be massaged. Patients must be educated to use proper injection techniques.

Gensulin M30 formulation is a ready-made defined insulin mixture of Gensulin R soluble insulin and Gensulin N isophane insulin designed to avoid the need for the patient to mix insulin products. A patient's treatment regimen should be based on their individual metabolic requirements.

4.3. Contraindications

Hypoglycaemia.
Hypersensitivity to human insulin or to any of the excipients listed in section 6.1, unless it is a part of a desensitisation programme.

Under no circumstances should Gensulin M30 be administered intravenously.

4.4. Special warnings and precautions for use

Transferring a patient to another type or brand of insulin should be done under strict medical supervision. Changes in strength, brand (manufacturer), type (soluble, isophane, mixture), species (animal, human, human insulin analogue), and/or method of manufacture (recombinant DNA versus animal-source insulin) may result in the need for a change in dosage.

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Some patients taking human insulin may require a change in dosage from that used with animal- source insulins. If an adjustment is needed, it may occur with the first dose or during the first several weeks or months.

A few patients who experienced hypoglycaemic reactions after transfer to human insulin have reported that the early warning symptoms were less pronounced or different from those experienced with their previous animal insulin. Patients whose blood glucose is greatly improved, e.g. by intensified insulin therapy, may lose some or all of the warning symptoms of hypoglycaemia and should be advised accordingly. Other conditions which may make the early warning symptoms of hypoglycaemia different or less pronounced include long duration of diabetes, diabetic nerve disease, or medications such as beta blockers. Uncorrected hypoglycaemic and hyperglycaemic reactions can cause loss of consciousness, coma or death.

The use of dosages which are inadequate or discontinuation of treatment, especially in insulin-dependent diabetics, may lead to hyperglycaemia and diabetic ketoacidosis; conditions which are potentially lethal.

Treatment with human insulin may cause formation of antibodies, but titres of antibodies are lower than those to purified animal insulin.

Insulin requirements may change significantly in diseases of the adrenal, pituitary or thyroid glands and in the presence of renal or hepatic impairment. Insulin requirements may be increased during illness or emotional disturbances.

Adjustment of insulin dosage may also be necessary if patients change their level of physical activity or change their usual diet.

Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous amyloidosis. There is a potential risk of delayed insulin absorption and worsened glycaemic control following insulin injections at sites with these reactions. A sudden change in the injection site to an unaffected area has been reported to result in hypoglycaemia. Blood glucose monitoring is recommended after the change in the injection site, and dose adjustment of antidiabetic medications may be considered.

Combination of human insulin with thiazolidinedione

Cases of cardiac failure have been reported when thiazolidinedione was used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. This should be kept in mind, if treatment with the combination of thiazolidinedione and human insulin is considered. If the combination is used, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Thiazolidinedione should be discontinued, if any deterioration in cardiac symptoms occurs.

Instruction for use and handling: To prevent the possible transmission of disease each cartridge must be used by one patient only, even if the needle on the delivery device is changed. Excipients: This medicinal product contains less than 1 mmol sodium (23mg) per dose, i.e., essentially "sodium-free".

4.5. Interactions with other medicinal products and other forms of interaction

A number of medicinal products are known to interact with glucose metabolism and therefore the physician should be consulted when using other medications in addition to human insulin (see section 4.4). The physician must therefore take possible interactions into account and should always ask his patients about any medicinal products they take.

Insulin requirements may be increased by substances with hyperglycaemic activity, such as glucocorticoids, thyroid hormones, growth hormone, danazol, beta2-sympatomimetics (such as ritodrine, salbutamol, terbutaline), thiazides.

Insulin requirements may be reduced in the presence of substances with hypoglycaemic activity, such as oral hypoglycaemics (OHA), salicylates (for example, acetylsalicylic acid), certain antidepressants (monoamine oxidase inhibitors), certain angiotensin converting enzyme (ACE) inhibitors (captopril, enalapril), angiotensin II receptor blockers, non-selective beta-blocking agents and alcohol.

Somatostatin analogues (octreotide, lanreotide) may both decrease or increase insulin dose requirements.

4.6. Fertility, 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.

4.7. Effects on ability to drive and use machines

The patient's ability to concentrate and react may be impaired as a result of hypoglycaemia. This may constitute a risk in situations where these abilities are of special importance (e.g. driving a car or using machine).

Patients should be informed to take precautions to prevent hypoglycaemia while driving. It is particularly important in those who have reduced or absent

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awareness of the warning signs of hypoglycaemia or have frequent episodes of hypoglycaemia. The advisability of driving should be considered in these circumstances.

4.8. Undesirable effects

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 (≥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 (≥ 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 (See section 4.4).

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

4.9. Overdose

Insulin has no specific overdose definitions, because serum glucose concentrations are a result of complex interactions between insulin levels, glucose availability and other metabolic processes. Hypoglycaemia may occur as a result of an excess of insulin relative to food intake and energy expenditure.

Hypoglycaemia may be associated with listlessness, confusion, palpitations, headache, sweating and vomiting.

Mild hypoglycaemic episodes will respond to oral administration of glucose or sugar products.

Correction of moderately severe hypoglycaemia can be accomplished by intramuscular or subcutaneous administration of glucagon, followed by oral carbohydrate when the patient recovers sufficiently. Patients who fail to respond to glucagon must be given glucose solution intravenously.

If the patient is comatose, glucagon should be administered intramuscularly or subcutaneously. However, glucose solution must be given intravenously, if glucagon is not available or if the patient fails to respond to glucagon. The patient should be given a meal as soon as consciousness is recovered.

Sustained carbohydrate intake and observation may be necessary because hypoglycaemia may occur after apparent clinical recovery.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

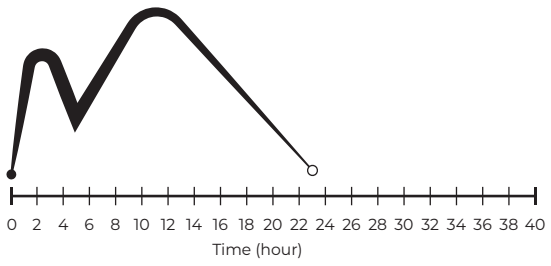
Pharmacotherapeutic group: Gensulin 30/70, ATC code: A10A D01. Gensulin 30/70 is a premixed suspension of rapid and intermediate acting insulin.

The prime activity of insulin is the regulation of glucose metabolism.

In addition insulin has several anabolic and anti-catabolic actions on a variety of different tissues. Within muscle tissue this includes increasing glycogen, fatty acid, glycerol and protein synthesis and amino acid uptake, while decreasing glycogenolysis, gluconeogenesis, ketogenesis, lipolysis, protein catabolism and amino acid output.

The typical activity profile (glucose utilisation curve) following subcutaneous injection is illustrated below by the heavy line. Variations that a patient may experience in timing and/or intensity of insulin activity are illustrated by the shaded area. Individual variability will depend on factors such as size of dose, site of injection temperature and physical activity of the patient.

Gensulin M30 (30/70)
Insulin activity



5.2. Pharmacokinetic properties

Insulin pharmacokinetics do not reflect metabolic activity of the hormone. Thus, while assessing insulin activity, it is more appropriate to analyse glucose utilisation curves (as explained above).

5.3. Preclinical safety data

Gensulin M30 is human insulin produced by recombinant technology. No serious adverse events have been reported in subacute toxicity studies. In a series of in vitro and in vivo toxicity tests, Gensulin M30 was not mutagenic.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Protamine sulphate
Metacresol
Phenol
Glycerol
Zinc oxide
Disodium phosphate dodecahydrate
Hydrochloric acid
Sodium hydroxide
Water for injections

The following may be used to adjust pH: hydrochloric acid and/or sodium hydroxide.

6.2. Incompatibilities

Gensulin M30 products must not be mixed with insulins of other manufacturers and animal insulin products.

6.3. Special precautions for storage

Unopened Cartridge:
Store in a refrigerator at temperature between 2°C and 8°C. Do not freeze. Keep the cartridge in the outer carton in order to protect from light. Protect from excessive heat and sunlight. Keep out of reach of children.
The container should be gently shaken before a dose is dialed.

In-use instruction:
Do not refrigerate. Do not freeze. Gensulin M30 cartridges that are in use can be kept at a temperature (not above 30°C) for up to 42 days.

6.4. Nature and contents of the container

5 x 3 mL colourless glass cartridges (Type 1) sealed using lined seals, plugged with plunger stoppers and glass bead.

6.5. Special precautions for disposal and other handling

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 suspension for injection in a 3 mL cartridge to be used in conjunction with reusable pen (Delfu pen and Penovva pen).

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.

7. MANUFACTURER

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Macierzysz, ul. Poznańska 12,
05–850 Ożarów Mazowiecki, Poland

8. PRODUCT REGISTRATION HOLDER

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9. DATE OF THE REVISION OF THE TEXT

July 2025