1802202815

Insulinagypt 70/30
100 I.U/ml Injection
70% human insulin isophane protamine and 30% regular human insulin
Suspension for S.C injection

1. NAME OF THE MEDICINAL PRODUCT
Insulinagypt 70/30 100 I.U/ml injection
2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 1 ml contains:
Human insulin (recombinant DNA origin) 100 I.U
70% human insulin isophane protamine suspension
30% regular human insulin injection
For the full list of excipients, see section 6.1.
3. PHARMACEUTICAL FORM
Suspension for S.C injection.
White suspension which on standing deposits white sediment and leaves a colorless to almost colorless supernatant liquid. The sediment is readily suspended by gentle shaking.
4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Insulinagypt is indicated for the treatment of insulin-dependent diabetic patients.
4.2 Posology and method of administration
The dosage should be determined by the physician, according to the requirements of the patient. During changes to a patient's insulin regimen, increase the frequency of glucose monitoring. Subcutaneous administration, preferably by the patient, 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 frequently than once a month, in order to reduce the risk of lipodystrophy and localized cutaneous amyloidosis. Do not inject into areas of lipodystrophy or localized cutaneous amyloidosis. Care should be taken to ensure that a blood vessel has not been inadvertently entered. The injection site should not be massaged.
The vial should be rotated in the palms of hands before use in order to resuspend.
4.3 Contraindications
Insulinagypt is contraindicated in hypoglycaemia.
Human insulin is contraindicated in patients with hypersensitivity to human insulin or any of its excipients (unless used as part of a desensitization program).
Insulinagypt 70/30 vials should not be administered by the intravenous route.
4.4 Special warnings and precautions for use
Any change in an insulin or human insulin analogue regimen should be made cautiously and only under medical supervision with increased frequency of glucose monitoring. Changes in strength, brand (manufacturer), type (regular, NPH, lente, etc.), 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.
Prompt recognition and appropriate management of the complications of insulin therapy are essential for the safe and effective control of diabetes mellitus. The number and size of daily doses and the time of administration, as well as diet and exercise, are problems that require direct and continuous medical supervision.
Under special circumstances (such as increased physical effort, insufficient food, etc.) the daily dose of insulin administered to the patient may represent an overdose. Patients should always carry some glucose with them. For symptoms, see section 4.9 Overdose. Insulin requirements may be increased during these or emotional disturbances. In the event of infectious diseases such as colds, boils, etc., the insulin requirements increase, in which case the patient must consult his physician in time to prevent the development of dangerous complications.
Patients whose glycaemic control is greatly improved, e.g. by flexible 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 a long duration of diabetes, diabetic nerve disease or medications such as beta blockers. Uncorrected hypoglycaemic or hyperglycaemic reactions can cause loss of consciousness, coma or death.
The presence of such diseases as acromegaly, Cushing's syndrome, hyperthyroidism, and phaeochromocytoma complicate the control of diabetes. Thiazolidinediones (TZDs) in combination with insulin are associated with an increased risk of oedema and heart failure, especially in patients with underlying cardiac disease.
Visual disturbances in uncontrolled diabetes due to refractive changes are reversed during the early phase of effective management. However, since alteration in osmotic equilibrium between the lens and ocular fluids may not stabilize for a few weeks after initiating therapy, it is wise to postpone prescribing new corrective lenses for 3 to 6 weeks.
Patients who are travelling overseas (or to destinations with substantially different time zones) should contact their doctor/ pharmacist/ diabetes educator for information.
Patients who receive insulin, which contains protamine, have an increased risk of severe reactions simulating anaphylaxis when protamine is used to reverse systemic heparinisation after cardiac catheterisation.
Injection technique
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.
Use in hepatic impairment
Insulin requirements may be reduced in the presence of hepatic impairment.
Use in renal impairment
Insulin requirements may be reduced in the presence of renal impairment.
Use in the Elderly
No data available.
Paediatric Use
No data available.
Effects on Laboratory Tests
No data available.
4.5 Interaction with other medicinal products and other forms of interaction
The physician should be consulted when using other medication in addition to human insulin (see section 4.4 Special warnings and precautions for use).
Insulin requirements can increase, decrease, or remain unchanged in patients receiving diuretics.
Insulin requirements may be increased if the patient is receiving concurrent administration of drugs with hyperglycaemic activity, e.g., oral contraceptives, corticosteroids, thyroid replacement therapy, growth hormone, glucagon, adrenaline, isoniazid, phenothiazines or beta-2 stimulants (such as salbutamol, terbutaline). The hypoglycaemic action of insulin may also be antagonised by phenytoin.
Insulin requirements may be reduced if the patient is receiving concurrent administration of drugs with hypoglycaemic activity, e.g., anabolic steroids, MAO inhibitors, guanethidine, propranolol (masking effect), oral hypoglycaemics, salicylates (for example, aspirin), sulphonamides, antidepressants, angiotensin converting enzyme inhibitors (captopril and enalapril), angiotensin II receptor blockers, other beta blockers, octreotide and alcohol.
Transferring from Other Insulins
A small number of patients transferring from insulins of animal source to insulins of recombinant DNA origin may require a reduced dosage especially if they are tightly controlled and bordering on hypoglycaemia. The dosage reduction may occur with the first dose or over a period of several weeks. There is a risk of hypoglycaemia if the insulin requirement is decreased, and both the physician and the patient should be aware of this possibility. The risk can be considered to be minimal if the daily dose is less than 40 units. Insulin-resistant patients receiving more than 100 units daily should be hospitalised for transferring from other insulins.
Pharmacological studies suggest that these human insulins may have a quicker onset of action and a shorter duration of effect than their beef or pork counterparts in patients already stabilised on a mixture of neutral and isophane insulin. Some adjustment of the proportions may be needed after transfer to human insulin.
A few patients who experienced hypoglycaemic reactions after being transferred to human insulin have reported that these early warning symptoms were less pronounced than they were with animal-source insulin.
4.6 Fertility, pregnancy and lactation
Effects on fertility
Carcinogenicity or fertility studies with human insulin have not been conducted.
Use in pregnancy
It is essential to maintain good control of the insulin-dependent diabetic patient throughout pregnancy. Insulin requirements usually decrease during the first trimester and increase during the second and third trimesters. Patients with diabetes should be advised to inform their doctor if they are pregnant or are contemplating pregnancy. Careful monitoring of the patient is required throughout pregnancy.
During the perinatal period, careful monitoring of infants born to mothers with diabetes is warranted.
Use in lactation
Patients with diabetes who are lactating may require adjustments in insulin dose, diet or both.
4.7 Effects on ability to drive and use machines
The patient's ability to concentrate and to 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 operating machinery). Patients should be advised to take precautions to avoid hypoglycaemia while driving, this is particularly important in those who have reduced or absent 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
The use of preparations of Insulinagypt should minimize the incidence of side effects which have been associated with insulins of animal source. However, there have been rare reports of patients with hypersensitivity reactions to human insulin who have tolerated insulins of animal origin.
The following reactions have been reported:
Hypoglycaemia
Hypoglycaemia is the most frequent undesirable effect of insulin therapy. Severe hypoglycaemia may lead to loss of consciousness and, in extreme cases, death.
Local Allergy
Including pruritus, rash, erythema, and induration. Local allergy in patients occasionally occurs as redness, swelling and itching at the site of insulin injection. This condition usually resolves in a few days to a few weeks. In some instances, this condition may be related to factors other than insulin, such as irritants in the skin cleansing agent or poor injection technique.
Systemic Allergy
Including anaphylactoid reaction, urticaria. Systemic allergy, less common 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.
Lipodystrophy
Rarely, administration of insulin subcutaneously can result in lipoatrophy or lipohypertrophy. A change in injection technique may help alleviate the problem.
Insulin resistance
Spontaneous data
Cases of oedema have been reported with insulin therapy, particularly if previous poor metabolic control is improved by intensified insulin therapy (see section 4.4 Special warnings and precautions for use).
Lipodystrophy and localised cutaneous amyloidosis at the injection site have occurred. Hyperglycaemia has been reported with repeated insulin injections into areas of lipodystrophy or localised cutaneous amyloidosis; hypoglycaemia has been reported with a sudden change to an unaffected injection site (see section 4.4 Special warnings and precautions for use).
Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:
- The Egyptian Pharmacovigilance Center (EPVC): pv.followup@edaegypt.gov.eg
or by scanning the QR code.
- MUP Pharmacovigilance department: pv@mup.com
4.9 Overdose
Symptoms
Hypoglycaemia can occur if the patient takes too much insulin, misses meals, exercise or works too hard just before a meal, or has an infection or becomes ill (especially with diarrhoea or vomiting) or if the body need for insulin changes for other reasons.
Symptoms include listlessness, confusion, palpitations, sweating, vomiting, hunger, faintness and dizziness. Patients also may experience headache, drowsiness, fatigue, anxiety, blurred vision, diplopia, or numbness of the lips, nose or fingers.
Symptoms are likely to appear when the blood sugar concentration falls below 2.22 mmol/L but may occur with a sudden drop in blood glucose even when the value remains above 2.22 mmol/L.
The clinical manifestations of hypoglycaemia can be masked by the concomitant administration of propranolol or other beta adrenergic blockers.
Treatment
Mild hypoglycaemic episodes will respond to oral administration of glucose or sugar and rest.
Correction of moderately severe hypoglycaemia can be accomplished by the intramuscular or subcutaneous administration of glucagon, 1 unit every 20 minutes for 2 or 3 doses, 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, intravenous administration of 10 to 20 g of dextrose in sterile solution is required.
5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Mechanism of action
The administration of suitable doses of insulin to patients with diabetes mellitus, along with controlled diet and exercise, temporarily restores their ability to metabolise carbohydrates, fats and proteins; to store glycogen in the liver; and to convert glucose to fat. When given in suitable doses at regular intervals to a patient with diabetes mellitus, the blood glucose is maintained within a reasonable range, the urine remains relatively free of glucose and ketone bodies, and diabetic acidosis and coma are prevented.
Studies indicate that immunogenicity problems with biosynthetic human insulin produced by recombinant DNA technology are no more likely to occur than with insulin that is derived from animal origin. Biosynthetic human insulin is devoid of all protein contaminants of pancreatic origin normally present even in trace amounts in all insulins of pancreatic origin.
The rigid purification procedures used in the manufacture of biosynthetic human insulin remove E. coli proteins detectable by presently available methods. Even if E. coli proteins are present in trace amounts, clinical studies indicate the absence of any detectable E. coli protein antibodies ascribable to the use of biosynthetic human insulin. Biosynthetic human insulin did not elicit an antigenic response when administered to E. coli polypeptide-sensitised rats and guinea pigs.
Although human insulins appear to produce less antigenicity than beef/pork insulins, they are not free of antigenicity.
5.2 Pharmacokinetic properties
Insulinagypt 70/30 is an intermediate-acting insulin with a more rapid onset of action than NPH alone. Insulinagypt 70/30 has a duration of activity of 16 to 18 hours and a peak activity at 2 to 12 hours.
6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Metacresol distilled
Glycerol
Phenol
Protamine sulfate
Dibasic sodium phosphate heptahydrate
Zinc oxide
Water for injection
Hydrochloric acid solution 10%
Sodium hydroxide solution 10%
6.2 Incompatibilities
None.
6.3 Shelf life
36 months, once opened, the vial may be stored for 28 days at 30°C.
6.4 Special precautions for 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.
6.5 Nature and contents of container
Insulinagypt 70/30 100 I.U/ml 4 ml injection
Carton box contains one clear colorless glass (type I) vial of 4 ml insulin suspension (100 I.U/ml), stoppered with rubber closure (made from off-white bromobutyl formulation) and sealed with aluminum seal combined with a plastic polypropylene flip top and an inner leaflet.
Insulinagypt 70/30 100 I.U/ml 10 ml injection
Carton box contains one clear colorless glass (type I) vial of 10 ml insulin suspension (100 I.U/ml), stoppered with rubber closure (made from off-white bromobutyl formulation) and sealed with aluminum seal combined with a plastic polypropylene flip top and an inner leaflet.
6.6 Special precautions for disposal and other handling
None.
7. LICENSE HOLDER & MANUFACTURER
7.1 License holder
Medical Union Pharmaceuticals
7.2 Manufacturer
Active substance
Eli Lilly and Company, Indianapolis, Indiana, IN 46285-USA
Finished product
Medical Union Pharmaceuticals, part no (1) - 2nd industrial area-6th October city-Giza-Egypt
8. REVISION DATE
26/10/2021

1802202815

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INSULINAGYPT 70/30 100 IU/ml INJECTION

180225249013

70% human insulin isophane protamine and 30% regular human insulin
Suspension for S.C injection

1. NAME OF THE MEDICINAL PRODUCT
Insulinagypt 70/30 100 IU/ml injection
2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 1 ml contains:
Human insulin (recombinant DNA origin) 100 IU
70% human insulin isophane protamine suspension
30% regular human insulin injection
For the full list of excipients, see section 6.1.
3. PHARMACEUTICAL FORM
Suspension for S.C injection.
White suspension which on standing deposits white sediment and leaves a colorless to almost colorless supernatant liquid. The sediment is readily suspended by gentle shaking.
4. CLINICAL PARTICULARS
4.1 Therapeutic Indications
Insulinagypt is indicated for the treatment of insulin-dependent diabetic patients.
4.2 Posology and method of administration
The dosage should be determined by the physician, according to the requirements of the patient. During changes to a patient's insulin regimen, increase the frequency of glucose monitoring. Subcutaneous administration, preferably by the patient, 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 frequently than once a month, in order to reduce the risk of lipodystrophy and localized cutaneous amyloidosis. Do not inject into areas of lipodystrophy or localized cutaneous amyloidosis.
Care should be taken to ensure that a blood vessel has not been inadvertently entered. The injection site should not be massaged.
4.3 Contraindications
Insulinagypt is contraindicated in hypoglycaemia.
Human insulin is contraindicated in patients with hypersensitivity to human insulin or any of its excipients (unless used as part of a desensitization program).
Insulinagypt 70/30 cartridge should not be administered by the intravenous route.
4.4 Special warnings and precautions for use
Any change in an insulin or human insulin analogue regimen should be made cautiously and only under medical supervision with increased frequency of glucose monitoring. Changes in strength, brand (manufacturer), type (regular, NPH, lente, etc.), 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.
Prompt recognition and appropriate management of the complications of insulin therapy are essential for the safe and effective control of diabetes mellitus.
The number and size of daily doses and the time of administration, as well as diet and exercise, are problems that require direct and continuous medical supervision.
Under special circumstances (such as increased physical effort, insufficient food, etc.) the daily dose of insulin administered to the patient may represent an overdose. Patients should always carry some glucose with them. For symptoms, see section 4.9 Overdose.
Insulin requirements may be increased during illness or emotional disturbances. In the event of infectious diseases such as colds, boils, etc., the insulin requirements increase, in which case the patient must consult his physician in time to prevent the development of dangerous complications.
Patients whose glycaemic control is greatly improved, e.g. by flexible 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 or hyperglycaemic reactions can cause loss of consciousness, coma or death.
The presence of such diseases as acromegaly, Cushing's syndrome, hyperthyroidism, and phaeochromocytoma complicate the control of diabetes.
Thiazolidinediones (TZDs) in combination with insulin are associated with an increased risk of oedema and heart failure, especially in patients with underlying cardiac disease.
Visual disturbances in uncontrolled diabetes due to refractive changes are reversed during the early phase of effective management. However, since alteration in osmotic equilibrium between the lens and ocular fluids may not stabilize for a few weeks after initiating therapy, it is wise to postpone prescribing new corrective lenses for 3 to 6 weeks.
Patients who are travelling overseas (or to destinations with substantially different time zones) should contact their doctor/ pharmacist/ diabetes educator for information.
Patients who receive insulin, which contains protamine, have an increased risk of severe reactions simulating anaphylaxis when protamine is used to reverse systemic heparinisation after cardiac catheterisation.
Injection technique
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.
Use in hepatic impairment
Insulin requirements may be reduced in the presence of hepatic impairment.
Use in renal impairment
Insulin requirements may be reduced in the presence of renal impairment.
Use in the Elderly
No data available.
Paediatric Use
No data available.
Effects on Laboratory Tests
No data available.
4.5 Interaction with other medicinal products and other forms of interaction
The physician should be consulted when using other medication in addition to human insulin (see section 4.4 Special warnings and precautions for use).
Insulin requirements can increase, decrease, or remain unchanged in patients receiving diuretics. Insulin requirements may be increased if the patient is receiving concurrent administration of drugs with hyperglycaemic activity, e.g. oral contraceptives, corticosteroids, thyroid replacement therapy, growth hormone, glucagon, adrenaline, danazol, phenothiazines or beta2 stimulants (such as salbutamol, terbutaline). The hypoglycaemic action of insulin may also be antagonised by phenytoin.
Insulin requirements may be reduced if the patient is receiving concurrent administration of drugs with hypoglycaemic activity, e.g. anabolic steroids, MAO inhibitors, guanethidine, propranolol (masking effect), oral hypoglycaemics, salicylates (for example, aspirin), sulphonamides, antidepressants, angiotensin converting enzyme inhibitors (captopril and enalapril), angiotensin II receptor blockers, other beta blockers, octreotide and alcohol.
Transferring from Other Insulins
A small number of patients transferring from insulins of animal source to insulins of recombinant DNA origin may require a reduced dosage especially if they are tightly controlled and bordering on hypoglycaemia. The dosage reduction may occur with the first dose or over a period of several weeks. There is a risk of hypoglycaemia if the insulin requirement is decreased, and both the physician and the patient should be aware of this possibility. The risk can be considered to be minimal if the daily dose is less than 40 units. Insulin-resistant patients receiving more than 100 units daily should be hospitalised for transferring from other insulins.
Pharmacological studies suggest that these human insulins may have a quicker onset of action and a shorter duration of effect than their beef or pork counterparts in patients already stabilised on a mixture of neutral and isophane insulin.
Some adjustment of the proportions may be needed after transfer to human insulin.
A few patients who experienced hypoglycaemic reactions after being transferred to human insulin have reported that these early warning symptoms were less pronounced than they were with animal-source insulin.
4.6 Fertility, pregnancy and lactation
Effects on fertility
Carcinogenicity or fertility studies with human insulin have not been conducted.
Use in pregnancy
It is essential to maintain good control of the insulin-dependent diabetic patient throughout pregnancy. Insulin requirements usually decrease during the first trimester and increase during the second and third trimesters. Patients with diabetes should be advised to inform their doctor if they are pregnant or are contemplating pregnancy. Careful monitoring of the patient is required throughout pregnancy.
During the perinatal period, careful monitoring of infants born to mothers with diabetes is warranted.
Use in lactation
Patients with diabetes who are lactating may require adjustments in insulin dose, diet or both.
4.7 Effects on ability to drive and use machines
The patient's ability to concentrate and to 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 operating machinery). Patients should be advised to take precautions to avoid hypoglycaemia while driving; this is particularly important in those who have reduced or absent 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
The use of preparations of Insulinagypt should minimize the incidence of side-effects which have been associated with insulins of animal source. However, there have been rare reports of patients with hypersensitivity reactions to human insulins who have tolerated insulins of animal origin.
The following reactions have been reported:
Hypoglycaemia
Hypoglycaemia is the most frequent undesirable effect of insulin therapy. Severe hypoglycaemia may lead to loss of consciousness and, in extreme cases, death.
Local Allergy
Including pruritus, rash, erythema, and induration. Local allergy in patients occasionally occurs as redness, swelling and itching at the site of insulin injection. This condition usually resolves in a few days to a few weeks. In some instances, this condition may be related to factors other than insulin, such as irritants in the skin cleansing agent or poor injection technique.
Systemic Allergy
Including anaphylactoid reaction, urticaria. Systemic allergy, less common 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.
Lipodystrophy
Rarely, administration of insulin subcutaneously can result in lipoatrophy or lipohypertrophy. A change in injection technique may help alleviate the problem.
Insulin resistance
Spontaneous data
Cases of oedema have been reported with insulin therapy, particularly if previous poor metabolic control is improved by intensified insulin therapy (see section 4.4 Special warnings and precautions for use).
Lipodystrophy and localized cutaneous amyloidosis at the injection site have occurred. Hyperglycaemia has been reported with repeated insulin injections into areas of lipodystrophy or localized cutaneous amyloidosis; hypoglycaemia has been reported with a sudden change to an unaffected injection site (see section 4.4 Special warnings and precautions for use).
Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:
-The Egyptian Pharmacovigilance Center (EPVC): pv.followup@edaegypt.gov.eg or by scanning the QR code:

-MUP Pharmacovigilance department: pv@mupeg.com
4.9 Overdose
Symptoms
Hypoglycaemia can occur if the patient takes too much insulin, misses meals, exercises or works too hard just before a meal, or has an infection or becomes ill (especially with diarrhoea or vomiting) or if the body need for insulin changes for other reasons.
Symptoms include listlessness, confusion, palpitations, sweating, vomiting, hunger, faintness and dizziness. Patients also may experience headache, drowsiness, fatigue, anxiety, blurred vision, diplopia, or numbness of the lips, nose or fingers. Symptoms are likely to appear when the blood sugar concentration falls below 3.33 mmol/L but may occur with a sudden drop in blood glucose even when the value remains above 3.33 mmol/L.
The clinical manifestations of hypoglycaemia can be masked by the concomitant administration of propranolol or other beta adrenergic blockers.
Treatment
Mild hypoglycaemic episodes will respond to oral administration of glucose or sugar and rest.
Correction of moderately severe hypoglycaemia can be accomplished by the intramuscular or subcutaneous administration of glucagon, 1 unit every 20 minutes for 2 or 3 doses, 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, intravenous administration of 10 to 20 g of dextrose in sterile solution is required.
5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Mechanism of action
The administration of suitable doses of insulin to patients with diabetes mellitus, along with controlled diet and exercise, temporarily restores their ability to metabolise carbohydrates, fats and proteins; to store glycogen in the liver; and to convert glucose to fat. When given in suitable doses at regular intervals to a patient with diabetes mellitus, the blood glucose is maintained within a reasonable range, the urine remains relatively free of glucose and ketone bodies, and diabetic acidosis and coma are prevented.
Studies indicate that immunogenicity problems with biosynthetic human insulin produced by recombinant DNA technology are no more likely to occur than with insulin that is derived from animal origin. Biosynthetic human insulin is devoid of all protein contaminants of pancreatic origin normally present even in trace amounts in all insulins of pancreatic origin.
The rigid purification procedures used in the manufacture of biosynthetic human insulin remove E. coli proteins detectable by presently available methods. Even if E. coli proteins are present in trace amounts, clinical studies indicate the absence of any detectable E. coli protein antibodies ascribable to the use of biosynthetic human insulin. Biosynthetic human insulin did not elicit an antigenic response when administered to E. coli polypeptide-sensitized rats and guinea pigs.
Although human insulins appear to produce less antigenicity than beef/pork insulins, they are not free of antigenicity.
5.2 Pharmacokinetic properties
Insulinagypt 70/30 is an intermediate-acting insulin with a more rapid onset of action than NPH alone. Insulinagypt 70/30 has a duration of activity of 18 to 19 hours and a peak activity at 2 to 12 hours.
6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Metacresol distilled
Glycerol
Phenol
Protamine sulfate
Dibasic sodium phosphate heptahydrate
Zinc oxide
Water for injection
Hydrochloric acid solution 10%
Sodium hydroxide solution 10%
6.2 Incompatibilities
None.
6.3 Shelf life
36 months, once used, the cartridge may be stored for 28 days below 30 °C.
6.4 Special precautions for 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.
6.5 Nature and contents of container
Carton box containing 5 glass tint (type I) cartridges each of 3 ml, sealed with rubber closures which consist of grey bromobutyl plunger at the bottom and laminated rubber disc seal at the top of the cartridge, which is made of yellow polyisoprene and off-white bromobutyl formulation and aluminum seal with insert pellet.
6.6 Special precautions for disposal and other handling
None.
7. LICENSE HOLDER & MANUFACTURER
7.1 License holder
Medical Union Pharmaceuticals
7.2 Manufacturer
Active substance
Eli Lilly and Company, Indianapolis, Indiana, IN 46285-USA
Finished product
Medical Union Pharmaceuticals, MUP - 6th October city, 3rd industrial zone- plot no. 1 Giza -Egypt
8. REVISION DATE
March 2022

MUP