FOR THE USE ONLY OF A REGISTERED MEDICAL PRACTITIONER OR A HOSPITAL OR A LABORATORY

Rx

100 IU/ml

Insulin Glargine Injection I.P. 100 IU/ml (r-DNA Origin)

Glaritus®

100 IU/ml

3ml multi-dose Cartridges

For SC use only

WOCKHARDT

1. Generic Name
Insulin Glargine Injection I.P. 100 IU/mL (r-DNA origin)
2. Qualitative and quantitative composition
Each mL contains
Insulin Glargine I.P. .....100 IU
m-Cresol U.S.P.....0.27% w/v
(as preservative)
Water for Injections I.P. .....q.s
3. Dosage form and strength
It is a 3 mL cartridge containing 100 IU/mL Insulin Glargine injection for subcutaneous use.
4. Clinical particulars
4.1 Therapeutic indication
Glaritus is indicated for the treatment of type-1 and type-2 diabetes mellitus patients who require basal (long acting) insulin for the control of Hyperglycemia.
Limitations of Use - Glaritus is not recommended for the treatment of diabetic ketoacidosis.
4.2 Posology and method of administration
Important Administration Instructions
- Administer Glaritus subcutaneously once daily at any time of day but at the same time every day.
- Prior to initiation of Glaritus, train patients on proper use and injection technique.
- Patient should follow the Instructions for Use of pen device to correctly administer Glaritus from cartridge.
- Administer Glaritus subcutaneously into the abdominal area, thigh, or deltoid, and rotate injection sites within the same region from one injection to the next to reduce the risk of lipodystrophy [see Undesirable effects (4.8)].
- Visually inspect Glaritus cartridges for particulate matter and discoloration prior to administration. Only use if the solution is clear and colorless with no visible particles.
- Refrigerate unused (unopened) Glaritus cartridges.
- Do not administer intravenously or via an insulin pump.
- Do not dilute or mix Glaritus with any other insulin or solution.
- The cartridges to be used in pen device are for single patient use only [see Special warnings and precautions for use (4.4)].

General Dosing Instructions
- Individualize and adjust the dosage of Glaritus based on the individual's metabolic needs, blood glucose monitoring results and glycemic control goal.
- Dosage adjustments may be needed with changes in physical activity, changes in meal patterns (i.e., macronutrient content or timing of food intake), during acute illness, or changes in renal or hepatic function. Dosage adjustments should only be made under medical supervision with appropriate glucose monitoring [see Special warnings and precautions for use (4.4)].

Initiation of Glaritus Therapy

Type 1 Diabetes
- In patients with type 1 diabetes, Glaritus must be used concomitantly with short-acting insulin. The recommended starting dose of Glaritus in patients with type 1 diabetes should be approximately one-third of the total daily insulin requirements. Short-acting, premeal insulin should be used to satisfy the remainder of the daily insulin requirements.

Type 2 Diabetes
- The recommended starting dose of Glaritus in patients with type 2 diabetes who are not currently treated with insulin is 0.2 units/kg or up to 10 units once daily. One may need to adjust the amount and timing of short- or rapid-acting insulins and dosages of any oral anti-diabetic drugs.

Changing To Glaritus from other Insulin Therapies
- If changing patients from once daily insulin glargine 300 Units/mL to once daily Glaritus, the recommended initial Glaritus dose is 80% of the insulin glargine 300 Units/mL dose that is being discontinued. This dose reduction will lower the likelihood of hypoglycemia.
- If changing from a treatment regimen with an intermediate- or long-acting insulin to a regimen with Glaritus, a change in the dose of the basal insulin may be required and the amount and timing of the shorter-acting insulins and doses of any oral antidiabetic drugs may be needed to be adjusted.
- If changing patients from once-daily NPH insulin to once-daily Glaritus, the recommended initial Glaritus dose is the same as the dose of NPH that is being discontinued.
- If changing patients from twice-daily NPH insulin to once-daily Glaritus, the recommended initial Glaritus dosage is 80% of the total NPH dose that is being discontinued. This dosage reduction will lower the likelihood of hypoglycemia.

4.3 Contraindications
Glaritus is contraindicated in the following conditions:
- During episodes of hypoglycemia.
- In patients with hypersensitivity to Glaritus or one of its excipients.

4.4 Special warnings and precautions for use
Never Share A GLARITUS Cartridge Or Needle Between patients - GLARITUS cartridges must never be shared between patients, even if the needle is changed. Patients using GLARITUS must never reuse or share needles with another person. Sharing poses a risk for transmission of blood-borne pathogens.
Hyperglycemia Or Hypoglycemia With Changes In Insulin Regimen - Changes in insulin strength, manufacturer, type, or method of administration may act glycemic control and predispose to hypoglycemia or hyperglycemia. These changes should be made cautiously and only under close medical supervision, and the frequency of blood glucose monitoring should be increased. For patients with type 2 diabetes, dosage adjustments of concomitant oral and anti-diabetic products may be needed.
Hypoglycemia -Hypoglycemia is the most common adverse reaction associated with insulin, including GLARITUS. Severe hypoglycemia can cause seizures, may be life-threatening or cause death. Hypoglycemia can impair concentration ability and reaction time; this may place an individual and others at risk in situations where these abilities are important (e.g., driving or operating other machinery). Hypoglycemia can happen suddenly and symptoms may differ in each individual and change over time in the same individual. Symptomatic awareness of hypoglycemia may be less pronounced in patients with longstanding diabetes, in patients with diabetic nerve disease, in patients using medications that block the sympathetic nervous system (e.g., beta-blockers), or in patients who experience recurrent hypoglycemia.
Risk Factors For Hypoglycemia - The risk of hypoglycemia after an injection is related to the duration of action of the insulin and, in general, is highest when the glucose lowering effect of the insulin is maximal. As with all insulin preparations, the glucose lowering effect time course of GLARITUS may vary in different individuals or at different times in the same individual and depends on many conditions, including the area of injection as well as the injection site blood supply and temperature. Other factors which may increase the risk of hypoglycemia include changes in meal pattern (e.g., macronutrient content or timing of meals), changes in level of physical activity, or changes to co-administered medication. Patients with renal or hepatic impairment may be at higher risk of hypoglycemia.
Risk Mitigation Strategies For Hypoglycemia - Patients and caregivers must be educated to recognize and manage hypoglycemia. Self-monitoring of blood glucose plays an essential role in the prevention and management of hypoglycemia. In patients at higher risk for hypoglycemia and patients who have reduced symptomatic awareness of hypoglycemia, increased frequency of blood glucose monitoring is recommended.
The long-acting effect of GLARITUS may delay recovery from hypoglycemia.
Medication Errors - Accidental mix-ups among insulin products, particularly between long-acting insulins and rapid-acting insulins, have been reported. To avoid medication errors between GLARITUS and other insulins, instruct patients to always check the insulin label before each injection.
Hypersensitivity And Allergic Reactions - Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with insulin products, including insulin glargine. If hypersensitivity reactions occur, discontinue insulin glargine; treat per standard of care and monitor until symptoms and signs resolve. Insulin glargine is contraindicated in patients who have had hypersensitivity reactions to insulin glargine or one of the excipients.
Hypokalemia - All insulin products, including GLARITUS, cause a shift in potassium from the extracellular to intracellular space, possibly leading to hypokalemia. Untreated hypokalemia may cause respiratory paralysis, ventricular arrhythmia, and death. Monitor potassium levels in patients at risk for hypokalemia if indicated (e.g., patients using potassium-lowering medications, patients taking medications sensitive to serum potassium concentrations).
Fluid Retention And Heart Failure With Concomitant Use Of PPAR-gamma Agonists - Thiazolidinediones (TZDs), which are peroxisome proliferator-activated receptor (PPAR)-gamma agonists, can cause dose-related fluid retention, particularly when used in combination with insulin. Fluid retention may lead to or exacerbate heart failure. Patients treated with insulin, including GLARITUS, and a PPAR-gamma agonist should be observed for signs and symptoms of heart failure. If heart failure develops, it should be managed according to current standards of care, and discontinuation or dose reduction of the PPAR-gamma agonist must be considered.
4.5 Drugs interactions
Drugs That May Increase the Risk of Hypoglycemia
Drugs: Antidiabetic agents, ACE inhibitors, angiotensin II receptor blocking agents, disopyramide, fibrates, fluoxetine, monoamine oxidase inhibitors, pentoxifylline, pramlintide, propoxyphene, salicylates, somatostatin analogs (e.g., octreotide), and sulfonamide antibiotics.
Intervention: Dose reductions and increased frequency of glucose monitoring may be required when insulin glargine is co-administered with these drugs.
Drugs That May Decrease the Blood Glucose Lowering Effect of GLARITUS
Drugs: Atypical antipsychotics (e.g. olanzapine and clozapine), corticosteroids, danazol, diuretics, estrogens, glucagon, isoniazid, niacin, oral contraceptives, phenothiazines, progestogens (e.g. in oral contraceptives), protease inhibitors, somatropin, sympathomimetic agents (e.g. albuterol, epinephrine, terbutaline), and thyroid hormones.
Intervention: Dose increases and increased frequency of glucose monitoring may be required when insulin glargine is co-administered with these drugs.
Drugs That May Increase or Decrease the Blood Glucose Lowering Effect of GLARITUS
Drugs: Alcohol, beta-blockers, clonidine, and lithium salts. Pentamidine may cause hypoglycemia, which may sometimes be followed by hyperglycemia.
Intervention: Dose adjustment and increased frequency of glucose monitoring may be required when insulin glargine is co-administered with these drugs.
Drugs That May Blunt Signs and Symptoms of Hypoglycemia
Drugs: beta-blockers, clonidine, guanethidine, and reserpine.
Intervention: Increased frequency of glucose monitoring may be required when insulin glargine is co-administered with these drugs.
4.6 Use in special populations
Pregnancy - There are no well-controlled clinical studies of the use of GLARITUS in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. All pregnancies have a background risk of birth defects, loss, or other adverse outcome regardless of drug exposure. This background risk is increased in pregnancies complicated by hyperglycemia and may be decreased with good metabolic control. It is essential for patients with diabetes or history of gestational diabetes to maintain good metabolic control before conception and throughout pregnancy. In patients with diabetes or gestational diabetes, insulin requirements may decrease during the first trimester, generally increase during the second trimester, and rapidly decline after delivery. Careful monitoring of glucose control is essential in these patients. Therefore, female patients should be advised to tell their physicians if they intend to become, or if they become pregnant while taking GLARITUS.
Nursing Mothers - Endogenous insulin is present in human milk; it is unknown whether insulin glargine is excreted in human milk. Because many drugs, including human insulin, are excreted in human milk, caution should be exercised when GLARITUS is administered to a nursing woman. Use of GLARITUS is compatible with breastfeeding, but women with diabetes who are lactating may require adjustments of their insulin doses.
Pediatric Use - The safety and effectiveness of insulin glargine have been established in pediatric patients (age 2 to 15 years) with type 1 diabetes in reported clinical studies. The safety and eff-ectiveness of insulin glargine in pediatric patients younger than 2 years of age with type 1 diabetes and pediatric patients with type 2 diabetes have not been established.
The dosage recommendation when changing to GLARITUS in pediatric patients (age 2 to 15 years) with type 1 diabetes is the same as that described for adults [see Posology and method of administration (4.2)]. As in adults, the dosage of GLARITUS must be individualized in pediatric patients (age 2 to 15 years) with type 1 diabetes based on metabolic needs and frequent monitoring of blood glucose. In the reported pediatric clinical study, pediatric patients (age 2 to 15 years) with type 1 diabetes had a higher incidence of severe symptomatic hypoglycemia compared to the adults in studies with type 1 diabetes.
Geriatric Use - Caution should be exercised when GLARITUS is administered to geriatric patients. In elderly patients with diabetes, the initial dosing, dose increments, and maintenance dosage should be conservative to avoid hypoglycemic reactions. Hypoglycemia may be difficult to recognize in the elderly.
Hepatic Impairment - The effect of hepatic impairment on the pharmacokinetics of GLARITUS has not been studied. Frequent glucose monitoring and dose adjustment may be necessary for GLARITUS in patients with hepatic impairment.
Renal Impairment - The effect of renal impairment on the pharmacokinetics of GLARITUS has not been studied. Some studies with human insulin have shown increased circulating levels of insulin in patients with renal failure. Frequent glucose monitoring and dose adjustment may be necessary for GLARITUS in patients with renal impairment.
Obesity - Subgroup analyses based on BMI in reported controlled clinical studies, did not show diff-erences in safety and efficacy between insulin glargine and NPH.
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 hypoglycemia. This may constitute a risk in situations where these abilities are of special importance (e.g. driving a car or operating machinery). Patients should therefore be advised to avoid hypoglycemia during driving. This is particularly significant in patients who have reduced awareness of the warning signs of hypoglycemia or have frequent episodes of hypoglycemia.
4.8 Undesirable effects
The following adverse reactions are discussed elsewhere:
- Hypoglycemia [see Special warnings and precautions for use (4.4)]
- Hypersensitivity and allergic reactions [see Special warnings and precautions for use (4.4)]
- Hypokalemia [see Special warnings and precautions for use (4.4)]

Peripheral Edema
Some patients taking insulin glargine have experienced sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy.
Lipodystrophy
Administration of insulin subcutaneously, including insulin glargine, has resulted in lipoatrophy (depression in the skin) or lipohypertrophy (enlargement or thickening of tissue) in some patients.
Insulin Initiation and Intensification Of Glucose Control
Intensification or rapid improvement in glucose control has been associated with a transitory, reversible ophthalmologic refraction disorder, worsening of diabetic retinopathy, and acute painful peripheral neuropathy. However, long-term glycemic control decreases the risk of diabetic retinopathy and neuropathy.
Weight Gain
Weight gain has occurred with some insulin therapies including insulin glargine and has been attributed to the anabolic effects of insulin and the decrease in glucosuria.
Allergic Reactions
Local Allergy
As with any insulin therapy, patients taking GLARITUS may experience injection site reactions, including redness, pain, itching, urticaria, edema, and inflammation.
Systemic Allergy
Severe, life-threatening, generalized allergy, including anaphylaxis, generalized skin reactions, angioedema, bronchospasm, hypotension, and shock may occur with any insulin, including insulin glargine and may be life threatening.
Immunogenicity
As with all therapeutic proteins, there is potential for immunogenicity. All insulin products can elicit the formation of insulin antibodies. The presence of such insulin antibodies may increase or decrease the ecacy of insulin and may require adjustment of the insulin dose.
Medication errors have been reported in which other insulins, particularly rapid-acting insulins, have been accidentally administered instead of insulin glargine. To avoid medication errors between GLARITUS and other insulins, patients should be instructed to always verify the insulin label before each injection.
Other adverse event reported in patients administered with insulin glargine include upper respiratory tract infection, peripheral edema, hypertension, influenza, sinusitis, cataract, bronchitis, arthralgia, pain in extremity, back pain, cough, urinary tract infection, diarrhoea, depression, headache, accidental injury, infection and retinal vascular disorder.
5. Pharmacological properties
5.1 Mechanism of Action
The primary activity of insulin, including insulin glargine, is regulation of glucose metabolism. Insulin and its analogs lower blood glucose by stimulating peripheral glucose uptake, especially by skeletal muscle and fat, and by inhibiting hepatic glucose production. Insulin inhibits lipolysis and proteolysis, and enhances protein synthesis.
5.2 Pharmacodynamic properties
The glucose-lowering effect on a molar basis (i.e., when given at the same doses) of intravenous insulin glargine is approximately the same as that for human insulin. Insulin Glargine differs because of its unique structure providing a smooth and peakless profile with a prolonged duration of action of 24 hours (end of observation period) compared to 14.5 hours for NPH human Insulin. The onset of action of Insulin Glargine is slower than NPH human Insulin.
The duration of action of insulin glargine after abdominal, deltoid, or thigh subcutaneous administration is reportedly similar. The time course of action of insulins, including GLARITUS, may vary between individuals and within the same individual.
Comparative Pharmacodynamics of Glaritus® with Innovator®
Pharmacodynamics of insulin glargine from Glaritus® was compared with that from Innovator in two separate studies – one in healthy volunteers (n=40 in two-way cross-over design) and second in patients of type 1 diabetes mellitus (n = 111 in parallel group design) with successful achievement of bioequivalence of Glaritus® to Innovator as displayed in the tables below.

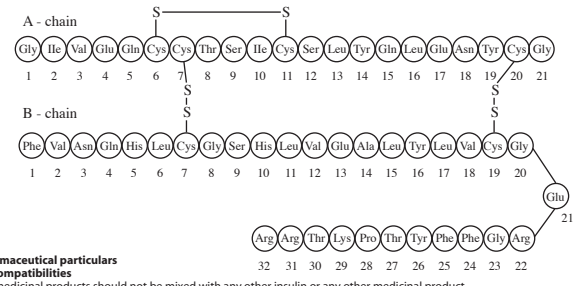
Table 1: Pharmacodynamic comparison of **Glaritus®** to Innovator in healthy volunteers

Pharmacodynamic Parameter	Geometric LSM		T/R Ratio	90% CI of T/R
	Glaritus® (T, N=69)	**Innovator** (R, N=65)		
GIR_{Max} (mg/kg/min, mean)	1.82	1.85	0.98	0.87 to 1.11
$AUC_{GIR0\text{-}24h}$ (h*mg/kg/min, mean)	20.99	21.63	0.97	0.83 to 1.14
GIR_T_{max} (hours, median)	12.83	12.83	P value 0.74	

Table 2: Pharmacodynamic comparison of **Glaritus®** to Innovator in Type 1 Diabetic patients (After exclusion of outlier values)

Parameter	Geometric LSM		T/R Ratio	90% CI of T/R
	Glaritus® (T, N=94)	**Innovator** (R, N=94)		
$AUC_{GIR\ 0\text{-}24}$ (h*mg/ min, mean)	1310.36	1377.55	95.1	85.3 to 106.1
GIR_{max} (hours, mean)	109.27	112.81	96.9	89.9 to 104.4

5.3 Pharmacokinetic properties
Absorption and Bioavailability - After subcutaneous injection of Insulin Glargine, the Insulin serum concentrations indicate a slower, more prolonged absorption and a lack of a peak in comparison to NPH human Insulin. Concentrations are thus consistent with the time profile of the pharmacodynamics activity of Insulin Glargine.
Metabolism and Elimination - A reported metabolism study in humans indicates that insulin glargine is partly metabolized at the carboxyl terminus of the B chain in the subcutaneous depot to form two active metabolites with in vitro activity similar to that of human insulin, M1 (21A-Gly-insulin) and M2 (21A-Gly-des-30B-Thr-insulin). Unchanged drug and these degradation products are also present in the circulation.
6. Nonclinical properties
6.1 Animal Toxicology
Single dose toxicity – There were no signs of toxicity in Swiss albino mice and Sprague Dawley rats treated at the dose level of 24IU/kg body weight of subcutaneous injections of Insulin Glargine.
Repeated dose toxicity - There were no signs of toxicity in Swiss albino mice and Sprague Dawley rats during a period of 28 days with subcutaneous injections of Insulin Glargine.
Dermal Toxicity - There were no signs of dermal irritation or skin sensitization in New Zealand white rabbits and Duncan Hartley guinea pigs with topical testing of Insulin Glargine.
Carcinogenicity and impairment of fertility- Carcinogenicity and fertility studies were not performed in animals.
7. Description
GLARITUS (insulin glargine injection) is a sterile solution of insulin glargine for subcutaneous use. Insulin glargine is a recombinant human insulin analog that is a long-acting, parenteral blood-glucose-lowering agent. Insulin glargine has low aqueous solubility at neutral pH. At pH 4 insulin glargine is completely soluble. After injection into the subcutaneous tissue, the acidic solution is neutralized, leading to formation of microprecipitates from which small amounts of insulin glargine are slowly released, resulting in a relatively constant concentration/time pro le over 24 hours with no pronounced peak. This profile allows once daily dosing as basal insulin. GLARITUS is produced by recombinant DNA technology utilizing a non-pathogenic laboratory strain of Escherichia coli as the production organism. Insulin glargine differs from human insulin in that the amino acid asparagine at position A21 is replaced by glycine and two arginines are added to the C-terminus of the B-chain.
Chemically, insulin glargine is 21^{A}-Gly-30^{a}-a-L-Arg-30^{b}-b-L-Arg-human insulin and has the empirical formula $C_{267}H_{404}N_{72}O_{78}S_6$ and a molecular weight of 6063.
Insulin glargine has the following structural formula:



8. Pharmaceutical particulars
8.1 Incompatibilities
These medicinal products should not be mixed with any other insulin or any other medicinal product.
8.2 Shelf-life
48 months.
8.3 Packaging information
PACK: Glaritus 100 IU/ml; 3ml Multi-dose Cartridge
8.4 Storage and handling instructions
- Insulin Glargine injection Cartridge which is not in use should be stored in a refrigerator (2°C - 8°C). Do not allow it to freeze.
- Do not put it next to the freezer compartment of your refrigerator, or next to a freezer pack.
- When in use, Cartridge may be used in mypen® 2 or may be carried at room temperature up to 30°C for up to 4 weeks.
- Do not expose to excessive heat or direct sunlight.
- Insulin Glargine injection Cartridge must be kept out of reach of children.
- If refrigeration is impossible, the cartridge of Insulin Glargine in use can be kept unrefrigerated for up to 28 days away from direct heat and light, as long as the temperature is not greater than 25°C. Unrefrigerated cartridges must be discarded after 28 days.
- Insulin Glargine must only be used if the solution is clear and colourless with no particles visible.
- Insulin Glargine must not be mixed with any other Insulin nor be diluted. Mixing or diluting can change its time/action profile and mixing can cause precipitation.
- Do not refill the Insulin Glargine Cartridge.
- Insulin Glargine cartridge should never be used after the expiry date.
- If your Cartridge is in cool storage, take it out 1 to 2 hours before you inject to allow it to arrive at room temperature. Cold insulin is more painful to inject.
- Insulin Glargine must not be mixed with any other Insulin nor be diluted. Mixing or diluting can change its time/action profile and mixing can cause precipitation.

9. Patient Counselling Information
Important Risks and Adverse drug reactions
Never Share a Glaritus cartridge or Syringe between patients
Advise patients using Glaritus cartridge, not to share needles, syringes, or DispoPen with another person. Sharing poses a risk for transmission of blood-borne pathogens.
Hypoglycemia
Inform patients that hypoglycemia is the most common adverse reaction with insulin. Instruct patients on self-management procedures including glucose monitoring, proper injection technique, and management of hypoglycemia and hyperglycemia, especially at initiation of Glaritus therapy. Instruct patients on handling of special situations such as illness, stress, or emotional disturbances, an inadequate or skipped insulin dose, inadvertent administration of an increased insulin dose, inadequate food intake, and skipped meals,
Instruct patients on the management of hypoglycemia. Advise patients to regularly carry some sugar lumps, sweets, biscuits, or sugary fruit juice to mitigate symptoms of hypoglycemia. Inform patients that their ability to concentrate and react may be impaired as a result of hypoglycemia. Advise patients who have frequent hypoglycemia or reduced or absent warning signs of hypoglycemia to use caution when driving or operating machinery. [see Special warnings and precautions for use(4.4)].
Hypoglycemia due to Medication Errors
Instruct patients that hypoglycemia may occur as a result of an excess of insulin relative to food intake, energy expenditure, or both. Instruct patients to always check the insulin label before each injection to avoid mix-ups between insulin products.
Hypersensitivity Reactions
Advise patients that hypersensitivity reactions can occur with Glaritus. Inform patients on the symptoms of hypersensitivity reactions and advice the patient to discontinue Glaritus and to seek medical attention if they occur [see Undesirable effects (4.8)].
Use in Special Population
Pregnant females
Advise pregnant patients that insulin requirements usually fall during the first trimester and increase during second and third trimesters of pregnancy. Careful monitoring is required throughout pregnancy. During the perinatal period, careful monitoring of infants born to mothers with diabetes is warranted. Instruct the female patients to tell their physicians if they intend to become, or if they become pregnant while taking GLARITUS.
Nursing Mothers
Advise the nursing mothers that caution should be exercised when GLARITUS is administered to a nursing woman and patient may require adjustments of their insulin doses.
Renal and Hepatic Impairment
Advise the patients that dosage adjustment of insulin may be needed and these patients are at increased risk of hypoglycemia thus requiring frequent blood glucose monitoring.
Administration Instructions
Instruct the patient to never use Glaritus cartridge if it is damaged or if you are not sure that it is working properly. Advise the patients on proper and safe disposal of the needle [see Instructions for use].
Storage and Handling
Instruct the patient that Glaritus cartridge which is not in use, should be stored in a refrigerator (2°C to 8°C) and should never be kept in the freezer compartment.
Instruct the patient that when in use, Glaritus cartridge may be carried at room temperature up to 30°C for up to 4 weeks.
10. Details of manufacturer
Manufactured in India by
WOCKHARDT LIMITED Biotech Park, H-14/2 MIDC, Waluj, Aurangabad 431136 Maharashtra State
11. Details of permission or licence number
Manufacturing License No: AD/004
12. Date of revision
Jan/2020.

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ACTUAL SIZE 110 X 320 MM

Pantone 2665 C

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Biotech Park MFG