

## INFORMATION FOR THE PATIENT

### Jusline R

REGULAR  
INSULIN HUMAN INJECTION, USP  
RECOMBINANT DNA ORIGIN

#### WARNINGS

This **JUSLINE** is a human insulin product that differs from animal source insulin because it is structurally identical to the insulin produced by your body's pancreas and because of its unique manufacturing process. Any change of insulin should be made cautiously and only under medical supervision. Changes in purity, strength, brand (manufacturer), type (regular, NPH, lente, etc.), species (beef, pork, beef-pork, human), and/or method of manufacturing (recombinant DNA versus animal-source insulin) may result in the need for a change in dosage.

Some patients taking **JUSLINE**<sup>®</sup> (Insulin human, recombinant-DNA origin) may require a change in dosage from that used with animal source insulins. If an adjustment needed, it may occur with the first dose or during the first several weeks or months.

#### DIABETES

Insulin is a hormone produced by the pancreas, a large gland that lies near the stomach. This hormone is necessary for the body's correct use of food, especially sugar. Diabetes occurs when the pancreas does not make enough insulin to meet your body's needs.

To control your diabetes, your doctor has prescribed injections of insulin to keep your blood glucose at a nearly normal level. Proper control of your diabetes requires close and constant cooperation with your doctor. In spite of diabetes, you can lead an active, healthy, and useful life if you eat a balanced diet daily, exercise regularly, and take your insulin injections as prescribed.

You have been instructed to test your body and/or your urine regularly for glucose. If your blood tests consistently show above-or-below-normal glucose levels or your urine tests consistently show the presence of glucose, your diabetes is not properly controlled and you must let your doctor know.

Always keep an extra supply of insulin and a spare syringe needle on hand. Always wear diabetic identification so that appropriate treatment can be given if complications occur away from home.

#### REGULAR INSULIN HUMAN

#### Description

**JUSLINE** is synthesized in a non-disease-producing special laboratory strain of *Escherichia coli* bacteria that has been genetically altered by the addition of the gene for human insulin production. **JUSLINE R** consists of zinc-insulin crystals dissolved in a clear fluid. **JUSLINE R** has had nothing added to change the speed or length of its action. It takes effect rapidly and has a relatively short duration of activity (4 to 12 hours) as compared with other insulins. The time course of action of any insulin may vary considerably in different individuals or at different times in the same individual. As with all insulin preparations, the duration of action of **JUSLINE R** is dependent on dose, site of injection, blood supply, temperature, and physical activity. **JUSLINE R** is a sterile solution and is for subcutaneous injection only. It should not be used intramuscularly. The concentration of **JUSLINE R** is 100 units/mL (U-100).

#### Identification

Insulin human is available in 3 formulations:

Regular (R), NPH (N, 30% as soluble insulin and 70% as isophane insulin (30/70)). Your doctor has prescribed the type of insulin that he/she believes is best for you: **DO NOT USE ANY OTHER INSULIN EXCEPT ON HIS/HER ADVICE AND DIRECTION.**

Always check the carton and the bottle label for the name and letter designation of the insulin you receive from your pharmacy to make sure it is the same as that your doctor has prescribed.

Always examine the appearance of your bottle of insulin before withdrawing each dose. **JUSLINE R** is a clear and colorless liquid with water like appearance and consistency. Do not use if appears cloudy, thickened, or slightly colored or if solid particles are visible. Always check the appearance of your bottle of insulin before using, and if you note anything unusual in the appearance of your insulin or notice your insulin requirements changing markedly, consult your doctor.

#### Storage

Keep the vial in the outer carton in order to protect from light. Store in a refrigerator (2 - 8°C). Avoid freezing. Do not use insulin if it has been frozen. Do not use a bottle of insulin after the expiration date stamped on the label.

#### Correct Syringe

Doses of insulin are measured in units. It is important that you understand the markings on your syringe, because the volume of insulin you inject depends on the strength, that is, the number of units/mL. For the reason, you should always use a syringe marked for the strength of insulin you are injecting. Failure to use the proper syringe can lead to a mistake in dosage, causing serious problems for you, such as a blood glucose level that is too low or too high.

#### Syringe Use

To help avoid contamination and possible infection, follow these instructions exactly. Disposable syringes and needles should be used only once and then discarded.

**NEEDLES AND SYRINGES MUST NOT BE SHARED.**

Reusable syringes and needles must be sterilized before each injection. Follow the package directions supplied with your syringe.

#### Preparing the Dose

1. Wash your hands.
2. Inspect the insulin. **JUSLINE R** should look clear and colorless. Do not use **JUSLINE R** if it appears cloudy, thickened, or slightly colored or if solid particles are visible.
3. If using a new bottle, flip off the plastic protective cap, but do not remove the stopper. When using a new bottle, wipe the top of the bottle with an alcohol swab.
4. If you are mixing insulin, refer to the instructions for mixing that follow.
5. Put the needle through rubber top of the insulin bottle.
6. Turn the bottle and syringe upside down.
7. Make sure that the tip of the needle is in the insulin, withdraw the correct dose of insulin into the syringe.
8. Before removing the needle from the bottle, check your syringe for air bubbles that reduce the amount of insulin in it. If bubbles are present, hold the syringe straight up and tap its side until the bubbles float to the top. Push them out with the plunger and withdraw the correct dose.
9. Remove the needle from the bottle and lay the syringe down so that the needle does not touch anything.

#### Mixing JUSLINE R with longer-acting Human Insulins

1. Regular human insulin should be mixed only with longer-acting human insulins only on the advice of your doctor.
  2. Insert the needle into regular human insulin bottle. Turn the bottle and the syringe upside down.
  3. Making sure the tip of the needle is in the insulin, withdraw the correct dose of regular insulin into the syringe.
  4. Before removing the needle from the bottle, check your syringe for air bubbles, which reduce the amount of insulin in it. If bubbles are present, hold the syringe straight up and tap its side until the bubbles float to the top. Push them out with the plunger and withdraw the correct dose.
  5. Remove the needle from the bottle of regular insulin and insert it into the bottle of longer-acting insulin. Turn the bottle and the syringe upside down. Hold the bottle and syringe firmly in one hand and shake gently. Make sure that the tip of the needle is in the insulin, withdraw your dose of longer-acting insulin.
  6. Remove the needle and lay the syringe down so that the needle does not touch anything.
- Follow your doctor's instruction on whether to mix your insulins ahead of time or just before giving your injection. It is important to be consistent in your method.
- Syringes from different manufacturers may vary in the amount of space between the bottom line and the needle, because of this do not change the sequence of mixing or the model and brand of syringes or needles that the doctor has prescribed.

#### Injection

Cleanse the skin with alcohol where injection is to be made. Stabilize skin by spreading it or pinching up a large area. Insert needle as instructed by your doctor. Push the plunger in as far as it will go. Pull the needle



out and apply gentle pressure over the injection site for several seconds. **Do not rub the area.** To avoid tissue damage, give the next injection at a site at least  $\frac{1}{2}$ " from the previous site.

#### DOSEAGE

Your doctor has told you which insulin to use, how much, and when, and how often to inject it. Because each patient's case of diabetes is different, this schedule has been individualized for you.

Your usual insulin dose may be affected by changes in your food, activity, or work schedule. Carefully follow your doctor's instructions to allow for these changes. Other things that may affect your insulin dose are:

**Illness:** Illness, especially with nausea and vomiting, may cause your insulin requirements to change. Even if you are not eating, you will still require insulin. You and your doctor should establish a sick day plan for you to use in case of illness. When you are sick, test your blood/urine frequently and call your doctor as instructed.

**Pregnancy:** Good control of diabetes is especially important for you and your unborn baby. Pregnancy may make managing your diabetes more difficult. If you are planning to have a baby, are pregnant, or are nursing a baby, consult your doctor.

**Medication:** Insulin requirements may be increased if you are taking other drugs with hyperglycemic activity, such as oral contraceptives, corticosteroids, or thyroid replacement therapy. Insulin requirements may be reduced in the presence of drugs with hypoglycemic activity, such as oral hypoglycemics, salicylates (for example, aspirin) sulfa antibiotics and certain antidepressants. Always discuss any medications you are taking with your doctor.

**Exercise:** Exercise may lower your body's need for insulin during and for some time after the activity. Exercise may also speed up the effect of an insulin dose, especially if the exercise involves the area of injection site (for example, the leg should not be used for injection just prior to running). Discuss with your doctor how you should adjust your regimen to accommodate exercise.

**Travel:** Persons traveling across more than 5 time zones should consult their doctor concerning adjustments in their insulin schedule.

#### COMMON PROBLEMS OF DIABETES

##### Hypoglycemia (Insulin Reaction)

Hypoglycemia (too little glucose in the blood) is one of the most frequent adverse events experienced by insulin users. It can be brought about by taking too much insulin; missing or delaying meals; exercising or working more than usual; an infection or illness (especially with diarrhea or vomiting); a change in the body's need for insulin; diseases of the adrenal, pituitary, or thyroid gland, or progress of kidney or liver disease; interactions with other drugs that lower blood glucose such as oral hypoglycemics, salicylates (for example, aspirin) sulfa antibiotics, and certain antidepressants; consumption of alcoholic beverages.

**Symptoms of mild to moderate hypoglycemia** may occur suddenly and can include sweating, dizziness, palpitation, tremor, hunger, restlessness, tingling in the hands, feet, lips or tongue, lightheadedness, inability to concentrate, headache, drowsiness, sleep disturbances, anxiety, blurred vision, slurred speech, depressive mood, irritability, abnormal behavior, unsteady movement and personality changes.

**Signs of severe hypoglycemia** can include disorientation, seizures, unconsciousness and death.

Therefore, it is important that assistance be obtained immediately.

Early warning symptoms of hypoglycemia may be different or less pronounced under certain conditions, such as long duration of diabetes, diabetic nerve disease, medications such as beta-blockers, change in insulin preparations, or intensified control (3 or more insulin injections per day) of diabetes.

A few patients who have experienced hypoglycemic reactions after transfer from animal-source insulin to human insulin have reported that the early warning symptoms of hypoglycemia were less pronounced or different from those experienced with their previous insulin.

Without recognition of early warning symptoms, you may not be able to take steps to avoid more serious hypoglycemia. Be alert for all of the various types of symptoms that may indicate hypoglycemia. Patients who experience hypoglycemia without early warning symptoms should monitor their blood glucose frequently, especially prior to activities such as driving. If the blood glucose is below your normal fasting glucose, you should consider eating or drinking sugar-containing foods to treat your hypoglycemia.

Mild to moderate hypoglycemia may be treated by eating foods or drinks that contain sugar. Patients should always carry a quick source of sugar, such as candy mints or glucose tablets. More severe hypoglycemia may require the assistance of another person. Patients who are unable to take sugar orally or who are

unconscious require an injection of glucagon or should be treated with intravenous administration of glucose at a medical facility.

You should learn to recognize your own symptoms of hypoglycemia. If you are uncertain about these symptoms, you should monitor your blood glucose frequently to help you learn to recognize the symptoms that you experience with hypoglycemia.

If you have frequent episodes of hypoglycemia or experience difficulty in recognizing the symptoms, you should consult your doctor to discuss possible changes in therapy, meal plans, and/or exercise programs to help you avoid hypoglycemia.

##### Hyperglycemia and Diabetic Acidosis

Hyperglycemia (too much glucose in the blood) may develop if your body has too little insulin. Hyperglycemia can be brought about by:

1. Omitting your insulin or taking less than the doctor has prescribed
2. Eating significantly more than your meal plan suggests
3. Developing a fever, infection, or other significant stressful situation.

In patients with insulin-dependent diabetes, prolonged hyperglycemia can result in diabetic acidosis. The first symptoms of diabetic acidosis usually come on gradually, over a period of hours or days, and include a drowsy feeling, flushed face, thirst, loss of appetite and acetone odor in the breath. With acidosis, urine tests show large amounts of glucose and ketone bodies. Heavy breathing and a rapid pulse are more severe symptoms. If uncorrected, prolonged hyperglycemia or diabetic acidosis can lead to nausea, vomiting, dehydration, and loss of consciousness or death. Therefore, it is important that you obtain medical assistance immediately.

##### Lipodystrophy

Rarely, administration of insulin subcutaneously can result in lipodystrophy (depression in the skin) or lipohypertrophy (enlargement or thickening of tissue). If you notice either of these conditions, consult your doctor. A change in your injection technique may help alleviate the problem.

##### Allergy to Insulin

**Local Allergy** – Patients occasionally experience redness, swelling, and itching at the site of injection of insulin. This condition, called local allergy, usually clears up 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. If you have local reactions, contact your doctor.

**Systemic Allergy** – Less common, but potentially more serious, is generalized allergy to insulin, which may cause rash over the whole body, shortness of breath, wheezing, reduction in blood pressure, fast pulse, or sweating. Severe cases of generalized allergy may be life threatening. If you think you are having a generalized allergic reaction to insulin, notify a doctor immediately.

#### THIS IS A MEDICAMENT

- Medicament is a product, which affects your health, and its consumption contrary to instruction is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines their benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of the children.

Council of Arab Health Ministers,  
Union of Arab Pharmacists

Any information? Call Our Toll Free No. (971) 800-4994



Produced by: **Juphar**  
Gulf Pharmaceutical Industries,  
Ras Al Khaimah, U. A. E.

