## INSULIN HUMAN INJECTION USP (RECOMBINANT DNA ORIGIN) WOSULIN™- R



REGULAR

Monocomponent Insulin (HUMAN)

in-Cresol
as preservative
Water for Inject 0.25% w/v Water for Injection USP DIABETES FOR SC, IM, IV USE ONLY 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

100 IU

body's correct use of lood, especially sugar. Uabelets occurs when the pancreas obes not make enough insulin to meet your body's needs.

To control your diabelets, your doctor has prescribed injections of insulin products to keep your blood glucose at a near-normal level. You have been instructed to fest your blood and/or your unit regularly for glucose. Studies have shown that some chronic complications of diabelets such as eye disease, kidney disease, and nerve disease can be significantly reduced if the blood sugar is maintained as close to normal as possible. Proper control of your diabelets requires dose and consteant cooperation with your doctor. Despite diabelets, you can lead an active and healthy life if you eat a balanced diet, accretise regularly, and take your insulin injections as prescribed. Always keep an extra supply of insulin as well as a spare syringe and needle handy.

WOSULIN-R is human recombinant insulin, which is synthesized in a special non-disease-producing laboratory strain of the yeast Hansenula polymorpha. This special host cell line has been genetically altered by the addition of the gene for Insulin

COMPOSITION

Insulin Human

human production:
WOSULIN-K contains zinc crystals dissolved in a clear solution. It is a sterile solution for parenteral use. It can be used subcutaneously, initizerenously or intramuscularly. The onset of action of WOSULIN-R is rapid and it has a relatively short duration of action (4-6 hrs) as compared with other longer-acting formulations of insulin.

obtation of action 4- of 13 as compared with other longer-acting joint leading to install the MECHAINSM OF ACTION
Like all other insulins, the glucose lowering effect of WOSULIN-R: do us the facilitated uptake of glucose in body tissues. This uptake occurs following the binding of insulin to its receptors present in the muscle and adjoose tissue. The blood glucose lowering effect of insulin also occurs due to the simultaneous inhibition of glucose output from the liver.

PHARMACOKINETICS

PHARMACOKINETICS Insulin has half-life of a few minutes in the blood stream. Consequently, 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 intensity and duration of action of WOSULIN-R is dependent on the dose, site of injection, blood supply, temperature, and physical solivity.

An average action profile after subcultaneous injection indicates:

Onset-within 30 minutes ● Peak livels attained between 1-3 hours ● Duration of action - approximately 4-8 hours

WOSULIN-R is indicated for the following

- Treatment of all patients with type 1 diabetes
  Treatment of patients with type 2 diabetes who are not adequately controlled by diet and / or oral hypoglycemic

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For the initial stablization of diabetes in patients with diabetic ketoacidosis, hyperosmoiar non-ketotic syndrome and during periods of stress such as severe infections and major surgery in diabetic patients.

Treatment of gestational diabetes

DOSAGE AND ADMINIST RATION

The dosage of WOOULLIN-R is determined by your doctor, as per your need. Your usual insulin dose may be affected by the patient of the desired of the desired strength, e.g., U-d or U-100 insulin preparations. Failure to use the important to use a syringe that is marked for the desired strength, e.g., U-d or U-100 insulin preparations. Failure to use the proper syringe can lead to a mistake in dosage, causing serious problems such as severe hypoglycemia or hyperglycemia. The average range of lotal daily insulin requirement for maintenance in type 1 diabetic glaterios ranges between 0.5 and 1.0 IU/Log. Further, in insulin resistance, the daily requirement of Insulin may be substantially higher. In patients with type 2 diabetes, the requirements of frouth are toweric, approximately 0.3 of 6.0 IU/kg/dsy.

WOSULIN-R is usually administered subcutaneously in the abdominal wall, the thigh, the gluteal region or the deltoid recion.

region. Infraruscular injections are possible under guidance by a physician. Infravenous administrations are suitable only for vial products and should be carried out under the guidance of a physician. To avoid lipocytopy, the site of subculaneous injection should be frequently changed. Any injection of insulin should be followed by a meal or snack containing carbonhydrates within 30 minutes. Adjustment of dosage may be necessary, if you undertake increased physicial activity or change your usual diel. 
\*\*USE ALONG WITH OTHER INSULINS\*\*

WOSULINE And he used either in combination with biphasic insulin (a combination of regular insulin and isophane insulin) or in combination with isophane insulin. However it should not be used with lente insulin because of increased risk of

hypoglycemia. CONTRAINDICATIONS

WOSULIN-Ris contraindicated in the following conditions
Hypoglycemia
Hypersensitivity to insulin
PRECAUTIONS

Pregnancy: There are no restrictions on the use of insulin during pregnancy since insulin does not cross the placer Pregnancy: There are no restrictions on the use of insulin during pregnancy since insulin does not cross the placental barner. Published studies with human insulins suggest that optimizing overall glycemic control, including postprandial control, before conception and during pregnancy improves fetal outcome. Although the fetal complications of maternal hyperglycemia have been well documented, fetal toxicity also has been reported with maternal hypogenycemia. Insulin requirements usually fall during the first timester and increase during the second and third trimesters. During the perinatal period, careful monitoring of inflants born to mothers with diabetes is warranted.

Nursing Mothers: There are no restrictions on the use of insulin in lactaling mothers as insulin treatment of nursing mothers does not involve any risk to the baby. However, caution should be exercised when administered to nursing mothers and the disage of firsulin may be reduced. Effects on the ability to drive and use machines: The patient's ability to concentrate and react may be impaired as a result of hypoglycemia. Inits may constitute a risk in situations where these abilities are of special importance (e.g. driving a car or operating machinery).

You are therefore advised to avoid hypoglycemia during driving. This is particularly significant in patients who have reduced awareness of the warning signs of hypoglycemia have frequent episcodes of hypoglycemia.

SWITCHING TO DIFFERENT TYPE OF INSULIN

If you are switching to another type of Insulin, it should be done under strict medical supervision. Changes in strength, brand

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Laboratory the dose from that used with usual insulin.

change modes from that used with usual insulin. LABORATORY TESTS
As with all insulins, the therapeutic response to human insulin should be monitored by periodic blood glucose tests. Periodic measurement of glycosylated hemoglobin is recommended for the monitoring of long term glycemic control. DRUG INTERACTIONS

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Insulin requirements may be increased by medications with hyperglycemic activity such as corticosteroids, isoniazid, certain lipidlowering drugs (e.g. niacin), estrogens, oral contraceptives, phenothiazines, and thyroid replacement longiant insulingular enteringular enter

The most commonly seen adverse reaction with WOSULIN-R are:

The most commonly seen adverse reaction with WUSULIN-H are:

1. Hypoglycemia is one of the most common adverse effect seen with the use of any type of insulin including human insulin.

Hypoglycemia is one of the following:

Use of too much insulin

Missed meal / delayed meal

Intercurrent infection or illness

Strenuous exercise. Strenuous exercises.

Diseases of the edrenal, plutilary, or thyroid gland, or progression of kidney or liver disease may also lead to hypoglycemia. Concomitant administration with other drugs that lover blood glucose such as or all hypoglycemics, salicylates (for example, assprin), sulfa antibiotics, and certain antidepressants may lear to hypoglycemia.

Concomitant consumption of alcoholic beverages may also lead to hypoglycemia. Symptoms of mild to moderate hypoglycemia and can include: Sweating, disclaress, papilation; tremor, hunger, restlessness, tingling

## PATIENT'S INFORMATION AND RECORD

- Points you should know:
  Remember the brand name and type of insulin prescribed.
  Never expose insulin lo exitemite temperatures.
  Use only the right concentration of the insulin prescribed (40 IU or 100 IU) with the right syringe.
  The insulin visit shave a protective colour-coded cap which must be removed before use. If the plastic cap is loose or missing, return the visit to the pharmacy.
  WOSULIN is the riton, insulin derived from Animals.

in the hands, feef, libs, or tongue; lightheadedness; inability to concentrate; headache; drowsiness; sleep disturbances; anxiety; blurred vision; slurred speech; depressive mood; irritability; abnormal behavior; unsteady movement; personality

anxiety, burned vision; surred speech; depressive mood; irritability; abnormal behavior; unsteady movement; personality changes.

Signs of severe hypoglycemia can include: Disorientation; unconsciousness; seizures; 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; co-administration of medications such as beta blockers, change in insulin inpections, or intensified control (3 or more insulin injections per day) of diabetes. If the blood glucose is betwey your normal fasting glucose, you should consider setting or drinking sugar containing foods to treat your, hypoglycemia. Mid to indoderate hypoglycemia may be treated by eating foods of drinks that contain sugar. Patients should always carry a quick source of sugar, such as candy or glucose tablets. More severe hypoglycemia may require the assistance of another person. The use of preparations of WOS/ULIN-R should minimize the incidence of adverse diffects associated with the use of animal insulins.

Cedema:Cedema and refraction anomalies may occur upon initiation of insulin therapy. These symptoms are usually of a transitory

3. Allergy to Insulin

3. Allergy to insulin:
3. a: 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, last pulse, or sweating. Severe cases of generalized allergy may be life threatenine.

3. b: Local Allergy: Patients occasionally experience redness, swelling, and tiching 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.

4. Lipoatrophy: All podystrophy occurs at the site of injection after long usage. However, this is less common with the newer preparations of insulin.

5. Insulin resistance:

When insulin requirement is increased (> 200 IU / day), insulin resistance is said to have developed. The following are the

5. Insulin resistance: When insulin requirement is increased (> 200 IU / day), insulin resistance is said to have developed. The following are the different grades of insulin resistance: Acute: Acute insulin resistance developes rapidly and is usually a short term problem. It usually occurs due to an underlying infection, trauma, surgery and emotional stress. Treatment is to overcome the precipitating factor and to give high doses of

regular insulin.

Chronic: This type of insulin resistance is generally seen in patients treated for years with conventional preparations of beef or pork insulins and it is more common in patients with Type 2 diabetes. Development of such a type of insulin resistance is an indication for whiching patients to the newer-perparations of insulin. After instituting the newer preparations, insulin requirement gradually declines over weeks and months and majority of patients stabilize at approximately 60 IU /day.

OVERDOSAGE

UVENUUSAGE

Hypoglycemia may occur as a result of an excess of insulin relative to food intake, energy expenditure, or both. Mild episodes of hypoglycemia usually can be treated with oral glucose, it is therefore recommended that the diabetic patient constantly carry some sugar lumps, sweets, biscuits, or sugary full juice. Adjustments in drug dosage, meal patterns, or exercise, may be needed. More severe episodes of hypoglycemia with coma, salzur, or neurologic impairment may be treated with intranuscular? subcutaneous glucagon or concentrated intravenous glucose. Glucose must also be given intravenously, if the patient does not respond to glucagon within 10 to 15 minutes. Sustained carbohydrate intake and observation may be necessary because hypoglycemia may recur after apparent clinical recovery.

STORAGE

STORAGE
WOSULIN-R should be stored in a refrigerator (2°C to 8°C) but not allowed to freeze. When in use, vial may be kept at room temperature (15°C to 25°C) for upto six weeks. Do not expose to excessive heat or direct sunlight. WOSULIN-R must be kept out of reach of children.

Insulin preparations, which have been frozen, must not be used. WOSULIN-R solutions should not be used if they do not appear water-clear and colouriess.

Once opened (when the stopper or seal has been punctured with a needle), WOSULIN-R is kept at room temperature. Cold insulin can be irritating to inject. Thus, patients should be asked to roll the vial in their hands 10 times prior to drawing it up in the syringe (after allowing) the vial to sit of 30 minutes at room temperature if the vial is stored in the refrigerator).

PACK: WOSULIN-R 100 tit/ml- 10ml vial

Manufactured by : WOCKHARDT LTD. Aurangabad, India TM Trademark of Wockhardt

## PROCEDURE FOR INSULIN ADMINISTRATION



Wash your hands carefully. Shake or roll Wosulin-R insulin vial 10 times to completely mix the insulin



6. Turn the bottle and syringe upside down. Hold the bottle and syringe firmly in one hand and shake gently. Making sure that the tip of the needle is in the liquid, withdraw the correct dose of insulin into the syringe.



Inspect the vial. Wosulin-R should appear uniformly cloudy or milky. The Insulin Injection should not be used if there is anything unusual appearance.



7. Before removing the needle from the vial, check the insulin syringe for air bubbles, which reduces the amount of insulin in it, if bubbles are present, hold the insulin straight up and tap its side until the bubbles float to the top. Push them out with the plunger and withdraw the correct dose again.



When using a new vial, flip off the plastic protective cap, but do not remove the stopper. The tip of the vial should be wiped with an alcohol swab



Lightly pinch up the skin, holding the syringe like a pencil.



Draw air into the syringe equal to your insulin dose



Insert the needle into the skin and push the plunger slowly. Make sure that the needle is all the way in.



Insert needle into vial through rubber top and push plunger to empty the air into the



10. Wait for 5 seconds and pull out the syringe. Do not rub the area.

## Your Daily Insulin Intake Calendar

DATE	INSULIN .	TIME	BRAND	DATE	INSULIN DOSE	BRAND