WOSULIN™- N



COMPOSITION Each ml of Isophane suspension contains: Insulin Human USP m-Cresol USP 100 IU 0.16% w/s as preservative Phenol USF as preservative WaterforInjection USP DIABETES

NPH Monocomponent Insulin (HUMAN)

For SC 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

body's needs. To control your diabetes, your doctor has prescribed injections of insulin products to keep your blood glucose at a neamormal level. You have been instructed to test your blood and/or your urine regularly for glucose. Studies have shown that some chronic complications of diabetes such as eye disease, kithery disease, and nerve disease can be significantly reduced if the blood sugar is manifianed as close to normal as possible. Proper control of your diabetes requires close and constant cooperation with your doctor. Despite diabetes, you can lead an active and healthy life if you eat a balanced diet, exercise regularly, and take your insulin injections as prescribed. Always keep an extra supply of insulin as well as a spare syringe and needle handly.

DESCRIPTION

Mechanism of action

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Recombinant isopiane insulin human suspension - WOSULIN-N is human recombinant insulin, which is synthesized in a
Recombinant isopiane insulin human suspension - WOSULIN-N 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 human insulin in the providing an intermediate - acting insulin with a
slower onset and a longer duration of activity than that of regular insulin. The onset of action of spohane insulin human
suspension-WOSULIN-N is dependent on dese, site of injection, blood supply, temperature and physical activity. The onset
of action is 1-2 hours, peak effect is seen at 6-12 hours and the duration of effect is about 18-24 hours. The time course of
action of any insulin may vay considerably in different individuals or a different times in the same individual.
It is a sterile solution and is for subcutaneous injection only. It should not be used intravenously or intramuscularly.

PARABARCHINETICS.

PHARMACOKINETICS
Insulin has a half-life of a law minutes in the blood stream. Consequently, the time course of action of any insulin may vary considerably indifferent individuals or at different times in the same individual. As with all insulin preparations, the intensity and duration of action of losphane insulin human suspension - WOSULIN-N is dependent on the dose, site of injection, bloodsupply, temperature, and physical activity.

An average action profile after subcutaneous injection indicates:

Onsel within 1-2 bours © Peak levels attained between 6-12 hours © Duration of action approximately 18-24 hours.

INDICATIONS

- Isophane insulin human suspension WOSULIN-N 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 appets.
- agents

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

 Teatment of gestational diabetic patients

 DOSAGE AND ADMINISTRATION

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DOSAGE.AND ADMINISTRATION
The disage of topophae insulin human suspension - WOSULIN-N is determined by the physician, as per the needs of the patient. With Isophane insulin human suspension - WOSULIN-N, it is important to use a syringe that is marked for the desired frength, for e.g. U-40 or I-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 total deliy insulin requirement for maintenance in they of tidebellic patients ranges between 0.5 and 1.0 IJ VB, Further, in insulin resistance, the daily requirement of insulin may be substantially higher. In patients with type 2 diabetes, the requirements of fishulin are lower ic. approximately 0.3 of IU VB/grds.

Sophane insulin human suspension- WOSULIN-N is administered subcutaneously in the abdominal wall, the thigh, oblivate pricing or the delibrid region.

Isophane install maintar studentistor. "VoCutinn's an immisseur succentarious system of installin should be followed glitted region:
 To avoid lipodystroph, the site of injection should be friequently changed. Any injection of installin should be followed by a medio or areak containing carbohydrates within 30 minutes. Adjustment of dosage may be necessary if you undertake nucreased physical activity or change your usual diet.

USEALONE WITH OF HER TYPES OF INSULIN. Its objection is suit in human regular.

CONTRAINDICATIONS

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sophane insulin human suspension - WOSULIN-N is contraindicated in the following conditions:

Hypoglycemia Hypersensitivity to insulin or any other component of the formulation

PRECALITIONS

Prepared Stuny to insulin or any other component or the insulin during preparety; since insulin does not cross the placental barrier. Published studies with human insulins suggest that optimizing overall glycenic control, including postprandial control, before conception and during preparancy improves feels outcome. Although the feel completion of material property control and before conception and during preparancy improves feels outcome. Although the feel completions of material property control and the property of the control of the cont

You are interiorie acvised to avoid typoglycemia during driving. This is particularly significant in platein is with later evolution warning signs of hypoglycemia or they frequent policy does of hypoglycemia. Changes in SMTCHING TO DIFFERENT TYPE OF INSULIN IT you are switching to another type of Insulin, it should be done under strict medical supervision. Changes in strength, train (manufacturer), type (explaid acting insulin, intermediate acting insulin, long acting insulin etc.), species (animal, Insulin human analog) and/or method of manufacturer (recombinant versus animal source insulin) may result in the need for a change in dose.

Patients switching to Isophane insulin human suspension - WOSULIN-N may require a change in dosage from that used

eir usual ir

LABORATORYTESTS

As with all insulins, the therapeutic response to human insulin should be monitored by periodic blood glucose lests, Periodic measurement of glycosylated hemoglobin is recommended for the monitoring of long term glycemic control.
DRUGINTERACTIONS

Insulin requirements may be increased by medications with hyperglycemic activity such as corticosteroids, isoniazid, certain lipid-lowering drugs (e.g. niacin), estrogens, or all contraceptives, phenothiazines, and thyroid replacement therapy. Insulin requirements may be decreased of the presence of drugs with hypolycomic activity, such as oral hypolycemic agents, salicylates, suifa antibiotics, certain antidepressants (monoamine oxidase inhibitors), certain angidensia converting enzyme inhibitors, betta adrenergic blockers, inhibitors of pancreatic function (e.g. Octredided), and alcohol. Beta adrenergic blockers may mask the symptoms of hypoglycemic an some patients.

Renal Impairment: Although impaired hepatic function does not affect the absorption of disposition of Isophane insulin human suspension. WOSULIN, carefull glucose monitoring and does a digitaments of insulin my he necessary.

ADVERSE EFFECTS

The most commonly seen adverse reaction with Isophane insulin human suspension. WOSULIN IN-N area.

The most commonly seen adverse reaction with Isophane insulin human suspension - WOSULIN-N are:

1. Hypoglycemia:

Hypoglycemia is one of the most common adverse effect seen with the use of any type of insulin including human insulin. This can occur because of the following:

Use of too much insulin

Missed meal / delayed meal
Intercurrent infection of ilness

Strenuose spercises

Intercurent intercuron in micros
Strenous exercise.

Strenous exercise.

Diseases of the adrenal, pibuliary, or thyroid gland, or progression of kidney or liver disease may also lead to hypoglycemia.

Concomitant administration with other drugs that lower blood glucose such as oral hypoglycemics, salicylates (for example, aspirin), sulfa antibiotics, and certain antidepressants may lead to hypoglycemia.

Concomitant consumption of alcoholic beverages may also lead to hypoglycemia. Symptoms of mild to moderate hypoglycemia may occur suddenly and can include: Sweating; dizziness; palpitation; tremor; hunger, restlessness; fingling

PATIENT'S INFORMATION AND RECORD

- Points you should know:

 Remember the brand name and type of insulin prescribed.

 Never expose insulin to extreme temperatures

 Use only the right conceintation of the insulin prescribed (40 IU or 100 IU) with the right syringe.

 Use only the right conceintation of the insulin prescribed (40 IU or 100 IU) with the right syringe.

 The insulin vials have a protective coolur-coded cap which must be removed before use. If the plastic cap is loose

or missing, return the vial to the pharmacy. WOSULIN is free from, Insulin derived from Animals

in the hands, feet, lips, or tongue: lightheadedness; inability to concentrate; headache; drowsiness; siete disturbances; anxiety; blurred vision: slurred speech; depressive moot; initiability, abnormal behavior; unsteady movement; personality changes. Signs of severe hypoglycemia can include:
Disorientation; unconsciousness; secures; death. Therefore, it is important that assistance be obtained immediately. Early warming 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 preparations, or intensified control (3 or more insulin injections per day) of diabetes. The use of preparations of sopharier insulin human suspension - WOSULIN-N should minimize the incidence of adverse effects associated with the use of animal insulins.

2. Oedema

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

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, fast pulse, or sweating. Severe cases of generalized in the fifther serious file threatening.

3. b: The condition called todal allergy, usually clears by in a few days to a few weeks. In some instances, this condition dated todal allergy, usually clears by in a few days to a few weeks. In some instances, this condition dated todal allergy, usually clears by in a few days to a few weeks in some instances, this condition and lipodystrophy.

4. Lipoatorphy and lipodystrophy cut.

5. Lipoatorphy and lipodystrophy cocurs at the site of injection after long usage. However, this is less common with the newer preparations of insulin.

5. Insulin resistance

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 develops 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 switching patients to the newer preparations 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

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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 fint juice. Adjustments in drug dosage, meal patterns, or exercise, may be needed. More severe episodes of hypoglycemia with coma, seizure, or neurologic impairment may be treated with inframuscular / subcutaneous glucagon or concentrated intervenous 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 Is a supersion WOSULIN-N 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 up to six weeks. Do not expose to excessive heat or direct sunlight, isophane insulin human suspension - WOSULIN-N must be kept out of reach of children. Insulin preparations, which have been frozen, must not be used. Once opened (when the stopper or seal has been punctured with a needle), insulin its kept at room temperature. Cold insulin can be irritating to inject. Thus, patients should be asked to roll the vale in their hands 10 times prior to drawing it up in the syringe (after allowing the vial to sit for 30 minutes at room temperature. if the vial is stored in the refrigerator).

PACK: WOSULIN-N 100 IU/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-N insulin vial 10 times to completely mix



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.

7. Before removing the needle from the vial, check the insulin syringe for air bubbles,

reduces the amount of insulin in it, if bubbles

which



3.

swab

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



are present, hold the insulin straight up and tap its side until the When using a new vial, flip off the bubbles float to the top. Push them out with the plunger and withdraw plastic protective cap, but do not the correct dose again. remove the stopper The tip of the vial should be wiped with an alcohol



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



Draw air into the syringe equal to your sulin 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



Wait for 5 seconds and 10. pull out the syringe. Do

Your Daily Insulin Intake Calendar

DATE INSULIN DOSE	BRAND	DATE	INSULIN DOSE	TIME	BRAND
					1100