SciLin® R – 100 IU

Recombinant Human Insulin
Solution for Injection S.C.

COMPOSITION
Each ml contains:
Recombinant Human Insulin100 IU
(as inactive m-cresol stabilised insulin solution)

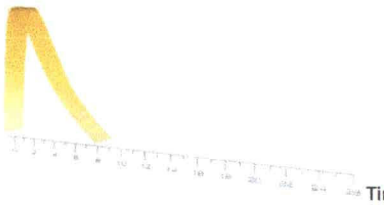
PRODUCT DESCRIPTION
SciLin® R is a sterile, transparent, colourless aqueous solution of human insulin obtained by *E. coli* DNA recombination.

The pen cartridge contains 3 ml of solution, corresponding to 300 IU of soluble insulin.

A typical activity profile (glucose consumption curve) on subcutaneous insulin administration is shown below. During therapy, deviations from the mean value in time and depending on insulin action intensity are recorded. Individual deviations may be associated with such factors as: dose size, injection site, body temperature and physical activity.

SciLin® R

Insulin activity



Time (hours)

SciLin® R consist of zinc-Insulin crystals dissolved in a clear fluid. **SciLin® R** has nothing added to change the speed or length of its action. It takes effect rapidly and has a relatively short duration of activity (4-12 hours) as compared with other insulins. The time course of action at 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 **SciLin® R** is dependent on dose, site of injection, blood supply, temperature, and physical activity.

PHARMACOLOGY
Insulin in the blood stream has a half-life of a few minutes. Consequently, the time-action profile of an insulin preparation is determined solely by its absorption characteristics. This process is influenced by several factors (e.g. insulin dosage, injection route and site) which is why considerable intra- and inter-patient variations are seen.

INDICATIONS
- Type 1 Diabetes Mellitus
- Diabetic ketoacidosis

CONTRA-INDICATIONS
Hypoglycaemia.
Hypersensitivity to insulin or to any of the excipients, unless it is a part of a desensitisation programme.

ADVERSE REACTIONS
In insulin therapy, the most frequent undesirable reaction is hypoglycaemia. Severe hypoglycaemia may lead to loss of consciousness and even death. The frequency of hypoglycaemia is not determined since hypoglycaemia can be a consequence of insulin administration as well as other factors, e.g. diet or physical activity.
A topical allergic reaction is a frequent (1/100 to <1/10) undesirable effect. At insulin injection site erythema, oedema and itching may occur. The symptoms usually disappear in a couple of days or weeks. In some cases topical reactions can be caused by factors other than insulin, e.g. irritating substances included in skin disinfectants or a wrong injection technique.
Systemic allergic reactions indicative of generalised hypersensitivity to insulin are very rare (<1/10 000) but are potentially more dangerous. The symptoms include: eruption all over body, dyspnoea, wheezing breath, lowered arterial pressure, accelerated pulse and sweating. In serious cases, generalised allergy symptoms can be life threatening. Rare cases of severe allergy to **SciLin® R** require immediate treatment. Insulin change or desensitisation can be necessary.
Infrequently (1/1000 to < 1/100) lipodystrophy at injection site occurs.

Following adverse reactions have been reported during post-marketing experience:
- Cases of oedema, particularly if previous poor metabolic control is improved by intensified insulin therapy;
- Cases of weight gain;
- Injection site reaction: injection site discoloration, injection site bleeding, injection site induration, injection site mass, injection site nodule, injection site pain, injection site rash, injection site urticaria, injection site pustule;
- Cases of pruritus and generalized pruritus:
- Cases of dizziness.

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Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation 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 national reporting system.

PRECAUTIONS
A change of the type or brand of insulin used requires doctor's supervision. A change of insulin strength, brand (manufacturer), type (soluble, isophane, biphasic), origin (animal, human, human insulin analogue) and/or production method (DNA recombination or animal origin) may require dose modification.
In some patients, a change from animal insulin to human insulin may require dose modification. If dose modification is required, it should be done at the administration of the first dose of the new insulin or during the first weeks or months following the change.
In some patients changing from animal insulin to human insulin, early warning symptoms of hypoglycaemia can be less distinctive or totally different from those developed during application of animal insulin. With better glycaemia control (e.g. with intensive insulin therapy), the warning symptoms of hypoglycaemia can be less distinctive or may not develop at all. Patients should be informed about the risk. Other factors changing or weakening early warning symptoms of hypoglycaemia are: long-lasting diabetes, diabetic neuropathy, some medications, e.g. β-adrenolytics. Uncontrolled hypoglycaemia or hyperglycaemia may lead to loss of consciousness, coma or death.
Inappropriate dosing or therapy discontinuation, especially in insulin-dependent diabetes, may cause hyperglycaemia and ketoacidosis – life threatening conditions.
Human insulin administration can lead to production of antibodies, however their titre is lower than in the case of purified animal insulin.
Insulin requirement can change significantly with adrenal, pituitary and thyroid disease, renal or hepatic dysfunction.
Insulin requirement can increase during illness or emotional disturbances.
Dose modification can also be required when the patient changes their physical activity or diet.

Concomitant administration of **SciLin® R** with pioglitazone:
Cardiac insufficiency cases have been reported with concomitant administration of insulin with pioglitazone, especially in patients with cardiac insufficiency risk factors. This should be considered before using any combination treatment with **SciLin® R** and pioglitazone. When combination treatment is administered, patients should be monitored for signs and symptoms of cardiac insufficiency, increased body weight and oedema. If cardiovascular symptoms occur, pioglitazone should be discontinued.

Pregnancy and Lactation
There are no restrictions on the treatment of diabetes with insulin during pregnancy as insulin does not pass the placental barrier, intensified control in the treatment of pregnant women with diabetes is recommended throughout pregnancy and when contemplating pregnancy.
Insulin requirements usually fall in the first trimester and increase subsequently during the second and third trimester.

DRUG INTERACTIONS
Some medicinal products can change glucose metabolism. The doctor should take the potential interaction into account and ask the patient about other medicaments used by them.
Insulin requirement can be increased by substances showing hyperglycaemic action, such as glucocorticosteroids, thyroid hormone, growth hormone, danazol, β_2-sympathicomimetics (ritodrine, salbutamol, terbutaline), diuretic thiazides and niacin.
Insulin requirement may decrease when hypoglycaemic agents are used, e.g. oral hypoglycaemic medications, salicylates (e.g. acetylsalicylic acid), some antidepressants (monoamine oxidase inhibitors), some angiotensin convertase inhibitors (captopril, enalapril), non-selective beta-adrenolytic drugs and alcohol.
Insulin requirement may be changed by somatostatin analogues (octreotide, lanreotide).

DOSAGES
Recommended Dose
Dosage is individual and determined by the physician in accordance with the needs of the patient. Use of injection should be notated so that the same site not used more than approximately once a month.
The average range of total daily insulin requirement for maintenance therapy in type 1 diabetic patients lies between 0.5 and 1.0 IU/kg. However, in pre-pubertal children it usually varies from 0.7 to 1.0 IU/kg, but can be much lower during the period of partial remission. In insulin resistance, e.g. during puberty or due to obesity, the daily insulin requirement maybe substantially higher.
Initial dosages for type 2 diabetic patients are often lower, e.g. 0.3 to 0.6 IU/kg/day.
In patients with diabetes mellitus optimised metabolic control delays the onset and slows the progression of late diabetic complications. Optimised metabolic control, including glucose monitoring, is therefore recommended.
In the elderly the primary aim of treatment is symptom relief and avoidance of hypoglycaemic events.

Mode of Administration
SciLin® R is usually administrated subcutaneously in the abdominal wall. The thigh, the gluteal region or the deltoid region may be used.
Intramuscular administrations are possible under guidance by a physician.
Subcutaneous injection into the abdominal wall ensures a faster absorption than from other injection sites.
Injection into a lifted skin fold minimizes the risk of intramuscular injection.
In order to avoid lipodystrophy, injection sites for a given insulin preparation should be rotated within an anatomic region.
SciLin® R is a short-acting insulin and is often used in combination with intermediate or long acting insulins. An injection should be followed by a meal or snack containing carbohydrates within 30 minutes.

OVERDOSAGE
Insulins have no specific overdose definitions. However, hypoglycaemia may develop over sequential stages:
- Mild hypoglycaemic episodes can be treated by oral administration of glucose or sugary products. It is therefore recommended that the diabetic patient constantly carry some sugar lumps or e.g. a few biscuits.
- Severe hypoglycaemic episodes, where the patient has become unconscious, can be treated by glucagon (0.5 to 1 mg) given intramuscularly or

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subcutaneously by a trained person or glucose given intravenously by a medical professional.
Upon regaining consciousness administration of oral carbohydrate is recommended for the patient in order to prevent relapse.

SHELF LIFE
The shelf life is 3 years.

PRESENTATION
Box of 5 cartridges @ 3 mL
Reg. No. DKI1908100743A1

HARUS DENGAN RESEP DOKTER

STORAGE
Store between 2°C - 8°C. Do not freeze. Protect from light, keep out of reach of children. **SciLin® R** which has been frozen must not be used. Insulin solutions should not be used if they not appear water-clear and colourless.
The storage life of **SciLin® R** after the first opening of the cartridge last maximally 28 days in room temperature (15°C to 25°C).

Manufactured by:
BIOTON S.A.,
Poland.

Imported by:
PT. Darya-Varia Laboratoria, Tbk.
Citeureup, Bogor - Indonesia

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