

Public Assessment Report

SCILIN® N

INFORMASI PRODUK

Nama obat	: Scilin® N
Bentuk sediaan	: Injeksi
Zat aktif	: Tiap mL mengandung : Human insulin 100 iu
Kemasan	: Dus, 5 cartridges @ 3 mL
Pendaftar	: PT. DEXA Medica
Produsen	: Bioton S.A., Ozarow Mazowiecki, Poland
Kategori Registrasi	: Registrasi produk biologi yang sudah terdaftar dengan indikasi dan posologi baru

Sudah disetujui di Indonesia	Yang diajukan
Indikasi: <i>Type 1 Diabetes Mellitus</i>	<i>Diabetes treatment for patients requiring insulin therapy.</i> <i>Gestational diabetes treatment.</i>

PENGANTAR

Scilin® N merupakan injeksi human insulin (biosimilar) produksi Bioton S.A., Ozarow Mazowiecki, Poland. Produk inovator yang telah terdaftar yaitu Humulin N, yang didaftarkan oleh PT. Pyridam Farma impor dari Lilly France, Perancis. Scilin® N telah terdaftar sebelumnya atas nama PT. Darya Varia, namun pada 2 Maret 2020 telah berganti pendaftar atas nama PT. DEXA Medica. Saat ini diajukan variasi perubahan indikasi.

ASPEK MUTU

N/A

ASPEK KHASIAT DAN KEAMANAN

Studi Non Klinik

N/A

Studi Klinik

Mengingat produk ini adalah produk biosimilar, maka:

1. Pengajuan indikasi *Diabetes treatment for patients requiring insulin therapy* diterima dengan perbaikan indikasi menyesuaikan dengan inovator yaitu “*For the treatment of patients with diabetes mellitus who require insulin for the maintenance of glucose homeostasis.*”
2. Pengajuan klim pada indikasi, yaitu “*Gestational Diabetes Treatment*” pada prinsipnya diterima karena sudah tercakup pada indikasi poin a, namun klim lebih detail dapat dicantumkan pada bagian *pregnancy and lactation* mengikuti klim yang sudah disetujui untuk inovator.

“*Pregnancy and lactation:*

It is essential to maintain good control of the insulin treated (insulin dependent or gestational diabetes patient throughout pregnancy. Insulin requirements usually fall during the first trimester and increase during the second and third trimesters. Patients with diabetes should be advised to inform their doctors if they are pregnant or are contemplating pregnancy. Careful monitoring of glucose control, as well as general health, is essential in pregnant patients with diabetes. Patients with diabetes who are lactating may require adjustment in insulin dose and/or diet.”

KEPUTUSAN

Mempertimbangkan data khasiat dan keamanan tersebut di atas, diputuskan registrasi variasi perubahan indikasi SciLin® N injeksi **diterima dengan perbaikan** indikasi sebagai berikut:

Indication

For the treatment of patients with diabetes mellitus who require insulin for the maintenance of glucose homeostasis”.

Dosage

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 effectively 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.

You must not apply any other Insulin preparation except the one recommended by your physician. Before use, you should always check on the label, name and a code of the Insulin and make sure it is identical with the prescribed one. You should check the expiry date on the container. Do not use after the expiry date.

Mode of Administration

SciLin® N in cartridges is only suitable for subcutaneous injections from a reusable pen.

SciLin® N in cartridges must not be administered intravenously or intramuscularly.

SciLin® N can be used in intensive insulin therapy to ensure basic insulin secretion.

SciLin® N can be used at initiation of insulin therapy in type 2 diabetes. The most popular scheme is a once daily injection in the evening time. Medicinal product SciLin® N is administered subcutaneously by injection in the abdominal wall, the thigh, the upper arm, the deltoid region or the gluteal region. Injection sites should always be rotated within the same region in order to reduce the risk of lipodystrophy and cutaneous amyloidosis.

While making an injection, caution should be used to prevent needle insertion into a blood vessel. Do not massage the injection site after insulin administration. Inform your patients how to make the injection correctly.

SciLin® N products can be used in combination with oral diabetes medications, e.g. metformin or glimepiride.

Drug preparation for use

Immediately before administering SciLin® N roll the cartridge in your hands 10 times and then turn it 10 times by 180 to obtain uniformly turbid or milky suspension. If the effect is not obtained, repeat the procedure till the ingredients are mixed. Cartridges contain a small glass bead that facilitates ingredients” mixing. Do not shake as foam formed in the container can make it difficult to properly measure the insulin dose. Check insulin appearance in cartridges often. Do not use the product, when lumps or white particles adhering to walls or bottom are visible or when the glass looks mat.

Each package contains the Patient Information Leaflet with an instruction on how to make an injection.

Administering SciLin[®] N in pen cartridges

Some SciLin[®] N products are presented in pen cartridges. 3 ml cartridges are intended to be used with the CE marked pen in accordance with the manufacturer's instruction.

a) Dose preparation

Cartridge construction makes it impossible to add different insulin to the cartridge. Used cartridges cannot be refilled.

Follow manufacturer's instruction attached to the pen concerning cartridge insertion into the pen, needle putting and making the injection.

b) Making the injection

Use the insulin dose recommended by the doctor or nurse in the diabetes clinic. Change injection sites, do not inject insulin into the same area more frequently than once a month.