ARTWORK	KALBE
Specification No.	0077/SPPM/II/R&D/2024
Packaging Name	BROSUR KALNEURON
Packaging Code	BK2100
Supersede Code	NA

GoodScience

Kalneuron™

BK2100

Composition
Each film coated tablet contains :
- Thiamine Mononitrate (Vitamin B1)..... 100 mg
- Pyridoxine Hydrochloride (Vitamin B6) ..... 200 mg
- Cyanocobalamin (Vitamin B12) ..... 200 mcg

Product Description
White convex film coated tablet, plain on both side.

Pharmacodynamics
Kalneuron is a combination of three essential neurotropic vitamins (B1, B6 and B12) in high dosage. Vitamin B1, B6 and B12 are of special importance for the metabolism in the peripheral and central nervous system. Their effect on the regeneration of nerves has been shown in various investigations using the vitamins individually and in combination. Vitamin B1 plays an important role in major metabolic processes. Vitamin B6 has an analgesic effect. Vitamin B12 ensures blood cell formation and prevents degenerative processes of the nervous system. Both individual function and the beneficial biochemical links between the three vitamins justify their combined use.

Pharmacokinetics
The combined administration of the vitamin B1, B6 and B12 has no effect on the pharmacokinetics of the individual vitamins.

Thiamine (Vitamin B1):
Shows a dose-related dual transport mechanism following oral dosing. Active absorption up to concentration of 2 µmol and passive diffusion for concentrations in excess of 2 µmol.

Studies using radiolabeled thiamine showed that duodenal absorption is highest, while absorption in the upper and medium small bowel segments is somewhat lower. Hardly any absorption is seen in the stomach and in the distal segments of the small bowel is not observed.

Following absorption by the intestinal mucosa thiamine is transported into the liver via the hepatic portal system. In the liver, thiamine is phosphorylated to thiamine pyrophosphate (TPP) and thiamine triphosphate (TTP) by the thiamine kinase.

The elimination half-life of thiamine is 1 hour. The primary excretion products are: thiamine carboxylic acid, pyramin, thiamine and some other metabolites not yet identified (renal excretion). The amount of unmetabolised thiamine eliminated by renal route within 4-6 hours will increase with increasing thiamine uptake.

Pyridoxine (Vitamin B6):
Vitamin B6 (pyridoxine, pyridoxal and pyridoxamine) is rapidly absorbed predominantly in the upper gastrointestinal tract and transported to the organs and into tissue. Vitamins are bound to albumin. Approximately 80% of pyridoxal phosphate is bound to proteins. Vitamin B6 passes into spinal fluid, is excreted in breast milk and crosses the placenta barrier. The main elimination product is 4-pyridoxine acid with the amount depending on the vitamin B6 dose administered.

Cyanocobalamin (Vitamin B12):
Absorption from the gastrointestinal tract is based on 2 different mechanisms:
- Release by gastric acid and immediate binding to the intrinsic factor forming the vitamin B12 intrinsic factor complex.
- Independent of the intrinsic factor by passive influx into blood.

When oral dose is increased, the intrinsic-factor-related absorption will reach saturation and diffusion-induced absorption will increase. Approximately 90% of plasma cobalamin is bound to proteins (transcobalamins). The major part of the non-circulating vitamin B12 in plasma is stored in the liver. Vitamin B12 is predominantly secreted into bile and largely reabsorbed by enterohepatic circulation. If the storage capacity of the body is excreted as a result of high doses and, in particular, parenteral administration, the excessive share will be eliminated in the urine.

Indications
Kalneuron is indicated for neurological and others disorders associated with disturbance of metabolic functions influenced by B complex vitamins, including diabetic polyneuropathy, alcoholic peripheral neuritis and post influenzal neuropathies.

Kalneuron is also recommended for the treatment of neuritis and neuralgia of the spinal nerves, especially facial paresis, cervical syndrome, low back pain, ischialgia.

Recommended dosage
1 coated tablet three times daily to treat moderate cases, or to provide interval and follow-up therapy for a course of injections unless prescribed otherwise by the physician. Kalneuron coated tablets are swallowed without chewing with a little liquid with or after meals. The duration of the treatment is determined by the doctor.

Route of administration
Oral administration.

200 mm

95 mm
FRONT

Contraindications
Kalneuron must not be used in patients hypersensitive to any of the active ingredients or excipients of the product. Kalneuron film coated tablet are not suitable for the treatment of children due to the high content of active ingredients.

Warning and precautions
In the literature neuropathies are described under long term intake (6-12 months) of more than 50 mg mean daily dose of vitamin B6. Therefore, under long-term treatment regular monitoring is recommended. Kalneuron film coated tablet contain sugar, its use is not recommended in patients with intolerance to some sugars (i.e., rare hereditary galactose or fructose intolerance, glucose-galactose malabsorption, Lapp lactase deficiency, or sucrose-isomaltase insufficiency).

Interaction with other medicaments
The effect of L-dopa may be reduced when vitamin B6 is administered concomitantly. Pyridoxine-antagonists, e.g. isoniazid (INH), cycloserin, penicillamine, hydralazine: the efficacy of vitamin B6 (pyridoxine) may be decreased.

Loop diuretics, e.g. furosemide: in long-term use, the blood level of thiamine may be reduced. Long term use of acid lowering agents may lead to Vitamin B12 deficiency.

Pregnancy and lactation
No risks have become known associated with the use of Kalneuron during pregnancy at the recommended dosage. Vitamin B1, B6 and Vitamin B12 are secreted into human breast milk, but risks of over dosage for the infant are not known. In individual cases, high doses of vitamin B1, B6 i.e., > 600 mg daily, may inhibit the production of breast milk.

Side effects
Hypersensitivity reactions to vitamin B1, such as sweating, tachycardia (rapid heartbeat), and skin reactions with itching and urticaria are very rare. Gastrointestinal complaints, such as nausea, vomiting, diarrhoea or abdominal pain may be occurred. Chromaturia ("reddish urine", appears during the first 8 hours after an administration and typically resolves within 48 hours) may occur.

Symptoms and treatment of overdose
Prolonged overdose of vitamin B6 i.e., for > 2 months and > 1 g/day, may lead to neurotoxic effects.

Effect on ability to drive and use machines
No effects of the product on the ability to drive or use machines are known.

Preclinical safety data
Not applicable.

Shelf life
24 months.

Pack size
Box contains 10 x 10 film coated tablets in aluminium strips.

Authorized Drug No
MALXXXXXXXX

Manufacturer
PT. Hexpharm Jaya Laboratories
Jl. Angsana Raya Blok A.3-1, Lippo Cikarang, Kelurahan Sukaresmi,
Kecamatan Cikarang Selatan, Kabupaten Bekasi, Provinsi Jawa Barat, Indonesia

Product Registration Holder
GoodScience
GoodScience Sdn Bhd
No.7, Jalan KPK 4/3, Kawasan Perindustrian Kundang,
Kundang Jaya, 48020 Rawang, Selangor, Malaysia.

Storage condition
Store in a cool dry place below 30°C.

Keep medicine out of reach of children.

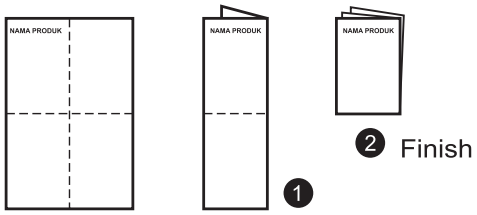
Date of revision: March 2024

HEXPHARM JAYA
A Kalbe Company
BEKASI - INDONESIA

95 mm
BACK

ARTWORK APPROVAL

Prepared by	Approved by	Approved by
Packaging Designer	Packaging Design Spv	Packaging Dev. Mgr

SPECIFICATION		
Shape	Rectangular paper	
Dimension	Length (L): 95 ± 1 mm (94 - 96 mm)	Width (W): 200 ± 1 mm (199 - 201 mm)
Printing	Both Sided	
Material	HVS 60 g/m²	
Color	Black	
Font Type & Size	Brand Name : Arial Bold, 22 pt Text : Arial, 6 pt	
Folding Type	A1 - A2 	
Packaging	Non Cartoning	
Folded Size	47.5 x 100 mm	

REVISION HISTORY		
Date	Specification Number	Description of Change
20 Sep 2023	NA	• Packaging Designer : RSU • Doc. No. 00024/FUPB/03/2023/KLBF - Start to editing
01 Mar 2024	0077/SPPM/II/R&D/2024	• Packaging Designer : EFD • Doc. No. 0024/FUPB/03/2023/KLBF - Revised compositions text - Revised “Date of revision” from Sep’23 to Mar’24
17 Apr 2024	0077/SPPM/II/R&D/2024	• Packaging Designer : EFD • Doc. No. 0024/FUPB/03/2023/KLBF - Revised composition redaction