RELASI	PT. MITSUBISHI TANABE PHARMA	cv SANIC SANIC SETTING
NAMA ITEM	BROSUR ASPAR-K (INDONESIA) BROSUR ASPAR-K OPSI 1 - BARCODE - NEW 1 REVISI	Tanggal Ajuan :20/04/2020 Disetujui oleh, (.....)
WARNA	HITAM	Tanggal Revisi : ...../...../.....
UKURAN	185 mm X 350 mm	Catatan :
FINISHING	POTONG JADI DAN LIPAT	
AJUAN	OPSI 1	

185,00 mm

15,00 mm

35,00 mm

8,00 mm

Mitsubishi Tanabe Pharma

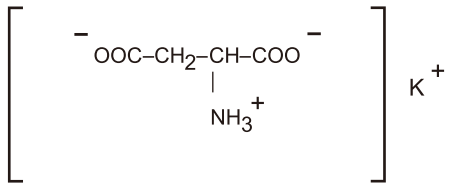
POTASSIUM ASPARTATE PREPARATION

ASPAR®-K

Reg. No. DKL7625202517A1

COMPOSITION AND DESCRIPTION

● Generic name : Potassium L-aspartate



$C_4H_6KNO_4$: 171.20

● White crystalline powder : odorless
● Freely soluble in water and practically insoluble in ethanol or acetone.

Product's name	Content of Potassium L-aspartate	Description of the product
ASPAR®-K	300 mg per tablet (K; 1.8 mEq)	White film-coated tablet

ACTIONS

PHARMACOLOGICAL ACTIONS :

A potassium ion, one of the main electrolytes in the cell, has actions such as to induce the membrane potential, to maintain the osmotic pressure and to control the acid-base equilibrium.
When the red blood cell is employed as a sample to examine the transport of potassium into the tissues, Potassium L-aspartate proves a better intake by the tissues than potassium chloride.

ABSORPTION AND EXCRETION :

When the amount of Potassium L-aspartate equivalent to 20 mEq/kg/day of potassium was administered for 32 days to rats fed on food lacking potassium for 24 days, the mean amount of potassium excreted in the feces was 26.1 μEq/head/day. Namely, the absorption rate of potassium from the intestines was not less than 99.5% because the mean administration amount of potassium was 5,497 μEq/head/day.

TOXICOLOGY AND TERATOLOGY :

1. Acute toxicity :
   The LD_{50} of Potassium L-aspartate in male rats is not less than 10,000 mg/kg, 4,061 mg/kg, 1,500 mg/kg and 667 mg/kg by oral, subcutaneous, intraperitoneal and intravenous routes, respectively.
2. Chronic toxicity :
   After administration of 4 g/kg/day of ASPAR®-K in oral route and 1 g/kg/day in intraperitoneal route to male and female rats for 3 months, no significant difference was observed in general condition, urinary findings, hematological findings and pathohistological findings between administration group and control group.
3. Teratology :
   Fetal toxicity in mice and rats was evaluated in accordance with the Measurements for Safety of Drugs by the Japanese Ministry of Health & Welfare, and no significant difference was observed between administration and control group.

INDICATIONS

Potassium supplement in the following diseases and symptoms accompanied with the imbalance of electrolytes :

● Cardiac diseases
● Liver disease
● Periodic tetraplegia due to hypokalemia
● Hypokalemia due to prolonged administration of antihypertensive diuretics, adrenal cortical steroids, digitalis and insulin
● Other disorders of potassium metabolism (pre- and post-operative course, diarrhea, vomiting).

ADMINISTRATION AND DOSAGE

Take 1 to 3 tablets three times daily.
The dose may be increased according to the severity of symptoms and condition of patients.

CAUTION ON USE

1. **CONTRAINDICATION :**
   1) Patients with Addison's disease untreated
   2) Patients with hyperkalemia
   3) Patients with hypersensitivity to the drug components.
2. **USES WITH CAUTION :**
   On administration to those patients with advanced hypo functioned or damaged kidneys, including those suspected of such disorders, whose serum and urinary electrolytes should be carefully examined.
3. **ADVERSE REACTION :**
   a. Digestive system : anorexia and gastric disturbances have been encountered.
   b. Heart : precordial heavy feeling has been noted.
4. **IT IS ADVISABLE NOT TO ADMINISTER THE DRUG** to premature infants, newborns and infants, because the drug is reported to cause at 250 mg/kg or more as aspartic acid some histopathological change in the nucleus arciformis of the hypothalamus in mice and rats at the age of 3 weeks or below.
5. **INTERACTION :**
   Since the following drugs may cause hyperkalemia, concurrent use with them should be exercised with much care.
   ● Antialdosterone preparation
   ● Triamterene

CAUTION ON HANDLING

As the tablets are hygroscopic, the container and tablets must be kept in a cool and dry place.

PRESENTATION

Box of 10 aluminum strips of 10 tablets.

STORAGE

Store in a tight and light-resistant container at below 30°C.
Shelf life : 3 years

ON DOCTOR'S PRESCRIPTION ONLY
HARUS DENGAN RESEP DOKTER

Under License from
Mitsubishi Tanabe Pharma Corporation
Osaka, Japan

Manufactured by
PT Mitsubishi Tanabe Pharma Indonesia
Bandung, Indonesia

350,00 mm

Brosur ASPAR-K OPSI 1 BARCODE NEW 1

185,00 mm

DISETUJUI OLEH BPOM : 02/05/2023

ID : EREG10002812300019