

NEW ZEALAND DATA SHEET

1. SPAN-K (potassium chloride 600mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Potassium chloride 600mg (= potassium 8mmol, chloride 8 mmol).

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Sustained release potassium chloride supplement. The tablets consist of potassium chloride crystals partially coated with an inert, soluble wax, then pressed into a wax matrix. The whole is then sugar coated (not enteric). The tablet does not disintegrate. The potassium chloride gradually leaches through the wax. The sustained release of the therapeutically correct formula, with no enteric association, provides conditions of maximum gastric tolerance and effective absorption for the treatment of all types of potassium deficiency, whether hypochloraemic or hypokalaemic alkalosis. Span-K does not alter normal kidney function, can be used in all age groups; replaces the essential chloride anion and potassium, and so prevents hypochloraemic alkalosis.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of all types of potassium deficiencies, particularly hypochloraemic or hypokalaemic alkalosis, associated with prolonged or intensive diuretic therapy, eg. in hypertension, cardiac failure or massive oedema (potassium replacement is particularly important to patients receiving digitalis, as the clinical response to this drug is seriously affected by hypokalaemia), in renal disease associated with increase potassium excretion eg. nephrotic syndrome, vomiting and diarrhoea, ulcerative colitis, steatorrhoea, diabetes insipidus and uncontrolled diabetes mellitus, ileostomy or colostomy patients, cirrhosis, Cushing's syndrome and dietary insufficiency, during prolonged or intensive treatment with corticosteroids, ACTH or carbenxolone, hyperaldosteronism in megaloblastic anaemia, during the early stages of treatment. Here Span-K is indicated if a diet rich in potassium cannot be guaranteed.

4.2 Dose and method of administration

An average dose is 1 or 2 tablets three times daily, each tablet swallowed whole with a little water, preferably during meals. Where Span-K is given routinely with an average daily maintenance dose of an oral diuretic, 1 or 2 tablets may be sufficient.

4.3 Contraindications

Severe tissue destruction including burns, advanced renal failure, untreated Addison's disease, acute dehydration, hyperkalaemia, in the presence of obstruction in the digestive tract (eg. resulting from compression of the oesophagus due to dilation of the left atrium or from stenosis of the gut).

4.4 Special warnings and precautions for use

If the patient develops severe vomiting, severe abdominal pains, flatulence or gastrointestinal haemorrhage, the preparation must be withdrawn at once. To

prevent the risk of hyperkalaemia, potassium supplements should not be administered with potassium sparing diuretic agents such as spironolactone, triamterene or amiloride. In cases of metabolic acidosis, hypokalaemia should not be treated with potassium chloride, but with a potassium salt containing an alkalinising anion (eg. potassium bicarbonate).

Caution is required in cases of chronic renal disease and hepatic cirrhosis because of the risk of hyperkalaemia.

Use in renal impairment

Span-K does not alter normal kidney function, can be used in all age groups; replaces the essential chloride anion and potassium, and so prevents hypochloraemic alkalosis.

4.5 Interaction with other medicines and other forms of interaction

No information available.

4.6 Fertility, pregnancy and lactation

Pregnancy

It is not known whether this product can cause harm to the foetus or affect reproductive capacity when it is administered to a pregnant women. It should only be given to a pregnant women if clearly needed.

Lactation

Many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from oral potassium supplements, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

4.7 Effects on ability to drive and use machines

No information available.

4.8 Undesirable effects

Oral potassium preparations can provoke gastrointestinal disturbances (eg nausea, vomiting, abdominal pain, diarrhoea). In rare cases Span-K may also cause these side effects. Should this occur, reduction in dosage or withdrawal of this drug may be necessary.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>

4.9 Overdose

No information available.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

No information available.

5.2 Pharmacokinetic properties

No information available.

5.3 Preclinical safety data

No information available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

No information available.

6.2 Incompatibilities

No information available.

6.3 Shelf life

No information available.

6.4 Special precautions for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container (and special equipment for use, administration or implantation)

PACKAGE QUANTITIES

A plastic bottle containing 200 or 500 tablets.

7. MEDICINE SCHEDULE

Pharmacy Only Medicine.

8. SPONSOR

Distributed by:-

Pharmacy Retailing New Zealand Limited

Trading as Healthcare Logistics

58 Richard Pearse Drive

Airport Oaks

Auckland

New Zealand

9. DATE OF FIRST APPROVAL

2 June 2005

10. DATE OF REVISION OF TEXT
April 2019

SUMMARY TABLE OF CHANGES

Section Changed	Summary of New Information
Format of Data sheet	As per new European SmPC style format

FURTHER INFORMATION

Nil