LABELLING STANDARD
ORAL POTASSIUM SUPPLEMENTS

CATEGORY: Oral potassium supplements

DESCRIPTION: Supplemental oral potassium for the treatment or prevention of hypokalemia

(ORAL) DOSAGE FORMS:

oral solution
for oral solution (i.e. powder, effervescent tablets)
for oral suspensions (i.e. granules)
elixir
tablet
extended-release tablets
extended-release capsules

MEDICINAL INGREDIENTS and CONCENTRATIONS:

" All finished products and ingredients used in the manufacture of the product comply with specifications of a Schedule B pharmacopoeia or equivalent standard.

The medicinal ingredients of a product complying with this standard consist of the following when used singly, within the established limits, or in an acceptable combination."

potassium acetate
potassium bicarbonate
potassium chloride
potassium citrate
potassium gluconate
potassium proteinate*****

Acceptable concentrations of the above 6 ingredients are those which provide daily doses of potassium within the following dosage range:

20 to 100 mEq (or 0.78 to 3.9 g) per day in 2 - 4 divided doses

In addition to the declaration of the medicinal ingredients as stated in Section C.01.004 of the Food and Drugs Regulations, the following information shall be provided:

mEq of potassium per dosage unit

***** Potassium is a monovalent cation and therefore cannot be chelated. The identification of a product as potassium proteinate, HAP (hydrolysed animal protein) or HVP (hydrolysed vegetable protein) is acceptable, as it implies only that a compound has been formed between potassium and a protein. The identification of a product as potassium chelate, amino acid chelate, HAP- or HVP- chelate is **not** acceptable for either the name of the product or a description of its ingredients as this would imply, incorrectly, that potassium is present in a chelated complex.

Table 1: Potassium Equivalents

1 gram potassium salt	Molecular Weight	mEq of potassium	g of potassium
potassium acetate	98.14	10.26	0.4
potassium bicarbonate	100.12	10	0.39
potassium chloride	74.55	13.41	0.52
potassium citrate (anhydrous)	306.4	9.74	0.38
potassium citrate (monohydrate)	324.41	9.26	0.36
potassium gluconate	234.25	4.27	0.17

K^+ MW = 39.098
1 g potassium = 25.6 mmol
1 mEq potassium = 0.039 g

Unacceptable Ingredients

Products which contain potassium tartrate will be referred to BHPD.

Permitted Combinations:

potassium chloride - potassium bicarbonate

NOTE: Single ingredient potassium drugs which provides **less** than 20 mEq (780 mg) of elemental potassium per day will be reviewed against requirements specified in the Mineral Labelling Standard. However, the only acceptable indication for these drugs is "potassium and/or mineral supplement."

ADEQUATE DIRECTIONS FOR USE:

Indications:

- treatment or prevention of hypokalemia (potassium depletion) which does not result from dietary deficiency and/or,
- for the treatment of digitalis toxicity and/or,
- potassium replacement therapy and/or,
- electrolyte replenisher

Additional acceptable indications:

(i) in the case of potassium chloride
-for the treatment of metabolic alkalosis

(ii) for alkalinizing potassium salts (gluconate, citrate, bicarbonate)
-for the treatment of metabolic acidosis

Dosage Directions: The inner and outer labels shall carry statements to indicate the following:

1. To be taken only on the advice of a physician

2. Prescribing information is available to physicians and pharmacists on request.

3. The dosage should be specified as "adult".

4. Take this medicine immediately after meals or with food to lessen possible stomach upset or laxative action

5(a) **For liquid formulations**
- dilute in at least 250 ml cold water or juice

(b) **for soluble granule, soluble powder or soluble tablet form**
- completely dissolve in 250 ml cold water or juice
- allow fizzing to stop before drinkin4g

(c) **for extended release tablets or capsules**
- do not chew, suck or crush tablets/capsules

6. Doses
(a) for the **prevention** of hypokalemia, 20 to 40 mEq/day in 2 to 4 divided doses.
(b) for the **treatment** of hypokalemia, 40 to 100 mEq/day in 2 to 4 divided doses.

This may be expressed as **number of dosage units** per day and **mEq** per day.

Warnings:

(a) **Coated tablets** containing more than 100 milligrams of elemental potassium **must** carry the following statement on the inner label

" WARNING: A probable association exists between the use of coated tablets containing potassium salts, with or without thiazide diuretics, and the incidence of serious small bowel ulceration. Such preparations should be used only when adequate dietary supplementation is not practical, and should be discontinued if abdominal pain, distention, nausea, vomiting or gastrointestinal bleeding occur" (C.01.134, C.01.136).

Other acceptable warnings:

(a) Where impaired renal function exists, the use of potassium supplements must be monitored closely.

(b) The use of potassium supplements with potassium sparing diuretics (spironolactone, triamterene, amiloride) may lead to hyperkalemia.

Prescribing Information:

The prescribing information must be submitted with the DIN application for review with the label. All information outlined in the **Adequate Directions for Use** and **Warnings** sections above should be included in the prescribing information. Additional information will be screened for acceptability at the time of review.

NOTE: This labelling standard describes those requirements that are specific to this class of drugs. Other requirements described in the **Regulations to the Food and Drugs Act** and in the **Guide for the Labelling of Drugs for Human Use** should also be met.

Product Regulation Division
Bureau of Nonprescription Drugs

References

1) American Medical Association, **Drug Evaluations Annual 1992**, Chapt. 39 pp.765-774, 1992.
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3) British Columbia Drug and Poison Information Center, **Drug Information Reference" 2nd Ed.,** 1987.
4) **Canadian Drug Identification Code Book,** 18th Edition, Health and Welfare Canada, 1992.
5) Canadian Medical Association, **Guide to Prescription and Over the Counter Drugs**, pp. 540, 1990.
6) Canadian Pharmaceutical Association, **Compendium of Pharmaceuticals and Specialties, 27th Ed.,** 1992.
7) Gennaro, A.R. (Ed.), **Remington's Pharmaceutical Sciences, 18th Ed.**. Mack Publishing Co., 1990.
8) Goodman, L.S. and Gilman A., **The Pharmacological Basis of Therapeutics, 8th Ed.** Pergamon Press, Chapt. 27 pp.697-704, 1990.
9) **Information Letter No. 685**, May 1985.
10) **The Merck Manual, 15th Ed.**, Chapt. 84, pp. 964-969, 1987.
11) **Notes No. 10**, A Technical Information Bulletin of the Drugs Directorate, September 1986.
12) Reynolds, J.E.F.(Ed.), **Martindale: The Extra Pharmacopoeia 29th Ed.,** The Pharmaceutical Press, 1989.
13) United States Pharmacopoeial Convention, **Advice for the Patient- Drug Information in Lay Language,** Vol II, United States Pharmacopoeial Convention, Inc., pp. 1041-1045, 1992.
14) United States Pharmacopoeial Convention, **Drug Information for the Health Professional,** Vol I, United States Pharmacopoeial Convention, Inc., pp. 2302-2311, 1993.
15) **Nutrition Recommendations:** The Report of the Scientific Review Committee, Health and Welfare, 1990.