Slow Sodium

Summary of Product Characteristics Updated 27-Jul-2015 | HK Pharma Limited

1. Name of the medicinal product

Slow Sodium®

2. Qualitative and quantitative composition

The active ingredient is Sodium Chloride Ph.Eur. Sodium Chloride contains not less than 99.0 per cent and not more than 100.5 per cent of NaCl. One coated tablet contains 600 mg sodium chloride.

3. Pharmaceutical form

Coated tablets.

4. Clinical particulars

4.1 Therapeutic indications

For the treatment and prophylaxis of sodium chloride deficiency.

4.2 Posology and method of administration

It is important that the tablets should be swallowed whole with water (approx. 70ml per tablet where kidney function is normal to avoid hypernatraemia), and not chewed.

Adults: For prophylaxis 4-8 tablets per day. For treatment dosage to be adjusted to individual needs up to a maximum of 20 tablets per day in cases of severe salt depletion. For control of muscle cramps during routine maintenance haemodialysis usually 10-16 tablets per dialysis. In some cases of chronic renal salt-wasting up to 20 tablets per day may be required with appropriate fluid intake.

C*hildren*: Dosage should be adjusted to individual needs.

Elderly: No special dosage adjustment.

4.3 Contraindications

Slow Sodium is contra-indicated in any situation where salt retention is undesirable, such as oedema, heart disease, cardiac decompensation and primary or secondary aldosteronism; or where therapy is being given to produce salt and water loss.

4.4 Special warnings and precautions for use

Warnings: None

Precautions Use of Slow Sodium without adequate water supplementation can produce hypernatraemia. The matrix (ghost) is often eliminated intact and owing to the risk of obstruction Slow Sodium should not be given to patients suffering from Crohn's disease or any other intestinal condition where strictures or diverticula may form.

4.5 Interaction with other medicinal products and other forms of interaction

In hypertensive patients with chronic renal failure Slow Sodium may tend to impair the efficacy of antihypertensive drugs.

4.6 Fertility, pregnancy and lactation

As with most medicines, consult your doctor first if you are pregnant or breastfeeding.

4.7 Effects on ability to drive and use machines

Nil.

4.8 Undesirable effects

No side effects have been reported with Slow Sodium at the recommended dosage.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system in the United Kingdom: Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

Signs and symptoms. Excessive intake of sodium chloride can result in hypernatraemia. Symptoms of hypernatraemia include restlessness, weakness, thirst, reduced salivation and lachrymation, swollen tongue, flushing of the skin, pyrexia, dizziness, headache, oliguria, hypertension, tachycardia, delirium, hyperpnoea and respiratory arrest.

Treatment. Treatment requires the use of sodium-free liquids and the cessation of excessive sodium intake. In the event of a significant overdose serum sodium levels should be evaluated as soon as possible and appropriate steps taken to correct any abnormalities. The use of a loop diuretic e.g. frusemide (with potassium supplementation as required) may be appropriate in severe cases of hypernatraemia. Levels should be monitored until they return to normal.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Mode of action: Sodium chloride is the principle salt involved in maintaining the osmotic tension of blood and tissues, changes in osmotic tension influence the movement of fluids and diffusion of salts in cellular tissue.

Slow Sodium provides a source of sodium (in the form of sodium chloride) where a deficiency exists.

5.2 Pharmacokinetic properties

Sodium chloride is readily absorbed from the gastro-intestinal tract. It is present in all body fluids but specially in the extracellular fluid. The amount of sodium lost (as sweat) is normally small. Osmotic balance is maintained by excretion of surplus amounts in the urine.

5.3 Preclinical safety data

No information available.

6. Pharmaceutical particulars

6.1 List of excipients

Cetostearyl alcohol

Gelatin

Magnesium stearate

Tablet coating

Hypromellose phthalate (E464)

Hydroxypropyl cellulose (E463)

Talc

Titanium dioxide (E171)

6.2 Incompatibilities

None known

6.3 Shelf life

Five years

6.4 Special precautions for storage

Protect from moisture and store below 30°C. The tablets should be dispensed in moisture proof containers.

Medicines should be kept out of reach of children.

6.5 Nature and contents of container

The tablets are available in containers of 100 tablets.

6.6 Special precautions for disposal and other handling

None.

7. Marketing authorisation holder

HK Pharma Ltd

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BEDFORD

MK45 9EB

8. Marketing authorisation number(s)

PL 16784/0003

9. Date of first authorisation/renewal of the authorisation

28 April 1998

10. Date of revision of the text

July 2015

Company Contact Details

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