KLUSIVIT SYRUP

SCHEDULING STATUS: Not scheduled.

PROPRIETARY NAME
(and dosage form):

KLUSIVIT SYRUP
Sugar Free

COMPOSITION
Each 5 ml contains:

Vitamin A	1250 iu
Vitamin D3	200 iu
Vitamin B12	2,00 µg
Vitamin C	20,00 mg
Calcium**	20,00 mg
Phosphorous	15,00 mg
Lysine	12,50 mg
Vitamin B3	5,00 mg
Vitamin B5	3,00 mg
Choline	2,50 mg
Inositol	2,50 mg
Elemental Iron*	1,50 mg
Magnesium*	1,50 mg
Potassium*	1,50 mg
Vitamin B1	1,00 mg
Vitamin B2	1,00 mg
Vitamin B6	0,60 mg
Manganese*	0,25 mg
Zinc**	0,25 mg
Sucralose	1.00 mg

*Gluconate **Lactate

PRESERVATIVES:
Methylparaben 0,18% m/v
Propylparaben 0,02% m/v
Potassium sorbate 0.2%mv

PHARMACOLOGICAL CLASSIFICATION:
Category A, 22.1 Multivitamins with minerals.

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PHARMACOLOGICAL ACTION: A dietary supplement.

INDICATIONS:
KLUSIVIT Syrup is indicated as a dietary supplement for the prophylaxis and treatment of iron and relevant vitamin and mineral deficiency states.

CONTRA-INDICATIONS:
Sensitivity to any of the active ingredients.
Iron-containing preparations are contra-indicated in the presence of haemochromatosis, haemosiderosis and haemolytic anaemia. Not intended for use in patients with pernicious anaemia.

DOSAGE AND DIRECTIONS FOR USE:
Children aged 1 year and older: 5ml daily, or as directed by a healthcare practitioner.
Adults: as directed by a healthcare practitioner.
Do not exceed the recommended dosage.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
There are no known side-effects to use of the vitamins and trace elements contained in KLUSIVIT Syrup at the recommended dosage levels. However, certain vitamins and trace elements do exert toxicity in massive doses - refer below and to *"KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT"*.

Vitamin A
Hypervitaminosis A, caused by the administration of excessive amounts of vitamin A over long periods is characterised by fatigue, irritability, anorexia, loss of mass, vomiting and other gastro-intestinal tract disturbances, low-grade fever, polyuria, hepatosplenomegaly, pruritis, loss of hair, cracking and bleeding lips, dry skin, hyperkeratosis and yellow pigmentation. Anaemia, headache, hypercalcaernia and visual disturbances may occur. These symptoms usually disappear rapidly on withdrawal of vitamin A. Subcutaneous swelling, pains in bones and joints and tenderness over the long bones commonly occur. In children, premature closure of the epihyses of the long bones may result in arrested bone growth.
Symptoms of chronic toxicity in children may also include raised intracranial pressure and papilloedema mimicking brain tumours, tinnitus, visual disturbances which may be severe and painful swelling over the long bones. Symptoms usually clear on withdrawal of vitamin A. Absorption of vitamin A from the gastro-intestinal tract may be reduced by the presence of neomycin and cholestyramine or liquid paraffin; absorption may be also be impaired in cholestatic jaundice, and fat malabsorption conditions.
Vitamin D
Hypervitaminosis D, caused by the administration of excessive amounts of Vitamin D over long periods, may occur. Excessive intake may cause hypercalcaemia. Vitamin D should not be prescribed to patients with hypercalcaemia. It should be administered with caution in infants as they may be more sensitive to its effects. If possible, women who have to take vitamin D should not breast-feed their Infants as this may lead to hypercalcaemia in the infant. The effects of Vitamin D may be reduced in patients receiving barbiturates or anticonvulsants.
Niacinamide
Flushing, a sensation of heat, faintness, pounding in the head, urticaria, pruritus, furunculosis, other skin lesions, abdominal cramps, diarrhoea, nausea and vomiting, malaise, anorexia, activation of peptic ulcer, amblyopia, jaundice and impairment of liver function, decrease in glucose tolerance, mild diabetes and hyperuricaemia may occur. Most of these effects subside on withdrawal of niacinamide. It should be given cautiously to patients with a history of peptic ulceration.
Vitamin C
Large doses may cause diarrhoea and the formulation of renal calcium oxalate calculi. Doses of 600 mg or more daily have a diuretic action. Vitamin C should be administered with care to patients with hyperoxaluria. Tolerance may be induced in patients taking high doses.
Vitamin B6
Long-term administrations of large doses of pyridoxine is associated with the development of severe peripheral neuropathies. Pyridoxine reduces the effects of levodopa but this does not occur if a dopa decarboxylase inhibitor is also given.

Vitamin B12
It can mask symptoms of subacute degeneration of the spinal cord. Allergic sensitivity reactions have been reported following the administration of vitamin B12 compounds, cyanocobalarmine and hydrocobalamine. Cyanocobalamine and hydrocobalamine should if possible not be given to patients without first confirming the diagnosis and should not be used to treat megaloblastic anaemia in pregnancy. Administrations of doses greater than 10 g may produce a haematological response in patients with a folate deficiency; indiscriminate use may mask the disease and prevent a precise diagnosis. Serum concentrations may be decreased by the concurrent administration of oral contraceptives.
Iron (Ferrous gluconate)
Gastro-intestinal discomfort, diarrhoea, constipation and vomiting may occur. Side-effects may be reduced by taking the medication with or immediately after food. Stools may become darkened or black in colour. The absorption of iron and tetracyclines is diminished when administered concomitantly. Antacids reduce absorption of iron. Iron salts should not be given to patients receiving repeated blood transfusions or in anaemias not produced by iron deficiency. Oral and parenteral iron should not be administered concurrently. Care should be taken in administration to patients with gastro-intestinal diseases.
Calcium
Oral administration may cause gastro-intestinal irritation and constipation. Excessive doses lead to hypercalcaemia. Calcium salts should be given with care to patients with impaired renal function, cardiac disease or sarcoidosis. Calcium enhances the effects of digitalis on the heart and may precipitate digitalis intoxication. Calcium salts inhibit absorption of tetracyclines.
Magnesium
Hypermagnesaemia has been reported after excessive use and in renal insufficiency.
Potassium
Nausea, vomiting, diarrhoea and abdominal cramps.
Zinc
Chelation may occur with tetracycline. Concurrent administration with penicillamine may diminish the effect of the latter substance.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Vitamin A
Acute intoxication is characterised by sedation, dizziness, nausea and vomiting, headache, irritability, papilloedema, erythema, pruritis, and generalised peeling of the skin.
Vitamin D
Symptoms of overdosage are anorexia, lassitude, nausea, vomiting, diarrhoea, mass loss, polyuria, sweating, headache, extreme thirst and vertigo. Calcium and phosphorous levels in serum and urine are raised, followed by hypertension and renal failure. Vitamin D therapy must be withdrawn immediately, and large quantities of fluid and electrolytes given. Concomitant administration of furosemide promotes urinary calcium excretion. Low calcium diet should be given and non-exposure to sunlight ensured. Careful monitoring of serum electrolytes is essential throughout therapy.
Calcium
Excessive use leads to hypercalcaemia. Symptoms may include weakness, nausea, vomiting, constipation, abdominal pain, muscle weakness, thirst, polyuria, drowsiness, confusion, bone pain, renal calculi and in severe cases, cardiac arrhythmia, coma and cardiac arrest. Calcium therapy must be withdrawn immediately, serum electrolytes and kidney function determined and intravenous infusion of sodium chloride to expand the extracellular fluid. If unsuccessful, calcitonin, the biphosphonates and corticosteroids may be employed.
Iron (Ferrous gluconate)
Symptoms of overdosage include epigastric pain, diarrhoea, vomiting and haematemesis. Circulatory collapse may follow. Metabolic acidosis, convulsions, coma, eventual hepatic coma and subsequent death may occur. Acute liver necrosis may develop. Possible corrosive effects on the gastro-intestinal mucosa, necrosis and perforation may occur, stricture formation may subsequently follow. Patients mistakenly given iron therapy when not suffering from iron-deficiency anaemia are also at risk as are those with pre-existing iron storage or absorption diseases. Speed is essential in treating iron poisoning, in order to block absorption from the alimentary tract. In acute poisoning, desferrioxamine, an iron chelating agent should be given. If not available, the stomach should be emptied by emesis and lavage using a 1 to 5% solution of sodium bicarbonate; leave about 300 ml of the solution in the stomach. Other measures include correction of lost fluid.
Magnesium
Symptoms include flushing of the skin, thirst, hypotension due to vasodilation, drowsiness, loss of tendon reflexes due to neuromuscular blockage, weakness, respiratory depression, cardiac arrhythmias, coma and cardiac arrest. Fluid deficit and electrolytes must be corrected.
Potassium
Excessive administration leads to development of hyperkalaemia; symptoms include paraesthesia of extremities, muscle weakness, paralysis, hypotension, cardiac arrhythmias, heart block and cardiac arrest.
Zinc
Ingestion of large quantities of zinc is rapidly followed by nausea and vomiting. Due to its corrosive action it causes a burning sensation in the oesophagus and stomach. Colic and diarrhoea with blood may follow, with convulsions, hypotension, coma and death. Treatment consists of emptying the stomach by aspiration and lavage and demulcents such milk and egg white should be given freely. Sodium calcium edetate may be administered. Morphine or pethidine may be given to relieve pain. Fluid and electrolyte balance should be corrected.

Generally: Treatment is symptomatic and supportive.

IDENTIFICATION: Light yellow cherry flavoured syrup.

PRESENTATION: KLUSIVIT Syrup is presented in bottles of 200 ml

STORAGE INSTRUCTIONS:
Keep tightly closed and store in a cool (below 25º C) place.
Keep out of reach of children

NAME AND BUSINESS ADDRESS OF APPLICANT:

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