Proviten® DX

Multivitamin

Presentation
Proviten® DX IV for injection/infusion:

Each vial of Proviten IV contains:

Vitamin A	3500	IU
Vitamin D_3	220	IU
Vitamin E	11.20	mg
Vitamin C	125	mg
Vitamin B_1	3.51	mg
Vitamin B_2	4.14	mg
Vitamin B_6	4.53	mg
Vitamin B_{12}	0.006	mg
Folic acid	0.414	mg
Pantothenic acid	17.25	mg
Biotin	0.069	mg
Nicotinamide	46	mg

Each 100ml Glass bottle Contains: 5% Dextrose USP Infusion

Description
Proviten DX IV is a sterile, lyophilized powder for injection/infusion which contains nine water-soluble and three fat soluble vitamins. Mixed micelles is used as a solubilizing agent. It is presented as a lyophilized, orange-yellow, sterile powder that is to be reconstituted with 5 ml of Water for injections or other parenteral fluids, (e.g. as 0.9% Sodium chloride or 5% Glucose solution), prior to administration by parenteral route.

Indications and Usage
Proviten DX IV is indicated as a daily multivitamin maintenance dosage for adults and children aged 11 years and above receiving parenteral nutrition. It is also indicated in other situations where administration by the intravenous route is required. Such situations include surgery, extensive burns, fractures and other trauma, severe infectious diseases and comatose states, which may provoke a "stress" situation with profound alterations in the body's metabolic demands and consequent tissue depletion of nutrients.

Dosage and Administration
Dosage
Adults and children aged 11 years and above: 1 vial/day

Administration
The single dose vial of Proviten DX IV is reconstituted by adding 5ml of sterile Water for injection or other intravenous fluids like 0.9% Sodium Chloride injection or 5% Glucose injection. 5 ml of diluent should be added by means of sterile syringe into the vial and gently mixed to dissolve the lyophilized powder. The entire volume of the resultant solution should then be administered by slow Intravenous injection (at least over 10 minutes) or further diluted for intravenous infusion. To minimize vitamin losses in parenteral nutrition admixtures, add the vitamins immediately prior to administration and complete administration within 24 hours.

Adverse effects
Anaphylactic reactions have been reported following large intravenous doses of Thiamine. Urticaria and rash have also been associated with this preparation. There have been very rare reports of anaphylactic reactions following IV injection/infusion with this preparation over 1-4 minutes.

Precautions
Anaphylactic reactions may occur in allergic subjects who are susceptible to Thiamine (Vitamin B_1) and nicotinamide components of this product. Mild allergic reactions such as sneezing or mild asthma are warning signs that further injection/infusion may give rise to anaphylactic shock. Due to glychocolic acid content, repeated and prolonged administration in patients with jaundice of hepatic origin or severe biochemical evidence of cholestatis requires careful monitoring of liver function. Also in the case of impaired kidney function, fat-soluble vitamin levels should be carefully monitored.

Contraindications
Proviten DX IV is contraindicated in patients with pre-existing hypervitaminosis or known hypersensitivity to any of the active ingredients. This product should not be injected to patients with pre-existing intolerance to thiamine. Similarly, this product should not be administered to patients with impaired hepatic function. This preparation should not be administered to those suffering from hyperparathyroidism due to hypercalcaemic complications.

Drug interaction
Patients receiving drugs that bind to a_1-acid glycoprotein should be closely monitored for increases in response to these drugs, e.g. propranolol, prazosin and quinidine. Folic acid may increase the metabolism of some antiepileptics, such as phenobartbitol, phenytoin and primidone. Pyridoxine can reduce the effect of levo-dopa. Bleomycin can be inactivated by ascorbic acid and riboflavin.

Use in Pregnancy and Lactation
The use of this preparation has not been studied in human during pregnancy. Proviten DX IV should be given to a pregnant woman only if clearly needed. The use of this product in lactating women is not recommended.

Overdosage
Accumulation of Vitamin A and Vitamin D may be occured with prolonged administration of high doses.

Storage
Before reconstitution: Store below 30°C. Protect from light and do not freeze.
After reconstitution: The reconstituted product should be used immediately or it should be stored at 2°C to 8°C for no more than 24 hours. Discard any unused portion of the reconstituted solution.

Commercial box
Proviten® DX IV for injection/infusion: Each box contains one vial of multivitamin, one 5 ml sterile disposable syringe, one bottle of 100 ml 5% Dextrose, one infusion set, Hanger, First aid band and Alcohol pad.

Manufactured by
Incepta Pharmaceuticals Ltd
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