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Product Soluvit N	Number 118-01	

SOLUVIT

Substance for infusion

Sterile, freeze-dried mixture of water-soluble vitamins

BO5X C00

Declaration.

1 injection vial contains: Thiamini mononitr. respond. thiamine 2.5 mg, natrii riboflav. phosph. respond. riboflavin. 3.6 mg, nicorinamid. 40 mg, pyridoxini chlorid. respond. pyridoxin. 4.0 mg, natrii pantothen. respond. acid. pantothen. 15 mg, natrii ascorb. respond. acid. ascorbic. 100 mg, biotin. 60 µg, acid. folic. 0.4 mg, cyanocobalamin. 5.0 µg, acid. aminoacet. 300 mg, natr. edet. 0.5 mg et methyli parahydroxybenz. 0.5 mg.

Vitamin content of an injection vial

Vitamin B ₁	2.5 mg
Vitamin B ₂	3.6 mg
Nicotinamide	40 mg
Vitamin B ₆	4 mg
Pantothenic acid	15 mg
Vitamin C	100 mg
Biotin	60 µg
Folic acid	0.4 mg
Vitamin B ₁₂	5.0 µg

Methylparahydroxybenzoate and sodium edetate are added as stabilisers.

Indications.

To provide the daily requirement of water-soluble vitamins with intravenous nutrition.

Dosage.

Adults: The content of a vial is the equivalent of the normal daily requirement of water-soluble vitamins.

Children up to 10 kg: 1/10 of the content per kg body weight and day.

Children over 10 kg: The content of one vial per day.

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Compatibility.

Adults and children 11 years and over: The content of one vial should be dissolved through aseptic addition of 10 ml of any of the following solutions.

1. VITALIPID ADULT
2. INTRALIPID 200 mg/ml (For adults INTRALIPID 300 mg/ml can also be added)
3. Sterile water
4. Glucose solution (50-500 mg/ml) for infusion
5. STRUCTOLIPID

Mixture 1 may be added to INTRALIPID, KABIMIX, VITRIMIX or STRUCTOLIPID. Mixture 2 may be added to INTRALIPID or KABIMIX. Mixture 3 may be added to INTRALIPID, KABIMIX, VITRIMIX, STRUCTOLIPID or glucose solution for infusion. Mixture 4 should be added to glucose solution for infusion and mixture 5 should be added to STRUCTOLIPID.

Children under 11 years: The content of one vial should be dissolved through aseptic addition of 10 mg of any of the following solutions.

1. INTRALIPID 200 mg/ml
2. Sterile water
3. Glucose solution (50-500 mg/ml) for infusion
4. VITALIPID INFANT (For children weighing over 10 kg)

Children weighing under 10 kg must be given 1 ml per kg body weight per day of mixtures 1, 2 or 3.

Children weighing 10 kg or over must be administered one vial (10 ml) per day of mixtures 1, 2, 3 or 4.

Because of differences in dosage for SOLUVIT and VITALIPID INFANT, mixture 4 cannot be recommended for children weighing under 10 kg. Mixture 1 should be added to INTRALIPID and mixture 2 should be added to INTRALIPID or glucose solution for infusion. Mixture 3 should be added to glucose solution for infusion and mixture 4 (for children weighing 10 kg or over) should be added to INTRALIPID.

SOLUVIT must be aseptically added to the solution for infusion not more than one hour before commencing the infusion.

For addition to mixtures in phthalate-free plastic bag, see INTRALIPID.

Contraindications.

Known hypersensitivity to any constituent component, e.g. methylparahydroxybenzoate or thiamine.

Warnings and precautions.

Administration of folic acid may mask pernicious anaemia.

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Interactions.

It is suspected that folic acid increases the metabolism of phenytoin. Pyridoxine may reduce the effect of L-dopa.

Stability.

Bearing in mind the risk of contamination, mixtures should be used immediately.

Storage.

To be kept at a maximum of 15°C and protected from light.

Certain vitamins are light-sensitive. If SOLUVIT is diluted with INTRALIPID the mixture does not need to be protected from light, as the fatty emulsion has a light-protective effect. However, if SOLUVIT is diluted with glucose solution the mixture must be protected against light, preferably with a light-filtering plastic bag, obtainable from Fresenius Kabi.

Packs and prices.

Substance for infusion (yellow substance)

10x1 inj. vials 269:-

Marketing Authorisation Holder.

Fresenius Kabi AB

751 74 Uppsala

Sweden

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