

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 80-515 -

FINAL PRINTED LABELING

Labeling: Original  
NDA No: 80-515 Rec'd 9/28/71  
Reviewed By: Robert W. ... 8-71

SUPPLEMENT - September 24, 1971  
ANDA 80-515  
CYANOCOBALAMIN INJECTION

SECTION 4. COPIES OF LABELS AND INSERTS

PACKAGE INSERT

Version used with ESI Labels

~~APPROVED~~  
~~10/2/71~~  
**CYANOCOBALAMIN**  
**INJECTION, U.S.P.**

**DESCRIPTION:**

A sterile aqueous solution of cyanocobalamin. See vial label for complete formula and potency.

**ACTIONS:**

Cyanocobalamin is essential for normal growth and nutrition. The hemopoietic activity is apparently identical with that of the anti-anemia factor of liver. When administered parenterally, cyanocobalamin produces the same results as does liver in patients with pernicious anemia. This route of administration also provides effective levels of cyanocobalamin in certain megaloblastic anemias (see Indications Section) where gastrointestinal absorption is poor or vitamin B<sub>12</sub> deficiency exists.

**INDICATIONS:**

Indicated for use in (a) pernicious anemia with or without neurologic manifestations; (b) megaloblastic anemia following gastrectomy or associated with gastric carcinoma; (c) megaloblastic anemia due to "blind loop" syndrome; (d) megaloblastic anemia due to *Diphyllobothrium latum* (fish tapeworm) infestation; (e) nutritional megaloblastic anemia involving vitamin B<sub>12</sub> deficiency; (f) Schilling test.

**CONTRAINDICATIONS:**

There are no known contraindications and toxic effects have been but rarely reported.

**PRECAUTIONS:**

Sensitivity-type reactions may follow the administration of any parenteral preparation, but there is no documented evidence that even large doses of vitamin B<sub>12</sub> are toxic. Patients sensitive to parenterally administered purified liver extract or to vitamin B<sub>12</sub> concentrates obtained from culture filtrates can take crystalline vitamin B<sub>12</sub> without untoward response. Rarely, reactions of an apparently allergic type have been reported following injection, however, it is not known whether these were related to the preservative, the vitamin, or neither. One case of a tuberculin-type skin reaction at the site of injection in a patient previously sensitized to cobalt and one case of transient diarrhea have been reported.

**ADVERSE REACTIONS:**

No unanticipated reactions have been reported. See Precautions Section.

**DOSAGE AND ADMINISTRATION:**

Cyanocobalamin is usually injected intramuscularly or subcutaneously. It may be given intravenously, but no advantage has been found in using this route.

Dosage requirements vary with different individuals and needs. Dosage should be sufficient to replenish stores, when necessary, to maintain body stores. The average effective dosage range is usually between 10 mcg and 100 mcg.

Pernicious anemia -- 50 mcg two or three times a week until remission, then 100 mcg monthly for life. Nervous system involvement requires a longer period of time for improvement, but the progression of the lesions is immediately arrested.

Malabsorption and nutritional megaloblastic anemias require individualized dosing according to the response of the patient.

For the flushing dose of Vitamin B<sub>12</sub> in The Schilling Test, inject 1000 mcg intramuscularly.

**HOW SUPPLIED:**

In 10 ml. and 30 ml. Multiple Dose Vials, 100 mcg per ml., 1000 mcg per ml.

Dosette Vials 1 ml., 100 mcg per ml. and 1000 mcg per ml.

Dosette Ampule 1 ml., 1000 mcg per ml.

Dosette Syringe 1 ml., 100 mcg per ml. and 1000 mcg per ml.

Keep in a cool place. Protect from light.

**CAUTION:** Federal law prohibits dispensing without prescription.

Revised July, 1971

ELKINS-SINN, INC., Cherry Hill, N.J. 08034

*Ben*

Labeling: Original  
NDA No: 80-515 Rec'd 9/28/71  
Reviewed By: Robert M. Walter

10-8-71

SUPPLEMENT - September 24, 1971  
ANDA 80-515-  
CYANOCOBALAMIN INJECTION

SECTION 4. COPIES OF LABELS AND INSERTS

ESI FINAL PRINTED LABELS

**APPROVED** **ESI**  
For I.M., S.C., or I.V.  
Use.  
PHARMACEUTICALS  
NDC 415-0410-03  
30 ml. Multiple Dose Vial  
**CYANOCOBALAMIN  
INJECTION, U.S.P.**  
(Crystalline Vit. B-12)  
100 mcg. per mL  
SEE ENCLOSED  
INSERT  
Product Code  
412250  
ELKINS-SINN, INC.  
Cherry Hill, N.J. 08034  
Contains benzyl alcohol  
1.5%, sodium chloride  
0.9%. pH adjusted  
with hydrochloric acid.  
Caution: Federal law  
prohibits dispensing  
without prescription.  
PROTECT FROM LIGHT  
A-2250  
*BW*

**APPROVED** **ESI**  
For I.M., S.C., or I.V.  
Use.  
PHARMACEUTICALS  
NDC 415-0440-03  
30 ml. Multiple Dose Vial  
**CYANOCOBALAMIN  
INJECTION, U.S.P.**  
(Crystalline Vit. B-12)  
1000 mcg. per mL  
SEE ENCLOSED  
INSERT  
Product Code  
412270  
ELKINS-SINN, INC.  
Cherry Hill, N.J. 08034  
Contains benzyl alcohol  
1.5%, sodium chloride  
0.9%. pH adjusted  
with hydrochloric acid.  
Caution: Federal law  
prohibits dispensing  
without prescription.  
PROTECT FROM LIGHT  
A-2270  
*BW*

**APPROVED** **ESI**  
For I.M., S.C., or I.V.  
Use.  
PHARMACEUTICALS  
NDC 415-0410-01  
10 ml. Multiple Dose Vial  
**CYANOCOBALAMIN  
INJECTION, U.S.P.**  
(Crystalline Vit. B-12)  
100 mcg. per mL  
SEE ENCLOSED  
INSERT  
Product Code  
412240  
ELKINS-SINN, INC.  
Cherry Hill, N.J. 08034  
Contains benzyl alcohol  
1.5%, sodium chloride  
0.9%. pH adjusted with  
hydrochloric acid.  
Caution: Federal law  
prohibits dispensing  
without prescription.  
PROTECT FROM LIGHT  
A-2240  
*BW*

**APPROVED** **ESI**  
For I.M., S.C., or I.V.  
Use.  
PHARMACEUTICALS  
NDC 415-0440-01  
10 ml. Multiple Dose Vial  
**CYANOCOBALAMIN  
INJECTION, U.S.P.**  
(Crystalline Vit. B-12)  
1000 mcg. per mL  
SEE ENCLOSED  
INSERT  
Product Code  
412260  
ELKINS-SINN, INC.  
Cherry Hill, N.J. 08034  
Contains benzyl alcohol  
1.5%, sodium chloride  
0.9%. pH adjusted with  
hydrochloric acid.  
Caution: Federal law  
prohibits dispensing  
without prescription.  
PROTECT FROM LIGHT  
A-2260  
*BW*