

VITAMIN B-COMPLEX

B - PRIME Capsule VITAMINS

FORMULATION:

Each capsule contains:

Thiamine Mononitrate (Vitamin B ₁),USP	100 mg
Pyridoxine Hydrochloride (Vitamin B ₆)	5 mg
Cyanocobalamin (Vitamin B ₁₂)	50 mcg

PRODUCT DESCRIPTION:

Vitamin B₁+B₆+B₁₂ (B-Prime) capsule product is a white to off white powder encapsulated in EGC size #1 with scarlet opaque cap and dull yellow opaque body.

WHAT IS IN THE MEDICINE?

This product contains B-complex vitamins such as vitamins B₁, B₆ and B₁₂. These vitamins are required for the normal nerve function, used as a treatment management for neuromuscular pain and alcoholic polyneuropathy.

Vitamins B₁+B₆+B₁₂ (B-Prime) Capsule have the following neuromuscular effects and functions.

VITAMINS	FUNCTION
<i>Thiamine mononitrate (Vitamin B₁)</i>	Helps in the production and release of the acetylcholine which is a neurotransmitter that is required in conveying signals between nerve cells.
<i>Pyridoxine hydrochloride (Vitamin B₆)</i>	It is required for the formation of neurotransmitter such as the gamma amino butyric acid (GABA), serotonin and epinephrine to facilitate the normal nervous system function.
<i>Cyanocobalamin (Vitamin B₁₂)</i>	It is required for the synthesis of the myelin, the white sheath that surrounds the nerve fibers.

STRENGTH OF THE MEDICINE:

Please see the drug formulation.

WHAT IS THIS MEDICINE USED FOR?

Used in the treatment and prevention of Vitamin B Complex deficiency.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

One capsule daily or as prescribed by the physician.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

If you have hypersensitivity to any component of the product.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?

Do not take more than the recommended dose.

Do not use after the expiration date on the label.

Administration of cyanocobalamin (Vitamin B₁₂) in doses greater than 10mcg may produce hematological response in patients with folate deficiency.

UNDESIRABLE EFFECTS:

Pyridoxine (Vitamin B₆)

Adverse neurologic effects have been reported following the chronic administration of high pyridoxine doses 100 mg-500 mg daily and long term (i.e. 2 months or longer) mega dose (2 grams or more daily) of pyridoxine use.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

The amount of vitamin B complex (B-Prime) capsule are not expected to interact with any food or medicines.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you miss a dose, just take the next dose and the subsequent doses at the usual recommended schedule. Do not double the dose unless directed by a physician.

SIGNS AND SYMPTOMS OF OVERDOSAGE?

Pyridoxine (Vitamin B₆)

Reversible sensory neuropathy have been reported developing at doses less than 500 mg per day (dose range:200-300 mg per day) taken for 36 months.

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

If you have taken more than the recommended dosage, consult a doctor immediately.

HOW SHOULD YOU KEEP THIS MEDICINE?

Keep out of reach of children.

Store at temperatures not exceeding 30°C.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

If any undesirable effect occurs.

AVAILABILITY:

Vitamin B complex (B-Prime) capsule– Alu/Red PVC Blister Pack x 10's (Box of 100's)

ADR REPORTING STATEMENT:

For suspected adverse drug reaction, report to the FDA: www.fda.gov

Seek medical attention immediately at the first sign of any adverse drug reaction.

FDA REGISTRATION NUMBER:

Vitamin B complex (B-Prime) capsule – DR-XY21704-B

DATE OF FIRST AUTHORIZATION:

Vitamin B complex (B-Prime) capsule –August 25, 1997

DATE OF REVISION:

Version number: 2

Revision date: 6/26/2021

MANUFACTURED FOR:

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