



Fidson Healthcare Plc

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

VITAMIN B COMPLEX INJECTION

Vitamin B1 20mg, Vitamin B2 1.37mg, Nicotinamide 100mg, Sodium D-panthothenate 10mg

Read all this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again before, during or after use of this medicine.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

In this leaflet:

1. What Vitamin B complex injection is and what it is used for
2. What you need to know before you are given Vitamin B complex injection
3. How to take Vitamin B complex injection
4. Possible side effects
5. How to store Vitamin B complex injection
6. Contents of the pack and other information

1. WHAT VITAMIN B COMPLEX INJECTION IS AND WHAT IT IS USED FOR

Vitamin B complex is a vitamin preparation, containing vitamin B1 (thiamine), vitamin B2, Nicotinamide and Sodium D-panthothenate. Vitamin B complex is used to treat diseases of the nervous system, associated with proven deficiency of B vitamins which cannot be corrected by diet.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN VITAMIN B COMPLEX INJECTION

Do not use Vitamin B complex:

- If you are allergic to thiamine hydrochloride (vitamin B1), pyridoxine hydrochloride (vitamin B6), cyanocobalamin (vitamin B12) or any of the other ingredients of this medicine.
- If you suffer from serious heart conduction disorders (i.e., the electrical impulses that coordinate your heartbeats don't work properly)
- If you suffer from acute congestive heart failure
- If you are pregnant or breast-feed your baby
- In children under 12 years due to the presence of benzyl alcohol and the high dose of vitamins

Warnings and precautions

Talk to your doctor or pharmacist before using Vitamin B complex.

Vitamin B complex must be injected into the muscles only.

It must not be injected into the vein.

In case Vitamin B complex is by mistake injected into your vein, your doctor will monitor your state closely.



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If used for longer than 6 months, this medicine can cause damage to your nerves (neuropathies). The symptoms are tingling, numbness or burning sensation in the feet or hands. Talk to your doctor if you have any of these symptoms. No special precautions are required in the elderly.

Taking other medicines with Vitamin B complex injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important to tell if you are taking any of the following medicines:

- medicines for tuberculosis (cycloserine, isoniazid);
- penicillamine (for rheumatoid arthritis);
- adrenaline (used to treat life threatening allergic reaction or to restart your heart if it has stopped) noradrenaline (used to increase blood pressure to normal levels);
- antibiotics belonging to a group of sulfonamides, e.g., sulfasalazine, sulfamethoxazole;
- levodopa (for Parkinson's disease); other vitamins;
- sulfite-containing medicines. Ask your doctor or pharmacist if you are not sure if any of your medicines contain sulfite

Pregnancy

If you are pregnant or think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Due to the amounts of the active ingredients, treatment during your pregnancy is only useful if vitamin B1 and B6 deficiency has been confirmed. Vitamin B complex should not be used during pregnancy unless your doctor considers it as clearly necessary.

Breast-feeding

If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine. Due to the amounts of the active ingredients, treatment while breast-feeding is only useful if vitamin B1 and B6 deficiency has been confirmed. Vitamin B complex should not be used while breast-feeding unless your doctor considers it as clearly necessary.

Driving and using machines

Vitamin B complex has no or negligible influence on the ability to drive and use machines.

Vitamin B complex contains benzyl alcohol, sodium and potassium. Benzyl alcohol may rarely cause allergy-like (anaphylactoid) reactions. This medicinal product contains less than 1 mmol sodium (23 mg) per dose (2 mL) i.e. essentially "sodium free". This medicine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially "potassium-free"

3. HOW TO TAKE VITAMIN B COMPLEX

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. The recommended dose is:



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- In cases of severe and acute pain, the recommended dose is one injection (2 ml) a day.
- After the pain is relieved or in case of less severe disease, the recommended dose is one injection (2 ml) 2 to 3 times a week.

Method of administration

Vitamin B complex solution for injection is injected deep into your muscle. It should not be given by any other route! (see also “Warnings and precautions”)

Duration of treatment

Your doctor will decide how long you will need the treatment and will assess your condition every week. As soon as possible, your doctor will advise you to start using oral vitamin B preparation.

If you think you have been given too much

If you are accidentally given too much of Vitamin B complex and you feel unwell, immediately contact a doctor.

If you missed a dose

It is unlikely that you will miss a dose as your doctor or nurse will be giving it to you. However, it is important not to have a double dose if you have missed one. Ask your doctor or nurse when you should have the next dose. If you have any further questions on the use of this product, ask your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you experienced any of the following side effects, stop treatment with Vitamin B complex and contact your doctor. You may need urgent medical treatment.

Rare side effects (may affect up to 1 in 1,000 people):

- Severe allergy-like (anaphylactoid) reactions may occur due to benzyl alcohol content.

Side effects of unknown frequency (frequency cannot be estimated from the available data):

- Allergic reactions, e.g., skin rash, shortness of breath, shock, swelling of the hands, feet, or ankles, the face, lips, tongue and /or throat with difficulty in swallowing or breathing (angioedema)
- Skin reactions, including itching and hives
- Acne
- Dizziness
- Drowsiness
- Slow heart rate (bradycardia), fast heart rate (tachycardia), irregular heart rate (arrhythmia)
- Vomiting



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- Sweating
- Cramps
- Burning at the injection site

If this medicine is by mistake injected into your vein or too large dose is injected, the following side effects may occur: dizziness, vomiting, slow or irregular heart rate, drowsiness, cramps.

5. HOW TO STORE VITAMIN B COMPLEX INJECTION

- Keep all medicines out of the reach of children.
- Store between 2°C – 8°C
- Do not use this medicine after the expiry date 'Exp. Date' which is stated on the label and carton. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

What Vitamin B complex contains



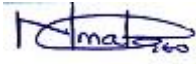
The active substances are Vitamin B1 20mg, Vitamin B2 1.37mg, Nicotinamide 100mg, Sodium D-panthothenate 10mg

What Vitamin B Complex Injection looks like and contents of the pack

Vitamin B complex is solution available as 10 x 1mL ampoules, placed in carton with insert

SUPPLIER AND MANUFACTURER

Fidson Healthcare Plc,
17-21, Fidson Avenue
Sango-Ota, Ogun State,
Nigeria.

	Prepared by	Approved by	
Signature			
Date	02/11/2023	05-02-2024	10-02-2024
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