

142.00 mm

# Pregabalin and Methylcobalamin Capsules PRENEURON PLUS



2 x 10 Capsules

Pregabalin and  
Methylcobalamin Capsules  
PRENEURON PLUS

90.00 mm

## Pregabalin and Methylcobalamin Capsules PRENEURON PLUS

20.00 mm

Each capsule contains:

Pregabalin : 75 mg  
Methylcobalamin : 750 mcg  
Excipients : Q.S.

Mfg. Lic. No. : G/28/1330

Batch No :

Mfg. Date :

Exp. Date :

Approved colours used  
in empty capsule shell

Dosage : As directed by the physician.

Store in a dry place below 30° C.

Protect from light.

Keep out of reach of children

Manufactured in India by :



Survey No. 198/2 & 198/3, Chachrawadi Vasna,  
Tal.: Sanand, Dist. : Ahmedabad 382 210, INDIA.

Pregabalin and  
Methylcobalamin Capsules  
PRENEURON PLUS

## Pregabalin and Methylcobalamin Capsules PRENEURON PLUS

10.00 mm

70.00 mm

24.00 mm

70.00 mm

10.00 mm

# Pregabalin and Methylcobalamin Capsules PRENEURON PLUS

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Approved colours used in empty capsule shell

Excipients : Q.S.

Methylcobalamin : 750 mcg

Pregabalin : 75 mg

Each capsule contains:

# Pregabalin and Methylcobalamin Capsules PRENEURON PLUS

184.00 mm

90.00 mm  
Print Repeatability

# PRENEURON PLUS

Pregabalin And Methylcobalamin Capsules

## 1. NAME OF THE MEDICINAL PRODUCT

PRENEURON PLUS Capsules

## 2.QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:  
Pregabalin : 75 mg  
Methylcobalamin: 750 mcg  
Excipients : Q.S  
Approved colours used in empty capsule shell

## 3.PHARMACEUTICAL FORM

Capsule  
For oral administration.

## 4.CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Pregabalin Methylcobalamin capsule is used for the treatment, control, prevention, & improvement of the following diseases, conditions and symptoms:

- Nerve damage pain
- Numbness and tingling
- Pain in neurological disorders
- Nerve damage
- Anxiety disorder in adults
- Anemia
- Anaemia
- Seizures

### 4.2 Posology and method of administration

For adults: 1 cap twice daily or as directed by a physician

**Method of administration:** Oral

### 4.3 Contraindications

Hypersensitivity to Pregabalin Methylcobalamin capsule is a contraindication. In addition, Pregabalin Methylcobalamin capsule should not be used if you have the following conditions:

- Hypersensitivity
- Lactation
- Peripheral edema
- Pregnancy

### 4.4 Special warnings and precautions for use

Before using this drug, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side effects of the drug.

Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

- Any allergy
- Avoid operating heavy machinery and driving
- Consult your doctor before taking the drug if suffering from heart and liver disease
- Consult your doctor for any side effects related to swelling of face, lip and tongue
- People having history of liver disease
- Pregnancy and breastfeeding

### 4.5 Interaction with other medicinal products and other forms of interaction

If you use other drugs or over the counter products at the same time, the effects of Pregabalin Methylcobalamin capsule may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that you doctor can help you prevent or manage drug interactions. Pregabalin Methylcobalamin capsule may interact with the following drugs and products:

- Alcohol
- Amino salicylic acid
- Antibiotics
- Chloramphenicol
- Colechicine
- H2 blockers

### 4.6 Pregnancy and lactation

#### Pregnancy

The topical and oral forms of this medicine are relatively safe for use till the first trimester of pregnancy. However, it should be used only if clearly needed. The oral form of this medicine is not recommended for use during pregnancy. Consult your doctor and discuss the potential benefits and risks before taking this medication.

#### Breast-feeding

The excretion of this medicine in breast milk is not known. Consult your doctor if you are breastfeeding while using this medicine.

### 4.7 Undesirable effects

The following is a list of possible side effects that may occur from all constituting ingredients of Pregabalin Methylcobalamin Capsule. This is not a comprehensive list. These side effects are possible, but do not always occur. Some of the side effects may be rare but serious. Consult you doctor if you observe any of the following side effects, especially if they do not go away.

- Irritability
- Muscle Cramps
- Fatigue
- Blurred Vision
- Clumsiness
- Unable To Sleep

### 4.8 Overdose

For Pregabalin, in the post-marketing experience, the most commonly reported adverse reactions observed when Pregabalin was taken in overdose included somnolence, confusional state, agitation, and restlessness.

In rare occasions, cases of coma have been reported.

Treatment of overdose with Pregabalin Methylcobalamin Capsule should include general supportive measures Pregabalin Methylcobalamin Capsule and may include haemodialysis if necessary.

## 5.PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

#### Mechanism of action

Combination of Pregabalin and Methylcobalamin not only decreases the release of neurotransmitters but also helps in regeneration of the myelin sheath.

Pregabalin also has got analgesic activity which reduces the pain associated with neuropathy. Thus the combination of Pregabalin and Methylcobalamin is useful for arresting the progress of diabetic neuropathy and also helps in relieving the pain associated with neuropathy. Methylcobalamin is a co-factor of methionine synthase, an enzyme that transfers methyl groups to homocysteine to regenerate methionine. Elevated homocysteine levels are a risk factor for coronary artery disease. Methionine can be transformed to S-adenosylmethionine (SAM) that is involved in a variety of methylation reactions in the body, one of which is alleviating depression.

### 5.2 Pharmacokinetic properties

#### Pharmacokinetics of Pregabalin:

Absorption: Pregabalin is rapidly absorbed when administered on an empty stomach, with peak plasma concentrations occurring within one hour.

Pregabalin oral bioavailability is estimated to be greater than or equal to 90% and is independent of dose. The rate of Pregabalin absorption is decreased when given with food resulting in a decrease in C<sub>max</sub> by approximately 25 to 30% and a delay in T<sub>max</sub> to approximately 2.5 hours.

Administration with food, however, has no clinically significant effect on the extent of absorption.

Distribution: In humans, the volume of distribution of Pregabalin for an orally administered dose is approximately 0.56 L/kg and is not bound to plasma proteins.

Metabolism: Pregabalin undergoes negligible metabolism in humans. Approximately 98% of the radioactivity recovered in the urine was unchanged Pregabalin.

The major metabolite is N-methyl Pregabalin.

Excretion: Pregabalin is eliminated from the systemic circulation primarily by renal excretion as unchanged drug. Renal clearance of Pregabalin is 73 mL/minute.

#### Pharmacokinetics of Methylcobalamin:

Mecobalamin is the neurologically active form of vitamin B12 and occurs as a water-soluble vitamin in the body. It is a cofactor in the enzyme methionine synthase, which functions to transfer methyl groups for the regeneration of methionine from homocysteine. In anaemia, it increases erythrocyte production by promoting nucleic acid synthesis in the bone marrow and by promoting maturation and division of erythrocytes.

Absorption: Peak plasma concentrations after 3 hr (oral); 0.9 hr (IM); 3 min (IV).

Excretion: Via urine.

## 6.PHARMACEUTICAL PARTICULARS

### 6.1 Special precaution for storage

Store in cool & dry place. Protected from light, heat & moisture.

KEEP OUT OF REACH OF CHILDREN

## 7.MARKETING AUTHORISATION HOLDER

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## 8.MARKETING AUTHORISATION NUMBER(S)

G/28/1330