

**B-LONG**

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**1. Generic Name:**

Pyridoxine Sustained Release Tablets

**2. Qualitative and quantitative composition:**

Each sustained release tablet contains:

Pyridoxine Hydrochloride I.P.....100 mg

Appropriate overages of vitamin added to compensate for loss on storage.

The excipients used are Talc, Ethyl Cellulose, Isopropyl Alcohol, Colloidal Silicon Dioxide and Magnesium Stearate.

**3. Dosage form and strength:**

**Dosage form:** Sustained release tablets

**Strength:** 100 mg

**4. Clinical particulars:**

**4.1 Therapeutic indication:**

It is indicated for deficiency of vitamin B<sub>6</sub> caused by usage of oral contraceptive pill/drug induced pyridoxine deficiency.

**4.2 Posology and method of administration:**

**Posology**

**Adults:** 50 to 150 mg daily in divided doses.

**Elderly:** Dosage requirements appear to be similar to those for young adults.

**4.3 Contraindications:**

A history of hypersensitivity to pyridoxine or to any of the excipients of the product.

**4.4 Special warnings and precautions for use:**

If symptoms persist or worsen, seek medical advice. Do not exceed the stated dose.

**4.5 Drug-Interaction:**

Many drugs may alter the metabolism or bioavailability of pyridoxine, including isoniazid, penicillamine and oral contraceptives, which may increase the requirements for pyridoxine. Pyridoxine hydrochloride may reduce the effect of levodopa, a drug used in the treatment of Parkinsons Disease unless a dopa decarboxylase inhibitor is also given.

**4.6 Use in special populations:**

Reported pregnancy data on exposed pregnancies indicate no adverse effects of pyridoxine in therapeutic doses on pregnancy or the health of the foetus or newborn child, or during lactation. Animal studies are insufficient with respect to effects on pregnancy, embryonal/foetal development, parturition or postnatal development.

Caution should be exercised when prescribing to pregnant women.

#### 4.7 Effects on ability to drive and use machines:

None known.

#### 4.8 Undesirable effects:

Long term administration of large doses of pyridoxine is associated with the development of severe peripheral neuritis.

##### Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:

[http://www.torrentpharma.com/Index.php/site/info/adverse\\_event\\_reporting](http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting).

#### 4.9 Overdose:

- a) Symptoms – None reported.
- b) Treatment – no treatment necessary.

### 5. Pharmacological properties:

#### 5.1 Mechanism of Action:

Pyridoxine hydrochloride is Vitamin B<sub>6</sub>. It is converted to pyridoxal phosphate, which is the co-enzyme for a variety of metabolic transformations. It is essential for human nutrition.

#### 5.2 Pharmacodynamic properties:

Pyridoxine is one of three similar compounds that may be referred to as Vitamin B<sub>6</sub>. The other two compounds are pyridoxal and pyridoxamine.

Pyridoxine, converted to pyridoxal phosphate, is a co-enzyme for transamination and is involved in many metabolic processes.

#### 5.3 Pharmacokinetic properties:

Pyridoxine hydrochloride is absorbed from the gastrointestinal tract and is converted to the active forms pyridoxal phosphate and pyridoxamine phosphate. It crosses the placental barrier and appears in breast milk. It is excreted in the urine as 4-pyridoxic acid.

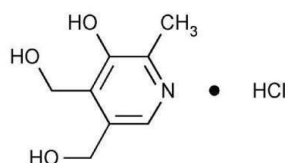
### 6. Nonclinical properties:

No further information available.

### 7. Description:

#### *Pyridoxine hydrochloride*

Pyridoxine hydrochloride is a vitamin B<sub>6</sub> analog. The chemical name for pyridoxine hydrochloride is 3,4-pyridinedimethanol, 5-hydroxy-6-methyl-, hydrochloride. The empirical formula is C<sub>8</sub>H<sub>11</sub>NO<sub>3</sub> • HCl and the molecular mass is 205.64. The structural formula is:



Pyridoxine Sustained Release Tablets are white coloured, round, biconvex, uncoated tablets with plain surface on both sides. The excipients used are Talc, Ethyl Cellulose, Isopropyl Alcohol, Colloidal Silicon Dioxide and Magnesium Stearate.

White coloured, round, biconvex, uncoated tablet with plain surface on both side.

## 8. Pharmaceutical particulars:

### 8.1 Incompatibilities:

None stated.

### 8.2 Shelf-life:

Do not use later than the date of expiry.

### 8.3 Packaging information:

B-LONG is available in blister strip of 30 Tablets.

### 8.4 Storage and handing instructions:

Store in a cool, dry place. Protect from light.

Keep out of reach of children.

## 9. Patient Counselling Information

### Package leaflet: Information for the user

#### B LONG TABLETS

Pyridoxine hydrochloride sustained release tablets 100 mg

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

9.1 What B LONG Tablets is and what it is used for

9.2 What you need to know before you take B LONG Tablets

9.3 How to take B LONG Tablets

9.4 Possible side effects.

9.5 How to store B LONG Tablets

9.6 Contents of the pack and other information.

### 9.1. What B LONG Tablets is and what it is used for

The active ingredient in B LONG Tablets is pyridoxine hydrochloride, which is Vitamin B<sub>6</sub>. B LONG Tablets are also used to treat low levels of Vitamin B<sub>6</sub> in the body.

### 9.2. What you need to know before you take B LONG Tablets

#### Do not take B LONG Tablets if:

- You are allergic to pyridoxine hydrochloride or any of the other ingredients of B LONG Tablets.

If the above statement applies to you, you should not take B LONG Tablets.

**Talk to your doctor before taking B LONG Tablets if:**

- The patient is a child. **B LONG Tablets are not recommended for children.**

**Taking other medicines**

Taking another medicine while you are taking **B LONG Tablets** can affect how it or the other medicine works. Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including those you may have bought yourself without a prescription. Please check with your doctor if you are taking any of the following (or any other medication):

- levodopa, a drug used in the treatment of Parkinson's disease
- isoniazid, used to treat tuberculosis
- oral contraceptives
- penicillamine, used to treat arthritis and other conditions.

If you have any doubts about whether you should take this medicine then discuss matters with your doctor before taking it.

**Pregnancy and breast-feeding**

You should let your doctor know if you are pregnant or wish to become pregnant, or wish to breast-feed, whilst taking these tablets.

**Driving and operating machines**

**B LONG Tablets** do not affect the ability to drive or operate machinery.

**9.3. How to take B LONG Tablets**

Your doctor will decide the dose which is best for you. Always follow your doctor's instructions completely and also follow any special instructions or warnings which appear on the label which the pharmacist has put on the package. Contact your doctor if your symptoms worsen or do not improve. If you do not understand, or are in any doubt, ask your doctor or pharmacist.

Unless instructed differently, take your tablets with a glass of water.

**For the treatment of low levels of Vitamin B<sub>6</sub> in the body**

The usual dose in adults is 50 to 150 mg daily in divided doses.

**Elderly**

If you are elderly, you will require similar doses to those given above.

**Children**

**B LONG Tablets** are not recommended for use in children.

**If you take more B LONG Tablets than you should**

If you accidentally take too many tablets contact your doctor or pharmacist or nearest hospital casualty department. Take this leaflet and any remaining tablets with you to show the doctor or pharmacist.

**If you miss a dose of B LONG Tablets**

If you forget to take a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. Do not take a double dose to make up for a forgotten tablet.

## Stopping B LONG Tablets

You should continue to take **B LONG** Tablets for as long as your doctor tells you to. Do not stop taking the medicine without talking to your doctor first.

### 9.4. Possible side effects.

Like many medicines, **B LONG** Tablets may cause side effects in some patients, although not everybody gets them.

If you take large doses of **B LONG** Tablets for a long time, you may develop problems with your nerves (peripheral neuritis). One of the symptoms of peripheral neuritis can be pins and needles.

### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:

[http://www.torrentpharma.com/Index.php/site/info/adverse\\_event\\_reporting](http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting).

### 9.5. How to store B LONG TABLETS

#### Keep out of the reach and sight of children.

Do not take this medicine if the expiry date on the label has passed. The expiry date refers to the last day of that month.

**B LONG** Tablets should not be taken if they show signs of deterioration.

Store in cool and dry place. Store in the original container or package in order to protect from light and moisture. Do not transfer the tablets to another container.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### 9.6. Contents of the pack and other information.

#### What B LONG Tablets contains

The active substances in **B LONG** tablets is pyridoxine hydrochloride.

**The other ingredients are** Talc, Ethyl Cellulose, Isopropyl Alcohol, Colloidal Silicon Dioxide and Magnesium Stearate.

**Contents of the pack:** Available in blister strip of 30 Tablets.

## 10. Details of manufacturer

### **Torrent Pharmaceuticals Ltd.**

32 No.Middle camp, NH-10, East District,  
Gangtok, Sikkim-737 135

OR

Manufactured by:

Windlas Biotech Limited (Plant-IV)

Plot No. 183 & 192,

Mohabewala Industrial Area,

Dehradun-248 110, Uttarakhand

## 11. Details of permission or licence number with date

**Torrent Pharmaceutical Ltd.**

Mfg Lic No. M/564/2010 issued on 23.12.2016

OR

Mfg Lic No. 60/UA/SC/P-2009 issued on 03.09.2020

**12. Date of revision**

Apr-2022

MARKETED BY



TORRENT PHARMACEUTICALS LTD.

**IN/B LONG Tablets 100 mg/Apr-22/03/PI**