# PATIENT COUNSELLING INFORMATION

# Doxylamine Succinate, Pyridoxine Hydrochloride and Folic Acid Tablets $\mathbf{Dol\text{-}B6}^{\text{@}}$

#### Read the entire leaflet carefully before you start taking this medicine:

- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

#### 1. What is Dol-B6<sup>®</sup> and what is it used for?

Dol-B6<sup>®</sup> is a combination of Doxylamine succinate, Pyridoxine hydrochloride and Folic acid tablets. Doxylamine succinate belongs to a group of medicines called 'antihistamines'. Pyridoxine hydrochloride is another name for Vitamin B6. Folic acid is another name for Vitamin B9.

Dol-B6<sup>®</sup> is used to prevent nausea (feeling sick) and vomiting (being sick) in pregnant women. It is used when changes in diet or other non-medicine treatments have not worked.

#### 2. What you need to know before you take Dol-B6<sup>®</sup>?

## Before taking Dol-B6<sup>®</sup>, tell your doctor if:

- you are allergic to Doxylamine succinate or other antihistamines (such as diphenhydramine), Pyridoxine hydrochloride, Folic acid or any of the other ingredients of this medicine.
- you have an untreated vitamin B12 deficiency such as in certain anaemias and lifelong vegetarians.
- you have pernicious anaemia (a form of anaemia caused by lack of vitamin B12) or another condition caused by vitamin B12 deficiency.
- you have a malignant (cancerous) disease.

#### **Warnings and precautions**

Talk to your doctor before taking Dol-B6<sup>®</sup> if you have ever had:

- asthma.
- increased eye pressure.
- an eye problem called 'narrow angle glaucoma'.
- a stomach ulcer.
- a blockage in your gut, between your stomach and small intestine.
- a blockage in your bladder.
- a folate dependent tumour.
- any disease that reduces the amount of vitamin B12 in the body.

## Other medicines and Dol-B6®

Please tell your doctor if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, and herbal medicines

Before taking Dol-B6<sup>®</sup>, tell your doctor if you are taking any of the following:

- Medicines for depression called 'monoamine oxidase inhibitors' (MAOIs) using these medicines with Dol-B6® can make side effects worse and last longer.
- Medicines such as cough and cold medicines, sleeping medicines or certain pain medicines (called central nervous system depressants) - using any of these with Dol-B6<sup>®</sup> can make you feel very sleepy. This can make you fall over or cause other accidents.
- antiepileptics (to treat epilepsy) such as phenytoin, phenobarbital, primidone, sodium valproate and carbamazepine.
- antibacterials (to treat infections) such as trimethoprim, chloramphenicol and cotrimoxazole.
- sulfasalazine (to treat ulcerative colitis, Crohn's disease or rheumatoid arthritis).
- methotrexate (to treat Crohn's disease, psoriasis or rheumatoid arthritis).

# Dol-B6<sup>®</sup> with alcohol

Do not drink alcohol while taking Dol-B6<sup>®</sup>.

#### Pregnancy and breast-feeding

Dol- $B6^{\otimes}$  is for use in pregnant women. Due to the Central Nervous System (CNS) effects of Doxylamine succinate on nursing infants, women should not breastfeed while using Dol  $B6^{\otimes}$ .

### Driving and using machines

Do not drive, cycle or use any tools or machines while taking this medicine. This is because you may feel sleepy after taking Dol-B6<sup>®</sup>. If this happens do not do other activities that need your full attention – unless your doctor tells you it is ok to do so.

#### 3. How to take Dol-B6<sup>®</sup>?

Always use this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose is two tablets orally at bedtime or as your doctor has told you.

Take on an empty stomach with a glass of water. Swallow tablets whole. Do not crush, chew, or split it.

## If you take more Dol-B6® than you should

It is important to take the dose as prescribed by your doctor. If you have taken more Dol-B6<sup>®</sup> than you should, then consult your doctor, if possible you should take the medicine pack with you.

## If you forget to take Dol-B6®

If you forget to take a dose, have it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose. This may increase the chance of you getting an unwanted side effect.

# If you stop taking Dol-B6®

If you stop taking Dol-B6<sup>®</sup>, your symptoms may return. Tell your doctor before stopping Dol-B6<sup>®</sup>.

## 4. What are the possible side effects of Dol-B6<sup>®</sup>?

Like all medicines, this medicine can cause side effects, although not everybody gets them. The common side-effects with Dol-B6® are anorexia, nausea, abdominal distension, flatulence, somnolence, allergic reactions comprising erythema, rash, pruritus, urticaria, dyspnoea, anaphylactic reactions (including shock) and falls or other accidents resulting from the effect of the combined use of Dol-B6® with CNS depressants including alcohol.

If you get any side-effects, talk to your doctor. This includes any possible side-effects not listed in this leaflet.

## 5. How to store Dol-B6®?

#### Store in a cool & dry place. Protect from light.

Keep out of reach of children.

Do not take this medicine after the expiry date shown on the pack. The expiry date refers to the last day of that month.

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For further information please write to:



Manufactured in India by:

MAPRA LABORATORIES PRIVATE LIMITED

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