<u>la Renon</u>

# Vomibune

Doxylamine Succinate 10 mg and Pyridoxal 5-Phosphate (Vitamin B6) 10 mg Tablets

## Vomibune-24

Doxylamine Succinate 20 mg and Pyridoxine Hydrochloride (Vitamin B6) 20 mg Extended Release Tablets



#### Nausea Vomiting in Pregnancy

Up To 90% Of Pregnant Women Will Experience Nausea And Vomiting In Pregnancy **(NVP)** Of Varying Severity, With Symptoms Generally Starting Around 4 - 9 Weeks Of Gestation, Peaking Around The 7<sup>th</sup> To 12<sup>th</sup> Week And Subsiding By The 16<sup>th</sup> Week.

#### Consequences Of NVP:

The Most Common Adverse Fetal Outcome With Severe Vomiting Is Low Birth Weight And Preterm Birth; The More Severe The Nausea And Vomiting, The Lower The Birth Weight.

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**Doxylamine** Is An Antihistamine That Blocks The Action Of Histamine And Controls Nausea, Vomiting And Dizziness.

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**Pyridoxine (Vitamin B6)** Is A Form Of Vitamin B That Has Anti-Nausea Properties And Provides Nutrition To The Body.

It Is A **Safe And Effective** That Blocks Chemical Actions In The Body That Trigger **NVP** And Make Women Feel Sick During Pregnancy. 3

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It Helps To **Effectively Manage NVP**Caused Due To Hormonal Changes In
Pregnancy.

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Vitamin B6 Provides Nutrition, Reduces NVP And Supports Baby's Brain Development & Immune System.

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In **Vomibune-24** The Extended-Release Formula And Dosage Schedule Provides 24-Hour Control Over **NVP** Symptoms. This Prevents The **NVP** From Progressing To Hyperemesis Gravidarum.

Improves The Patient's Quality Of Life.

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# Demonstration Of Early Efficacy Results Of The Combination Of Doxylamine-Pyridoxine For The Treatment Of Nausea And Vomiting In Pregnancy

Subject: Doxylamine Succinate And Pyridoxine Hydrochloride (N = 131) Or Placebo (N = 125)

**Duration: 14 Days** 

Dose: 2-4 Tablets A Day

End Point: Change In The Pregnancy-Unique Quantification Of Emesis (Puge) Score

Result: The Use Of Doxylamine Succinate And Pyridoxine Hydrochloride Resulted In:

A Significantly Lower Puge Score By 0.9 Puge Units When Compared To Placebo.

• 40% Change From Baseline Puqe Score Compared To A 28.4% Change For The Placebo-Treated Group.

#### Conclusion:

The Use Of Doxylamine Succinate And Pyridoxine Hydrochloride Tablets Show Improved NVP Symptom Control As Compared To Placebo On Days 3,4 And 5, With Sustained Efficacy Until The End Of The Trial



One (20 Mg Doxylamine Succinate & 20 Mg Pyridoxine) Was Bioequivalent To Two Combination Tablets Of 10 Mg Doxylamine Succinate And 10 Mg Pyridoxine Hydrochloride.

The Combination Has Shown An Immediate Peak Concentrations, Followed By A Delayed Release Phase.

Combination Allows For The Bedtime Dose To Be Effective Immediately And Also Provide With Sustained Control Of **NVP** Symptoms Throughout The Day.

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Indication: Nausea Vomiting In Pregnancy (NVP)/ Morning Sickness

Mechanism:

Primary Mechanism: Direct Inhibition Of Histamine At H1 Receptor And Anti-Cholinergic Effect

Secondary Mechanism: Indirect Effect On Vestibular System By Decreasing Stimulation Of Vomiting Centre



Most Proven &
Effective Medication

Provides Rapid And Continuous Relief Of Morning Sickness Symptoms Throughout The Day & Night

First-Line Treatment Recommendations For Nausea & Vomiting During Pregnancy As Per The American College Of Obstetricians & Gynecologists (ACOG)

Effectively Alleviates **NVP** Symptoms & Improves The Patient's Quality Of Life

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5 Cost Effective

#### Dosage:

As Directed By The Physician.

#### Presentation:

Vomibune Is Available As A Strip Of 10 Tablets Vomibune-24 Is Available As A Strip Of 10 Tablets

La Renon Healthcare Private Limited

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VOMIRUNE 24

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10x10 Tablets