

# Xyquil<sup>TM</sup> DR Tablets

(Doxylamine Succinate + Pyridoxine HCl)

## DESCRIPTION:

Xyquil<sup>TM</sup> DR is the combination of doxylamine succinate (an antihistamine) and pyridoxine hydrochloride (vitamin B<sub>6</sub>)

## COMPOSITION:

Each delayed release tablet contains:  
Doxylamine succinate USP..... 10mg  
Pyridoxine HCl BP..... 10mg

## CLINICAL PHARMACOLOGY:

Doxylamine succinate, an antihistamine, provides the antinauseant and antiemetic activity; pyridoxine HCl provides a supplement of vitamin B<sub>6</sub> to prevent a possible pyridoxine deficiency during pregnancy

## PHARMACOKINETICS:

Doxylamine and pyridoxine are absorbed in the gastrointestinal tract, mainly in the jejunum  
The C<sub>max</sub> of doxylamine and pyridoxine are achieved within 7.5 and 5.5 hours, respectively the administration of food delays the absorption of both doxylamine and pyridoxine. This delay is associated with a lower peak concentration of doxylamine, but the extent of absorption is not affected.  
Doxylamine is biotransformed in the liver by N-dealkylation to its principle metabolites N-desmethyl doxylamine and N, N-didesmethyl doxylamine

Pyridoxine is a prodrug primarily metabolized in the liver. The terminal elimination half-life of doxylamine and pyridoxine are 12.5 hours and 0.5 hours, respectively

## INDICATION:

Treatment of pregnancy associated nausea and vomiting

## LIMITATIONS OF USE:

Xyquil<sup>TM</sup> DR has not been studied in women with hyperemesis gravidarum

## PRECAUTIONS:

Due to a risk of drowsiness, Xyquil<sup>TM</sup> DR must be prescribed with caution to automobile drivers and machine operators. It must also be used with caution in combination with alcohol and other CNS depressing drugs or with epileptic patients

## DRUG INTERACTIONS:

Use of Xyquil<sup>TM</sup> DR is contraindicated in women who are taking monoamine oxidase inhibitors (MAOIs), which prolong and intensify the anticholinergic (drying) effects of antihistamines. Concurrent use of alcohol and other CNS depressants (such as hypnotic sedatives and tranquilizers) with Xyquil<sup>TM</sup> DR are not recommended

## PREGNANCY RISK CATEGORY A:

### Nursing Mothers:

Women should not breast-feed while using Xyquil<sup>TM</sup> DR because the antihistamine component (doxylamine succinate) in Xyquil<sup>TM</sup> DR can pass into breast milk

## ADVERSE REACTIONS:

Doxylamine succinate may cause drowsiness, vertigo, nervousness, epigastric pain, headache, palpitation, diarrhea, disorientation, irritability, convulsions, urinary retention or insomnia. Pyridoxine is a vitamin that is generally recognized as having no adverse effects







## SYMPTOMS AND TREATMENT OF OVERDOSE:

Symptoms of overdose may include severe drowsiness, restlessness, dilated pupils, vertigo, mental confusion, tachycardia, severe dry mouth, trouble breathing, fainting, hallucinations, and seizures

**Treatment:** If treatment is needed, it consists of gastric lavage, emetics or activated charcoal and a symptomatic treatment

## DOSAGE AND ADMINISTRATION:

2 tablets at bedtime. Add 1 tablet in the morning and 1 tablet in mid-afternoon when nausea or vomiting occurs during the day or in severe cases

The dosing strategy for 24-hour control of symptoms of nausea and vomiting of pregnancy is as follows:		
		Take two (2) tablets at bedtime to control NVP* occurring in the morning
		Take another one (1) tablet in the morning to control mid-day NVP*
		And one (1) tablet mid-afternoon to control evening NVP*

\*NVP = Nausea and Vomiting of Pregnancy

OR  
As directed by physician

## AVAILABILITY:

Xyquil<sup>TM</sup> DR tablets available in pack of 30's

## STABILITY:

See expiry on the pack

## INSTRUCTIONS:

Keep out of reach of children  
Avoid exposure to heat, light and humidity  
Store between 15 to 30°C  
Improper storage may deteriorate the medicine

## زائیکوئیل ڈی آر ٹیبلٹ

(ڈوکسولامین سبسکینٹ ہائیڈروکلورائیڈ + پیریدوکسین ہائیڈروکلورائیڈ)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں  
بچوں کی پہنچ سے دور رکھیں

دوا کو دھوپ، گرمی اور نمی سے محفوظ رکھیں۔ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ  
کے درمیان میں رکھیں ورنہ دوا خراب ہو جائے گی



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