For use by Healthcare professionals only

Xonvea®

doxylamine succinate/
pyridoxine hydrochloride

Tear-off pad - Information for patients who have been prescribed XONVEA®

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store. Adverse events should also be reported to Exeltis UK Limited by email to uk.pharmacovigilance@exeltis.com

Prescribing Information and references can be found overleaf

EXE-E/INP-XON-1444 V2 April 2025

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Xonvea (doxylamine succinate/pyridoxine hydrochloride) 10 mg/10 mg gastro-resistant tablets. Prescribing Information UK. Consult Summary of Product Characteristics (SmPC) before prescribing. Care should be taken when prescribing in pregnancy as medicines can cross the placenta and may affect the foetus.

Product name and active ingredients: Xonvea 10 mg/10 mg gastro-resistant tablets. Each tablet contains 10 mg doxylamine succinate and 10 mg pyridoxine hydrochloride. **Excipients with known effect:** Each tablet contains 6.04 mcg azo colouring agent Allura red AC aluminium lake (E 129) and 0.02 mcg benzoic acid (E 210). **Indications:** Xonvea is indicated for the treatment of nausea and vomiting of pregnancy in pregnant women ≥18 years who do not respond to conservative management (i.e., lifestyle and diet change). **Dosage and administration:** For adults (≥18 years) only. Recommended starting dose is two tablets (total dose: 20 mg doxylamine succinate/20 mg pyridoxine hydrochloride) at bedtime (Day 1). If this dose adequately controls symptoms the next day, continue taking two tablets at bedtime. If symptoms persist into afternoon of Day 2, continue the two tablets at bedtime (Day 2) and on Day 3 take three tablets (one in the morning, two at bedtime). If three tablets do not adequately control symptoms on Day 3, take four tablets starting on Day 4 (one in the morning, one mid-afternoon, two at bedtime). Maximum recommended daily dose is four tablets (one in the morning, one mid-afternoon, two at bedtime). Xonvea should be taken as a daily prescription and not on an as needed basis. Continued need for Xonvea should be reassessed as pregnancy progresses. To prevent sudden return of symptoms, gradual tapering of dose is recommended at discontinuation. Xonvea should be swallowed whole (not crushed, split or chewed) on an empty stomach with a glass of water. **Contraindications:** Hypersensitivity to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride or any excipient; concomitant use with monoamine oxidase inhibitors (MAOIs). **Special warnings and precautions for use:** Xonvea may cause somnolence due to anticholinergic properties of doxylamine succinate, an antihistamine. Xonvea is not recommended concurrently with central nervous system (CNS) depressants including alcohol, hypnotic sedatives and tranquilizers. Xonvea has anticholinergic properties and should be used with caution in patients with asthma, increased intraocular pressure, narrow angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction and bladder-neck obstruction. Xonvea contains pyridoxine hydrochloride, a vitamin B6 analog, additional levels from diet and vitamin B6 supplements should be assessed. There is limited evidence in cases of hyperemesis gravidarum, these patients should be treated by a specialist. There are reports of false positive urine screening tests for methadone, opiates, and phencyclidine phosphate (PCP). Xonvea contains azo colouring agent Allura red AC aluminium lake (E 129), which may cause allergic reactions. **Interactions:** MAOIs: Prolong and intensify anticholinergic effects of antihistamines. CNS depressants: Concurrent use is not recommended as the combination may result in severe drowsiness. Food: Delay in Xonvea's onset of action may be further delayed when taken with food, and a reduction in absorption may occur. Interference with urine screen for methadone, opiates and PCP: False positive may occur. **Pregnancy and lactation:** Xonvea is intended for use in pregnant women. Excitement, irritability and sedation have been reported in nursing infants, presumably exposed to doxylamine succinate through breast milk. Infants with apnoea/other respiratory syndromes may be particularly vulnerable to sedative effects resulting in worsening of their apnoea/respiratory conditions. A decision must be made whether to discontinue breast-feeding or discontinue/abstain from Xonvea, considering the benefit of breast feeding for the child, and of Xonvea for the woman. **Effects on ability to drive and use machines:** Moderate to major influence. Activities requiring complete mental alertness (e.g. driving, operating heavy machinery) to be avoided until cleared by a healthcare provider. **Undesirable effects:** *Very common (≥1/10);* somnolence. *Common (≥1/100 to <1/10)*; dizziness, dry mouth, fatigue. Severe drowsiness may occur if Xonvea is taken with CNS depressants, including alcohol. Anticholinergic effects of Xonvea may be prolonged and intensified by MOAIs. *Rarely*: Agranulocytosis, haemolytic anaemia, leukopenia, thrombocytopenia and pancytopenia have been reported in a few patients receiving some antihistamines. Increased appetite and/or weight gain also occurred in patients receiving antihistamines. **For a full list of adverse reactions, please refer to the SmPC. Legal category:** POM. **Presentation and cost:** 20 tablets £28.50 **Marketing authorisation holder and number:** Exeltis Healthcare S.L. PL 44081/0006. **Date of last revision:** May 2024. Further information available from Exeltis UK Limited, Two Snowhill, 7th Floor, Birmingham, B4 6GA. **Date of preparation of PI:** November 2024, **Job Code:** EXE-E/IPR-XON-1579

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Reference:
1. Xonvea 10 mg/10 mg gastro resistant tablets Summary of Product Characteristics

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The information below is not intended to replace that provided by your healthcare professional. Always read the full patient information leaflet inside the XONVEA® (doxylamine succinate 10 mg/pyridoxine hydrochloride 10 mg) pack.

XONVEA® is used in pregnant women aged 18 years and older, to help stop them feeling sick (nausea) and being sick (vomiting). It is used when changes in diet or other non-medicine treatments have not worked. XONVEA® contains doxylamine succinate which is an antihistamine and pyridoxine hydrochloride which is another name for vitamin B6.

How to take XONVEA®

Your doctor will start you on a low dose and possibly increase it - this will depend on your symptoms and how you are feeling.

Day 1
- Take 2 tablets, by mouth, at bedtime.

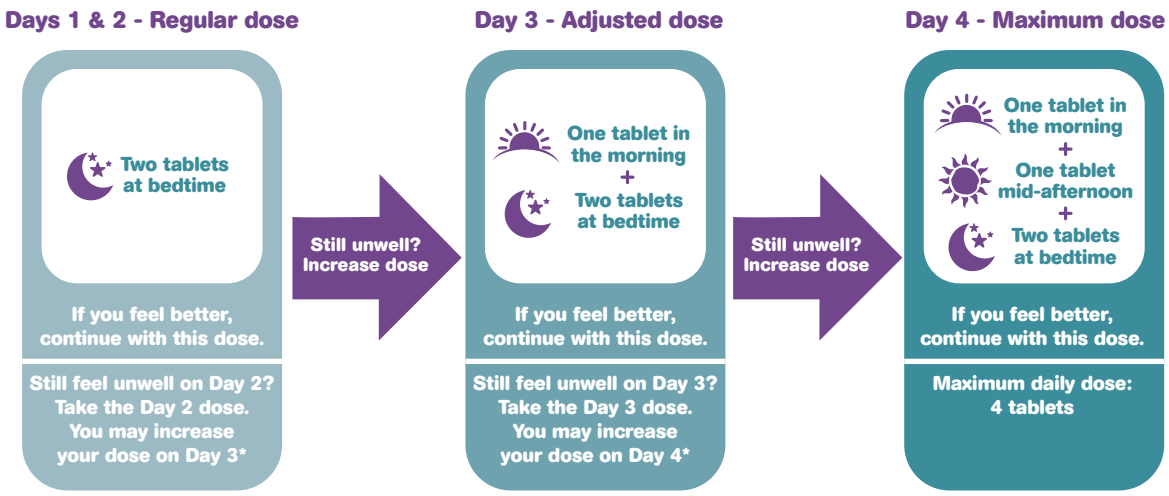
Day 2
- Take 2 tablets, by mouth, at bedtime.
- If your nausea and vomiting is better or controlled on Day 2, continue to take 2 tablets every night at bedtime. This will be your usual dose unless your doctor, pharmacist or nurse tells you otherwise.

Day 3
- If you still had nausea and vomiting on Day 2, take 3 tablets, by mouth on Day 3 (1 tablet in the morning and 2 tablets at bedtime).

Day 4
- If your nausea and vomiting was better or controlled on Day 3 continue to take 3 tablets each day (1 tablet in the morning and 2 tablets at bedtime). This will be your usual dose unless your doctor, pharmacist or nurse tells you otherwise.
- If you still had nausea and vomiting on Day 3, take 4 tablets, by mouth each day (1 tablet in the morning, 1 tablet in the mid-afternoon, and 2 tablets at bedtime).
- Do not take more than 4 tablets each day (1 in the morning, 1 in the mid-afternoon, and 2 at bedtime).

Taking this medicine:

- Take XONVEA® on an empty stomach
- Swallow the tablet whole with a glass of water
- Do not crush, chew, or split the tablets before swallowing
- If you cannot swallow XONVEA® tablets whole, tell your doctor, pharmacist or nurse



* Always take XONVEA® exactly as advised by your healthcare professional. This information is not intended to replace their advice.

If you take more XONVEA® than you should

If you take more XONVEA® than you should, stop taking XONVEA® and talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

The following effects may happen:

- feeling restless
- sleepy or dizzy
- dry mouth
- larger black part of the eye (dilated pupils)
- confusion
- fast heart rate

If the amount of medicine in your body is very high, you may also have fits, muscle pain or weakness or sudden severe kidney problems. These may even lead to death. If you have these signs - stop taking XONVEA® and talk to a doctor or go to a hospital straight away.

Keep away from children

For more information about XONVEA®, refer to the patient information leaflet (PIL) provided in the XONVEA® pack.

If you stop taking XONVEA®

Do not stop taking XONVEA® without talking to your doctor first. If you stop taking this medicine suddenly your feeling sick (nausea) and being sick (vomiting) may come back. Your doctor will tell you how to stop taking this medicine slowly over time to help avoid this. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

When you feel that your nausea and vomiting symptoms are improving and less severe, speak to your doctor, nurse or pharmacist about a gradual reduction in your dose of XONVEA® to prevent a sudden return of symptoms.

Possible side effects of XONVEA®

Like all medicines, this medicine can cause side effects, although not everybody gets them. Please ensure that you read your leaflet in the pack, which will have all side effects listed.

Very common:

may affect more than 1 in 10 people[1]

- feeling very sleepy

Common:

may affect up to 1 in 100 people[1]

- feeling dizzy
- feeling tired
- dry mouth

Driving and using machines

Ask your doctor about driving whilst on XONVEA®.

It is very important your doctor knows about all of your medicines, including any bought over the counter.

If you have any further questions, talk to your doctor, pharmacist or nurse.

Reporting of side effects

If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects that are not listed in the Patient Information Leaflet in the medication box. You can also report side effects directly via the yellow card scheme at: https://yellowcard.mhra.gov.uk. By reporting side effects you can help provide more information on the safety of this medicine.

Developed by Exeltis for patients prescribed XONVEA®
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