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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

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