

Package leaflet: Information for the user

Xonvea 10 mg/10 mg gastro-resistant tablets

doxylamine succinate/pyridoxine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Xonvea is and what it is used for
2. What you need to know before you take Xonvea
3. How to take Xonvea
4. Possible side effects
5. How to store Xonvea
6. Contents of the pack and other information

1. What Xonvea is and what it is used for

What Xonvea is

Xonvea contains two medicines ('active substances') called: 'doxylamine succinate' and 'pyridoxine hydrochloride'.

- Doxylamine succinate belongs to a group of medicines called 'antihistamines'.
- Pyridoxine hydrochloride is another name for Vitamin B₆.

What Xonvea is used for

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.

2. What you need to know before you take Xonvea

Do not take Xonvea if:

- you are allergic to doxylamine succinate or other antihistamines (such as diphenhydramine), pyridoxine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- you are taking medicines for depression called 'monoamine oxidase inhibitors' (MAOIs)

Do not take Xonvea if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before taking Xonvea.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Xonvea 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.

Also, talk to your doctor or pharmacist or nurse before taking Xonvea if:

- you are taking cough or cold medicines, sleeping medicines or certain pain medicines
- you have been drinking alcohol.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking Xonvea.

If you suffer from severe nausea and vomiting of pregnancy, a condition called hyperemesis gravidarum, you have to be treated by a specialist.

If you are having a urine drug screen, taking Xonvea may show ‘false positive’ results for methadone, opiates, and phencyclidine phosphate (PCP) when some test methods are used. If this happens, a more specific test can be performed.

Children and adolescents

Xonvea is not meant for use in children under 18 years old. It is not known if Xonvea is safe and effective in this age group.

Vitamin B

Talk to your doctor, pharmacist or nurse before taking any additional vitamin B – this could be through your diet, from supplements or multi-vitamins.

Other medicines and Xonvea

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

In particular, do not take Xonvea and tell your doctor or pharmacist or nurse if you are taking any of the following:

- Medicines for depression called ‘monoamine oxidase inhibitors’ (MAOIs) - using these medicines with Xonvea 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 Xonvea can make you feel very sleepy. This can make you fall over or cause other accidents.

Xonvea with alcohol

Do not drink alcohol while taking Xonvea.

Pregnancy and breast-feeding

Xonvea is for use in pregnant women.

If you are breastfeeding, a decision should be made with your doctor whether to discontinue breast-feeding or to discontinue the drug. This is because Xonvea can pass into your breast milk and may harm your baby.

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 Xonvea. If this happens do not do other activities that need your full attention - unless your doctor tells you it is ok to do so.

Xonvea contains Allura red AC aluminium lake (E 129), benzoic acid (E 210) and sodium

This medicine contains the azo coloring agent Allura red AC aluminium lake (E 129) which may cause allergic reactions.

This medicine contains 0.02 micrograms benzoic acid (E 210) in each gastro-resistant tablet.

This medicine contains less than 1 mmol sodium (23 mg) per gastro-resistant tablet, that is to say essentially 'sodium-free'.

3. How to take Xonvea

Always take this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

How much to take

Your doctor will start you on a low dose and possibly increase it - this will depend on how well the medicine works for you.

How to start taking Xonvea and increase your dose, if needed:

- **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 1 tablet in the morning and 2 tablets at bedtime by mouth on Day 3.
- **Day 4**
 - If your nausea and vomiting was better or controlled on Day 3 continue to take 1 tablet in the morning and 2 tablets at bedtime by mouth each day. 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 1 tablet in the morning, 1 tablet in the mid-afternoon, and 2 tablets at bedtime, by mouth on Day 4. This will be your usual dose unless your doctor, pharmacist or nurse tells you otherwise.

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 to preserve the effect of this medicine.
- If you cannot swallow Xonvea tablets whole, tell your doctor, pharmacist or nurse.

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, even you feel well. 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 be lifethreatening. If you have these signs - stop taking Xonvea and talk to a doctor or go to a hospital straight away.

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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common: may affect more than 1 in 10 people

- feeling very sleepy.

Common: may affect up to 1 in 10 people

- feeling dizzy
- feeling tired
- dry mouth.

Not known: frequency cannot be estimated from the available data

- hypersensitivity (allergic reaction)
- feeling anxious, difficulty in sleeping (insomnia), nightmares, feeling disorientated
- headaches or migraines
- tingling, pricking or numbness of skin
- restlessness and a need to move constantly
- problems with eyesight or blurred vision
- sensation of spinning dizziness
- difficulty breathing, awareness of heartbeat or increased heart rate
- full or bloated feeling, stomach pains, constipation or diarrhoea
- excessive sweating, skin reactions such as itchiness or rash
- difficulties or pain with passing urine
- discomfort in the chest
- general discomfort or feeling irritable

Other side effects reported with medicines in the same drug class as doxylamine

Anticholinergic effects include (blockage of the activity of organs that receive nerve impulses through a substance called acetylcholine): dry mouth, nose and throat; double vision (diplopia); ringing or humming in the ears (tinnitus); inflammation of the inner ear which develops within a short time (acute labyrinthitis); shaking (tremors) and nervousness; involuntary repetitive movements of the face (facial dyskinesia). In addition, feeling of tightness in the chest, thick mucus in the chest (bronchial secretions); high-pitched whistling sound often associated with difficulty in breathing (wheezing); stuffy nose; feeling chills; early menses; altered state of mind such as hallucinations, delusions, confusion and disturbed thoughts (toxic psychosis); or feeling faint have been reported.

Rarely, low levels of white blood cells (agranulocytosis), reduced blood in the body due to increased destruction of blood cells (haemolytic anaemia), decreased clotting blood cells (thrombocytopenia), decreased red, white and clotting cells in the blood (pancytopenia), and increased appetite, sometimes with weight gain, have been reported.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Xonvea

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton or blister after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Xonvea contains

- The active substances are doxylamine succinate (an antihistamine) and pyridoxine hydrochloride (vitamin B₆). Each gastro-resistant tablet contains 10 mg of doxylamine succinate and 10 mg of pyridoxine hydrochloride.
- The other ingredients are, carnauba wax, croscarmellose sodium, hypromellose (E 464), indigo carmine aluminium lake (E 132), macrogol (E 1521), magnesium stearate, magnesium trisilicate, methacrylic acid-ethyl acrylate copolymer (1:1), microcrystalline cellulose, Allura red AC aluminium lake (E 129), polysorbate 80 (E 433), propylene glycol (E 1520), colloidal anhydrous silica, shellac, simethicone emulsion (contains benzoic acid (E 210), sodium hydrogen carbonate (E 500), sodium lauryl sulfate (E 487), talc (E 553b), titanium dioxide (E 171), triethyl citrate and simethicone.

What Xonvea looks like and contents of the pack

- Xonvea gastro-resistant tablets are white, round, and film-coated with a pink image of a pregnant woman on one side.
- Xonvea is available in blister packs containing 20, 30 or 40 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

The product marketing authorisation holder is:

Exeltis Healthcare S.L.
Avda. de Miralcampo 7,
Pol. Ind. Miralcampo, 19200
Azuqueca de Henares (Guadalajara)
Spain

Manufacturer

Elara Pharmservices Europe Limited
239 Blanchardstown
Corporate Park
Ballycoolin
Dublin
D15 KV21
Ireland

Laboratorios Liconsa S.A.
Avda. Miralcampo, 7, Pol. Ind. Miralcampo, Azuqueca de Henares, 19200
Guadalajara Spain

This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Ireland	Xonvea 10 mg/10 mg gastro-resistant tablets
United Kingdom (Northern Ireland)	Xonvea 10 mg/10 mg gastro-resistant tablets
The Netherlands	Xonvea 10 mg/10 mg maagsapresistente tabletten
Finland	Xonvea 10 mg/10 mg enterotabletti
Iceland	Xonvea 10 mg/10 mg magasýrupolin tafla
Norway	Xonvea 10 mg/10 mg enterotablett
Denmark	Xonvea 10 mg/10 mg enterotablett
Sweden	Xonvea 10 mg/10 mg gastro-resistant tablets

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