

Package leaflet: Information for the user

Xonvea MR 20 mg/20 mg modified-release tablets

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

1. What Xonvea MR is and what it is used for

What Xonvea MR is

Xonvea MR 20 mg/20 mg modified-release tablets contains two medicines ('active substances') called: 'doxylamine hydrogen succinate' and 'pyridoxine hydrochloride'.

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

What Xonvea MR is used for

Xonvea MR is used in pregnant women, 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.

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

2. What you need to know before you take Xonvea MR

Do not take Xonvea MR if:

- you are allergic to doxylamine hydrogen 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) or have taken MAOIs in the last 14 days
- you suffer from porphyria (a very rare metabolic disorder).

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Xonvea MR if you have ever had:

- asthma or other breathing disorders such as chronic bronchitis (persistent inflammation of the bronchi) and pulmonary emphysema (disease that affects the lungs making breathing difficult)

- 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
- liver and/or kidney disease
- prolonged QT interval syndrome (heart disease)
- epilepsy
- low levels of potassium in the blood or other electrolytic alterations.

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

- you are taking cough or cold medicines, sleeping medicines or certain pain medicines (also refer to ‘Other medicines and Xonvea MR below)
- you have been drinking alcohol.

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

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

Xonvea MR can increase sensitivity to light, so sunbathing is not recommended during the treatment.

Xonvea MR can increase dehydration and cause heat stroke due to decreased sweating.

Be aware of any signs of abuse or dependence on this treatment. If you have any substance use disorders (alcohol, medication or other), talk to your doctor.

If you are having a urine drug screen, taking Xonvea MR 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.

This medicine can cause a false negative result in skin tests in which allergenic extracts are used (allergy tests). You should stop taking this medicine several days before taking the test.

Look out for side effects

- Xonvea MR may make you feel sleepy - do not drive, cycle or use any tools or machines while taking this medicine. Also, do not do other things that need your full attention – unless your doctor tells you it is okay to do so.
- Do not take Xonvea MR while taking cough and cold medicines, sleeping medicines, certain pain medicines or if you have been drinking alcohol. Taking Xonvea MR with other medicines that affect the ‘central nervous system’ can make you feel very sleepy - this can make you fall over or cause other accidents.

Children and adolescents

It is not known if Xonvea MR is safe and effective in children under 18 years old.

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 MR

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.

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

- Anticholinergics such as antidepressants or medicines for the treatment of Parkinson's, monoamine oxidase inhibitors or MAOIS (treatment for depression), antipsychotics (medicines for the treatment of mental disorders), atropine for the treatment of spasms or disopyramide (for the treatment of certain heart problems) because it can increase the toxicity.
- Central nervous system depressants (e.g. barbiturates, hypnotics, sedatives, anxiolytics, opioid analgesics, antipsychotics, procarbazine or sodium oxibate).
- Antihypertensive medicines (medicine for controlling blood pressure) which have an effect on the central nervous system such as guanabenz, clonidine or alpha-methyldopa.
- If you are taking other medicines which have a toxic effect on the ear, such as carboplatin or cisplatin (for cancer treatment), chloroquine (to prevent and treat malaria) and some antibiotics (medicines to treat infections) such as erythromycin or intravenous aminoglycosides among others since this medicine could mask the toxic effects of these medicines, so you should have periodic check-ups on your ears.
- Medicines which decrease the elimination of others such as some antifungals (terbinafine), some antidepressants (fluoxetine and fluvoxamine), some medications to treat heartbeat problems (amiodarone), some medicines used to reduce lipids (gemfibrozil) or some medicines used to treat gastric ulcer (cimetidine), since they could increase the effect of this medicine.
- Some diuretics (medicines which promote the production of urine).
- Medicine which can have an effect on the heart such as those used for treating arrhythmias (irregular heartbeat), some antibiotics, certain medicines for malaria, certain antihistamines, certain medicines used to reduce lipids (fats) in the blood or certain neuroleptics (medicines for the treatment of mental disorders).
- Medicines which have a photosensitizing effect (increased reaction of the skin when exposed to sunlight) such as some antiarrhythmics (amiodarone, quinidine), some antibiotics (tetracyclines, fluoroquinolones azithromycin, and erythromycin, among others), some antidepressants (imipramine, doxepin, amitriptyline), some antifungals (griseofulvin), antihistamines (promethazine, chlorphenamine, and diphenhydramine, among others), some anti-inflammatory agents (piroxicam, and naproxen, among others), some antivirals (amantadine, ganciclovir), some diuretics (furosemide, chlorothiazide) because it can cause an additive photosensitizing effect.
- Levodopa since the pyridoxine contained in this medicine could reduce its effect.
- Medicine for the treatment of epilepsy (phenobarbital, phenytoin) as pyridoxine could decrease their levels in the blood.
- Medicines such as hydroxyzine, isoniazid or penicillamine, since their combination with pyridoxine could cause vitamin B6 deficiency.

Xonvea MR with alcohol

Do not drink alcohol while taking Xonvea MR . See section 3 for information about how to take Xonvea MR .

Pregnancy and breast-feeding

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

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Xonvea MR contains Allura Red AC Aluminum Lake (E129) which is an azo colouring agent.
Xonvea MR contains Allura Red AC Aluminum Lake (E129) which may cause allergic reactions.

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

3. How to take Xonvea MR

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 MR and increase your dose, if needed:

- **Day 1**
 - Take 1 tablet, by mouth at bedtime.
- **Day 2**
 - Take 1 tablet, by mouth at bedtime.
 - If your nausea and vomiting is better or controlled on Day 2, continue to take 1 tablet every night at bedtime.
- **Day 3**
 - If you still had nausea and vomiting on Day 2, take 1 tablet in the morning and 1 tablet at bedtime, by mouth on Day 3 (for a total of 2 tablets per day).

Do not take more than 2 tablets each day (1 in the morning and 1 at bedtime).

Some women may achieve symptom control at intermediary doses of 30mg/30mg. This dose is not achievable with Xonvea MR 20mg/20mg. Other formulations of doxylamine hydrogen succinate/pyridoxine hydrochloride are available which provide for greater flexibility to dose adjust according to severity of symptoms. With Xonvea MR 20mg/20mg modified-release tablet formulation, the maximum daily recommended dosing of 40mg/40mg consists of only two tablets daily.

Taking this medicine

- Take Xonvea MR 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 MR tablets whole, tell your doctor, pharmacist.

Use in children and adolescents

Xonvea MR is not recommended for use in children under 18 years old, due to lack of clinical data.

If you take more Xonvea MR than you should

If you take more Xonvea MR than you should, stop taking Xonvea MR 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 MR and talk to a doctor or go to a hospital straight away.

If you stop taking Xonvea MR

Do not stop taking Xonvea MR 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
- increased bronchial secretion
- dry mouth.

Uncommon: may affect up to 1 in 100 people

- confusional state
- eye-related problems: glaucoma, double vision (diplopia)
- ringing in the ears (tinnitus)
- head rush due to change of posture (rapid standing from a sitting or lying position)
- nausea, vomiting
- photosensitivity reactions
- swelling of the arms and legs
- weakness

Rare: may affect up to 1 in 1000 people

- shakiness, convulsion or agitation
- blood problems such as haemolytic anaemia

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, 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
- difficulty breathing (dyspnoea)

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; difficulties or pain with passing urine; sensation of spinning dizziness; problems with eyesight or blurred vision; double vision (diplopia); ringing or humming in the ears (tinnitus); inflammation of the inner ear which

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develops within a short time (acute labyrinthitis); difficulty in sleeping (insomnia); shaking (tremors) and nervousness; feeling irritable; 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; sweating and feeling chills; early menses; altered state of mind such as hallucinations, delusions, confusion and disturbed thoughts (toxic psychosis); headaches; tingling, pricking or numbness of skin; or feeling faint have been reported.

- Rarely, low levels of white blood cells (leukopenia and 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. Website: www.hpra.ie

5. How to store Xonvea MR

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 MR contains

- The active substances are doxylamine hydrogen succinate (an antihistamine) and pyridoxine hydrochloride (vitamin B₆). Each tablet contains 20 mg of doxylamine hydrogen succinate and 20 mg of pyridoxine hydrochloride.
- The other ingredients are, ammonium hydroxide 28% (E527), carnauba wax, croscarmellose sodium, hypromellose (E464), indigo carmine aluminium lake (E132), iron oxide red, macrogol (3350) (E1521), magnesium stearate, magnesium trisilicate, methacrylic acid-ethyl acrylate copolymer (1:1), microcrystalline cellulose, allura red AC aluminium lake (E129), propylene glycol (E1520), polyvinyl alcohol-part. hydrolyzed, silica colloidal anhydrous, shellac (E904), simeticone, Simeticone emulsion, sodium hydrogen carbonate (E500), sodium lauryl sulfate (E487), talc (E553b), titanium dioxide (E171), triethyl citrate.

What Xonvea MR looks like and contents of the pack

- Xonvea MR modified-release tablets are pink, round, and film-coated with a pink image of a pregnant woman on one side and the letter “D” on the other side.
- Xonvea MR is available in blister packs containing 10, 20, 30 or 40 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Manufacturer

Laboratorios Liconsa
Avda. de Miralcampo 7,
Pol. Ind. Miralcampo, 19200
Azuqueca de Henares (Guadalajara)
Spain

This medicine is authorised in the Member States of the European Economic Area under the following names:

| | |
|-------------|---|
| Ireland | Xonvea MR 20mg /20mg modified-release tablets |
| Estonia | Xonvea 20 mg/20 mg toimeainet modifitseeritud vabastavad tabletid |
| Lithuania | Xonvea 20mg /20mg modified-release tablets |
| Latvia | Xonvea 20 mg/20 mg modificētās darbības tabletes |
| Slovakia | Xonvea 20 mg/20 mg tablety s riadeným uvoľňovaním |
| Czechia | Xonvea |
| Spain | Bonjesta 20 mg/20 mg comprimidos de liberación modificada |
| France | BONJESTA 20 mg/ 20 mg, comprimé à libération modifiée |
| Italy | Bonjesta |
| Portugal | Bonjesta |
| Austria | Xonvea 20 mg/20 mg Tablette mit veränderter Wirkstofffreisetzung |
| Netherlands | Embagyn 20 mg/20 mg tabletten met gereguleerde afgifte |
| Luxembourg | Bonjesta 20/20 |
| Hungary | Vombee 20/20 mg módosított hatóanyagleadású tablettá |

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