

## **Bijsluiter: informatie voor de gebruiker**

### **Embagyn 20 mg/20 mg tabletten met gereguleerde afgifte**

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

#### **1. What Embagyn is and what it is used for**

##### **What Embagyn is**

Embagyn **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 B<sub>6</sub>.

##### **What Embagyn is used for**

Embagyn 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 Embagyn**

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

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Embagyn 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 Embagyn if:

- you are taking cough or cold medicines, sleeping medicines or certain pain medicines (also refer to ‘Other medicines and Embagyn 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 Embagyn.

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

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

Embagyn 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 Embagyn 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**

- Embagyn 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 Embagyn while taking cough and cold medicines, sleeping medicines, certain pain medicines or if you have been drinking alcohol. Taking Embagyn 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 Embagyn 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 Embagyn**

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 Embagyn 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, procabazine 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 azole (antifungals such as fluconazole, ketoconazole, and itraconazole) or macrolide (antibiotics such as clarithromycin, azithromycin, and erythromycin) derivatives, 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.

### **Embagyn with alcohol**

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

### **Pregnancy and breast-feeding**

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

**Embagyn** contains Allura Red AC Aluminum Lake (E129) which is an azo colouring agent.

**Embagyn** 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 Embagyn**

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 Embagyn 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 Embagyn 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 Embagyn 20mg/20mg modified-release tablet formulation, the maximum daily recommended dosing of 40mg/40mg consists of only two tablets daily.

#### **Taking this medicine**

- Take Embagyn 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 Embagyn tablets whole, tell your doctor, pharmacist.

#### **Use in children and adolescents**

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

#### **If you take more Embagyn than you should**

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

#### **If you stop taking Embagyn**

Do not stop taking Embagyn 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 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](http://www.hpra.ie)

## 5. How to store Embagyn

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 Embagyn contains

- The active substances are doxylamine hydrogen succinate (an antihistamine) and pyridoxine hydrochloride (vitamin B<sub>6</sub>). 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 Embagyn looks like and contents of the pack

- Embagyn 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.
- Embagyn is available in blister packs containing 10, 20, 30 or 40 tablets. Not all pack sizes may be marketed.

### Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:

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

Fabrikant:

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

**Dit medicijn is in het register ingeschreven onder:**

RVG 128835

**Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:**

Ierland	Xonvea MR 20/20 modified-release tablets
Estland	Embagyn
Litouwen	Xonvea 20mg /20mg modifikuoto atpalaidavimo tabletės
Letland	Embagyn 20 mg/20 mg modified-release tablets
Slowakije	Xonvea
Tsjechië	Xonvea
Spanje	Bonjesta 20 mg/20 mg comprimidos de liberación modificada
Frankrijk	BONJESTA 20 mg/ 20 mg, comprimé à libération modifiée
Italië	Bonjesta
Portugal	Bonjesta
Oostenrijk	Xonvea 20 mg/20 mg Tablette mit veränderter Wirkstofffreisetzung
Nederland	Embagyn
Luxemburg	Bonjesta 20/20
Hongarije	Vombee 20/20

**Deze bijsluiter is voor het laatst goedgekeurd in juli 2023.**