Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil
Bealach amach 5, M50, An Bóthar Thuaidh, Fionnghlas
Baile Átha Cliath 11, D11 XKF3
Fón: (01) 864 7100 Facs: (01) 834 3589

Health Service Executive, Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: (01) 864 7100 Fax: (01) 834 3589

3rd January 2023

Circular 001/23

RE: Cariban® (doxylamine/pyridoxine)

Dear Pharmacist,

As part of Budget 2023, the Minister announced funding for Women's Health Initiatives in 2023, to include dedicated funding for Cariban® (doxylamine/pyridoxine). Cariban® is an Exempt Medicinal Product i.e. not licensed with the Health Products Regulatory Authority (HPRA) in Ireland. Following the recommendations of the HSE Medicines Management Programme (MMP), this product will be made available on an individual patient basis for those patients who meet the criteria under Community Drug Schemes (GMS, DPS) from 1st January 2023 where Consultant Obstetrician initiated.

Under Community Drug Schemes, Exempt Medicinal Products must be Consultant initiated. However, whilst the original prescriber is a Consultant and specialist in the relevant field, the HSE will accept a GP prescription further to the initial hospital prescription for approved patients.

In order to approve reimbursement of Cariban®, by exceptional arrangements, the prescribing Hospital Consultant must complete an application for individual reimbursement of Cariban® (enclosed). The completed application form is submitted to PCRS via email: PCRS.ExemptMed@hse.ie.

Claims can be submitted for approved patients using the administrative code below. Claims for patients who are not approved will not be paid.

Administrative Code	Drug Name	Pack Size	Pharmaceutical Form	Reimbursement Price
66892	Cariban 10mg/10mg modified release	24	hard capsules	€34.90

Yours faithfully,

Shaun Flanagan
Assistant National Director
Primary Care Reimbursement Service

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Case Reference	*Date Received*

Application for Individual Reimbursement of Cariban® (unlicensed) by Consultant Obstetricians

Date of Application:	Nominated Community Pharmacy: (Name & address – *leave blank if uncertain)*
In order to approve reimbursement of this medicine, by exceptional arrangements, the prescribing consultant must provide the following information and submit to the Primary Care Reimbursement Service (PCRS). **Unlicensed Product Declaration** Cariban® is an unlicensed medicine. Licensed medicines should be used where possible. This individual is aware that this product is unlicensed and I, the prescriber, believe this is the best therapeutic option for this person at this time. ☐ **Yes** ☐ **No**	

Name of Prescribing Consultant	
Medical Council No.	
Contact Details:	Hospital & Address:
	Telephone:
	Email:

Patient name	
Date of birth	D D M M Y Y Y Y
Community Identifier Number **(**Please tick and insert number)	GMS ☐ DPS ☐ LTI ☐ Number: _____ PPSN : _____ *(if community identifier unknown)*

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Patient Clinical History

Please indicate whether the patient meets the following criteria (*please tick which apply and complete requested detail*):

1. This individual has nausea and vomiting of pregnancy (NVP) which, in my opinion, requires systemic treatment**.** **Yes** ☐ **No** ☐

2. This individual has been assessed using the pregnancy unique quantification of emesis and nausea (PUQE) assessment tool and the appropriate treatment algorithm has been followed.

   Yes ☐ **No** ☐

3. This individual has not responded to conservative management.

   Yes ☐ **No** ☐

Recommended Treatment Protocol

- The recommended starting dose of Cariban® is two capsules at bedtime if nausea and vomiting occurs in the morning (Day 1). If this dose controls the symptoms, this dose should be continued. However, if symptoms persist until the afternoon of Day 2, the individual should continue with the usual dose of two capsules at bedtime (Day 2) and on Day 3 take one capsule in the morning and two capsules at bedtime. If these three capsules do not adequately control the symptoms on Day 3, the individual can take one capsule in the morning, one capsule in the middle of the afternoon and two capsules at bedtime.
- The maximum daily dose of Cariban® is four capsules daily: one capsule in the morning, one capsule in the middle of the afternoon and two capsules at bedtime.
- A maximum quantity of 120 tablets per month, for a maximum period of three months will be reimbursed.
- Application for continued reimbursement support in cases where NVP continues beyond this time period would be required.
- The delayed-release formulation permits the antiemetic action to occur 4-6 hours after ingestion, therefore the bedtime dose is effective in the early morning, the morning dose is effective in the afternoon and the afternoon is effective in the evening-providing 24-hour control of NVP if necessary.

4. This person will be treated as per protocol above. **Yes** ☐ **No** ☐

5. This patient has been provided with written information in English regarding the appropriate use of Cariban®[i]. **Yes** ☐ **No** ☐

[i]Available at: https://cima.aemps.es/cima/dochtml/p/44139/P_44139.html **Note:** only certain browsers can translate the above patient information into English e.g. Microsoft Edge and Google Chrome.

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Additional space for supporting information

Signature of Prescribing Consultant _____

Institution _____

Date: _____

Data Protection Notice

- The information on this form will be used by the Health Service Executive (H.S.E.) to assess the suitability of the items listed to be provided under Section 23 of the Health (Pricing and Supply of Medical Goods) Act 2013.
- Details of prescription items dispensed to the named person may be notified to the H.S.E. by the dispensing pharmacist to ensure that the named person receives the items required.
- The named person may access information relating to themselves only, on prescription claims processed in their name by the H.S.E.
- We may share information with the Department of Health, healthcare practitioners and other healthcare bodies.
- We may also disclose information to other parties if the law requires us to do so.
- The PCRS Privacy Statement can be located at www.pcrs.ie

Completed forms should be submitted to:
Pharmacy Function Unit, Primary Care Reimbursement Service (PCRS), Exit 5, M50, North Rd, Finglas, Dublin 11, D11 XKF3
Or email PCRS.ExemptMed@hse.ie