



Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: 01- 8647100

Jennifer Whitmore, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

5th March, 2021

PQ: 9487/21

To ask the Minister for Health if a drug (details supplied) is being considered by the HSE drugs payment group for reimbursement; and if so, the status of the application. -Jennifer Whitmore.

Cariban; Used in treatment of women suffering extreme nausea /Hyperemesis gravidarum during pregnancy.

Dear Deputy Whitmore,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 9487/21), which you submitted to the Minister for Health for response.

Cariban (doxylamine / pyridoxine) is an unlicensed product that is not reimbursable under GMS and Community Drug Schemes. Only licensed products are added to the formal GMS Reimbursement List in line with the Health (Pricing and Supply of Medical Goods) Act 2013.

Xonvea (doxylamine / pyridoxine) is the licensed product with the Health Products Regulatory Authority (HPRA) in Ireland indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management. Xonvea is currently undergoing formal pricing and reimbursement assessment <http://www.ncpe.ie/drugs/doxylamine-pyridoxine-xonvea/>.

Under the legislation there are formal processes which govern applications for the pricing and reimbursement of medicines. The HSE does not reimburse medicines or agree reimbursement terms in advance of the completion of the required processes. The HSE does not intend to reimburse Cariban under Community Drug Schemes or Discretionary Hardship Arrangements. As there is a licensed product now available in Ireland going through the formal process, the clinical evidence for this product will be examined as part of the national pricing and reimbursement assessment.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Suzanne Doyle'.

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service