All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

Final Appraisal Recommendation

Advice No: 3814 – November 2014

Leuprorelin acetate (Prostap® SR DCS/Prostap® 3 DCS) 3.75 mg and 11.25 mg powder and solvent for prolonged-release suspension for injection in pre-filled syringe

Limited submission by Takeda UK Ltd

Recommendation of AWMSG

Leuprorelin acetate (Prostap® SR DCS/Prostap® 3 DCS) is recommended as an option for use within NHS Wales as neoadjuvant treatment prior to radiotherapy in patients with high risk localised or locally advanced prostate cancer.

Additional note(s):

- Please refer to the Summary of Product Characteristics for the full licensed indication.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 2419), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.

Marketing authorisation holder on first issue	Takeda UK Ltd
Date of first issue	November 2014
Last reviewed	December 2017