FOI 23/864

Dear

Thank you for your email dated 09 November 2023 where you asked-

> *"I would be much obliged if you could please provide us with the PAR for PL 00057/1019 - Noriday 350 microgram Tablets and PL 00057/1054 - Utovlan 5mg tablets …*
>
> *Please be informed that these are not available on the MHRA Products website.."*

Our response:

We do not hold public assessment reports (PARs) for these products as they were approved before the legislation requiring MHRA to publish PARs.

PL 00057/1019 Noriday 350 microgram tablets
Noriday was approved by a change of ownership (COA) application on 30 July 2010. It was originally approved on 21 March 1996 (PL 08221/0036) as a simple abridged application, under Article 4.8a(i) of Directive 65/65/EEC (as amended), referring to PL 00286/0024R.

PL 00057/1054 Utovlan 5mg tablets
Utovlan was approved by a COA on 18 September 2013. It was first authorised on 29 March 1996 (PL 08821/0043) as a simple abridged application, under Article 4.8a(i) of Directive 65/65/EEC (as amended), referring to PL 00286/5007R.

Please be advised if you wish to establish what could be a suitable reference product for the actives as mentioned, please send a query to ris.na@mhra.gov.uk who should be able to advise you further.

Kind regards
HQA FOI Team