Theramex
Sloane Square House
1 Holbein Place
London SW1W 8NS
info@theramex.com

Healthcare Professional Communication

20 December 2021

Evorel Sequi (estradiol, norethisterone acetate): discrepancy in Marketing Authorisation Number on the Evorel 50 pouch (PL 49105/0006) within the Evorel Sequi carton (PL 49105/0010) for a limited number of new batches.
This is an update to the letter dated 23rd June 2021 since further batches have been included.

Dear Healthcare Professional,

Theramex HQ UK Limited, in agreement with MHRA, would like to inform you of the following: There is a discrepancy between the marketing authorisation number on the Evorel 50 pouch (PL 49105/ 0006} within the Evorel Sequi carton (PL 49105/0010) for a limited number of batches.

Summary
For the Evorel 50 batches listed below, the Marketing Authorisation number detailed on the Evorel 50 pouch (PL 49105/0006) within the Evorel Sequi carton will differ from the Marketing Authorisation number on the Evorel Sequi carton (PL 49105/0010).

The Evorel 50 batch number is: BN: 591240A
Evorel Sequi carton batch numbers that will contain the above Evorel 50 pouches are:

5912407	**5912408**	**5912409**

These batches will be on the market in December 2021 and January 2022.

The discrepancy in the MA number is to support the supply of the product and has no impact on the quality of the product.

There is no change to the Patient Information Leaflet related to the administration, posology, therapeutic indications, safety and usage instructions.

Overall, there is no impact on safety and efficacy of the product.

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Background to the safety issue

Evorel Sequi is indicated for hormone replacement therapy (HRT) for oestrogen deficiency symptoms in peri- and post-menopausal women and prevention of osteoporosis in post-menopausal women at high risk of future fractures who are intolerant of, or contraindicated for, other medicinal products approved for the prevention of osteoporosis. The experience treating women older than 65 years is limited.

Evorel Sequi is a transdermal therapy composed of:

- Evorel Conti (3.2 mg of estradiol / 11.2 mg of norethisterone acetate, corresponding to a nominal release of 50 mcg of estradiol/ 24 hrs and 11.2 mg of norethisterone acetate, corresponding to a nominal release of 170 mcg of norethisterone acetate/ 24 hrs).
- Evorel 50 (3.2 mg of estradiol, corresponding to a nominal release of 50 mcg of estradiol/24hrs).

In order to ensure maximum product availability during the relaunch of the Evorel range of patches,Theramex manufactured an excess of Evorel 50 pouches last year. Following the stabilisation of demand for Evorel 50, these excess pouches will now be utilised within Evorel Sequi carton.

The reason for disseminating the DHPC at this point in time is to ensure transparency to the patient and alleviate any concerns which may be caused by the differing numbers.

Call for reporting

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Cardscheme.

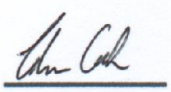
You can report via:

- the Yellow Card website www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 7316789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours. When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Company contact details

Should you require any further information, pls contact:medinfo.uk@theramex.com

Signed: 

John Cook
Director, Quality