EVOREL® 25,50,75,100 (estradiol/patch) Abbreviated Prescribing Information

Please consult the Summary of Product Characteristics for other adverse reactions and full prescribing information

Presentation: Evorel 25: 1.6mg estradiol patch; Evorel 50: 3.2mg estradiol patch; Evorel 75: 4.8mg estradiol patch; Evorel 100: 6.4mg estradiol patch. **Indication:** Hormone Replacement Therapy (HRT) for oestrogen deficiency symptoms in peri- and post-menopausal women. Evorel 50, 75 and 100 only: 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. **Dosage & administration:** ***Adults:*** Evorel is an oestrogen-only HRT patch applied to the skin twice weekly. For initiation and continuation of treatment of menopausal symptoms, the lowest effective dose for the shortest duration should be used. For women with an intact uterus progestogen should normally be added to Evorel for the prevention of adverse endometrial effects, e.g. hyperplasia and cancer. The regimen may be either cyclic or continuous sequential. Only progestogens approved for addition to oestrogen treatment may be prescribed (e.g. oral norethisterone, 1mg/day or medroxyprogesterone acetate, 2.5mg/day) and should be added for at least 12-14 days every month/28-day cycle. Unless there is a previous diagnosis of endometriosis, it is not recommended to add a progestogen in hysterectomised women. ***Treatment of oestrogen deficiency symptoms:*** Therapy should be started with one Evorel 50 patch (delivering 50 µg of estradiol/24 hours) and the dose adjusted after the first month if necessary, depending on efficacy and signs of over-oestrogenisation. For maintenance therapy the lowest effective dose should be used; a maximum dose of 100 µg of estradiol/24 hours should not be exceeded. ***Evorel 50, 75, 100: Prevention of post-menopausal osteoporosis:*** Therapy should be started with Evorel 50. The dose may be adjusted depending on efficacy and signs of over-oestrogenisation. The efficacy of Evorel 25 for the prevention of post- menopausal osteoporosis has not been demonstrated. For maintenance therapy, the lowest effective dose should be used. A dose of 100 µg of estradiol/24 hours should not be exceeded. ***Guidance on how to start therapy:*** Post-menopausal women currently not on HRT may start Evorel at any time. Peri-menopausal women who are still having regular menstrual cycles and are not currently on HRT should start Evorel within 5 days of the start of bleeding. Peri-menopausal women with irregular menstrual cycles, for whom pregnancy has been excluded, can start Evorel at any time. ***Switching from other HRT:*** The switch from another oestrogen-only therapy in post-menopausal women to Evorel may occur at any time. Women on a continuous combined regimen wishing to switch from another oestrogen to Evorel may do so at any time. Women on a cyclic or continuous sequential regimen wishing to switch from a sequential combined HRT preparation to Evorel may do so at the end of a cycle of the current therapy or after a 7-day hormone free interval. ***Method of Administration:*** Evorel should be applied to the skin as soon as it is removed from the wrapper and should remain in place during bathing and showering. Recommended application sites are on clean, dry, healthy, intact skin and each application should be made to a slightly different area of skin on the trunk below waistline. Evorel Should not be applied on or near the breasts. ***Missed Dose*****:** If the patient forgets to change their patch, they should change it as soon as possible and apply the next one at the normal time. However, if it is almost time for the next patch, the patient should skip the missed one and go back to their regular schedule. Only one patch should be applied at a time. There is an increased likelihood of break-through bleeding and spotting when a patch is not replaced at the normal time. ***Children*****:** Not indicated. ***Elderly:*** Data are insufficient in the elderly (>65 years old). ***Route of administration:*** Transdermal use. **Contraindications:** Known, current or past or suspected breast cancer. Known or suspected oestrogen-dependent malignant tumours. Undiagnosed genital bleeding. Untreated endometrial hyperplasia. Previous or current venous thrombo-embolism (VTE). Known thrombophilic disorders. Active or recent past arterial thrombo-embolic (ATE) disease. Acute liver disease, or a history of liver disease if liver function tests have failed to return to normal. Known hypersensitivity to the active substances or to any of the excipients. Porphyria. **Special warnings and precautions for use:** For the treatment of menopausal symptoms, HRT should only be initiated for symptoms that adversely affect quality of life. Before initiating or re-instituting HRT, a complete personal and family medical history should be taken. Physical (including pelvic and breast) examination should be guided by this and by the contraindications and warnings for use. ***Conditions which need supervision:*** If any of the following conditions are present, occurred previously, have been aggravated during pregnancy or previous hormone treatment, supervise patient closely. Conditions may recur or be aggravated during treatment, in particular: Leiomyoma or endometriosis, risk factors for thrombo-embolic disorders, risk factors for oestrogen dependent tumours, hypertension, liver disorders, diabetes mellitus with or without vascular involvement, cholelithiasis, migraine or (severe) headache, systemic lupus erythematosus, history of endometrial hyperplasia, epilepsy, asthma, otosclerosis, hereditary angioedema and mastopathy. ***Conditions which require monitoring while on oestrogen therapy:*** Oestrogens may cause fluid retention. Cardiac or renal dysfunction should be carefully observed. Disturbances or mild impairment of liver function. History of cholestatic jaundice. Pre-existing hypertriglyceridaemia. Rare cases of large increases of plasma triglycerides leading to pancreatitis have been reported with oestrogen therapy in this condition. ***Therapy should be discontinued if a contraindication is discovered and in the following situations:*** jaundice/deterioration in liver function, significant increase in blood pressure, new onset of migraine-type headache, pregnancy. For Evorel 75 and 100 the endometrial safety of added progestogens has not been studied. ***Special warnings and precautions for use are also required in respect to:*** Endometrial hyperplasia and carcinoma, Breast cancer, Ovarian cancer, Venous thrombo-embolism, Coronary Artery disease, Ischaemic stroke – please refer to the SmPC for full details. **Interactions:** The metabolism of oestrogens (and progestogens) may be increased by concomitant use of substances known to induce drug-metabolising enzymes, specifically cytochrome P450 enzymes, such as anticonvulsants, anti-infectives and bosentan. Ritonavir, nelfinavir and herbal preparations containing St. John's Wort may induce the metabolism of oestrogens and progestogens. Clinically, an increased metabolism of oestrogens and progestogens may lead to decreased effect and changes in the uterine bleeding profile. Oestrogen-containing oral contraceptives have been shown to significantly decrease plasma concentrations of lamotrigine when co-administered due to induction of lamotrigine glucuronidation. This may reduce seizure control. Therefore, dose adjustment of lamotrigine may be necessary. **Pregnancy and lactation:** Not indicated. **Side effects:** Adverse reactions observed in clinical trials: **Very common** (≥1/10)**:** Application site pruritus, Application site rash. **Common** (≥1/100 to <1/10)**:** Depressed mood, Migraine, Dizziness, Headache, Abdominal pain, Diarrhoea, Nausea, Pruritus, Rash, Arthralgia, Breast pain, Metrorrhagia, Pain, Application site erythema, Application site oedema, Application site reaction, Weight change. **Uncommon** (≥1/1,000 to <1/100)**:** Genital candidiasis, Hypersensitivity, Palpitations, Flatulence, Myalgia, Dysmenorrhoea, Breast enlargement, Oedema Generalised Oedema. **Rare** (≥1/10,000 to <1/1,000)**:** Breast cancer, Epilepsy, Thrombosis, Abdominal distension, Cholelithiasis, **Frequency not known** (cannot be estimated from the available clinical trial data)**:** Endometrial cancer**,** Cerebrovascular accident, Myocardial infarction, Deep vein thrombosis, Pulmonary embolism, Angioedema. **Overdose:** Effects can if necessary be reversed by removal of the patch. **Package Quantities & Cost:** Each Evorel patch size is presented in a sealed protective pouch. The pouches are packed in a cardboard carton. Cost: 25 (1x8) £4.07; 50 (1x8) £4.62; 50 (1x24) £13.87; 75 (1x8) £4.90; 100 (1x8) £5.09. **Marketing authorisation number:** Evorel 25 PL 49105/0005; Evorel 50 PL 49105/0006; Evorel 75 PL 49105/0007; Evorel 100 PL 49105/0008. **Marketing authorisation holder:** Theramex HQ UK Limited, 50 Broadway, 5th Floor, London, SW1H 0BL, UK.

Legal classification: POM. **Date of Preparation:** October 2024. EVOR_UK_EN_20241_v1(V1.3)

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EVOREL® Conti (estradiol hemihydrate norethisterone acetate) Abbreviated Prescribing Information

Please consult the Summary of Product Characteristics (SmPC) for other adverse reactions and full prescribing information

Presentation: Evorel Conti 3.2 mg of estradiol hemihydrate, 11.2 mg of norethisterone acetate transdermal patch. **Indication:** Hormone Replacement Therapy (HRT) for oestrogen deficiency symptoms in postmenopausal women more than 6 months post-menopause (or 18 months since last period). Prevention of osteoporosis in postmenopausal women at high risk of future fractures who are intolerant of, or contraindicated for, other medicinal products approved for the prevention of osteoporosis. **Dosage & administration:** ***Adults:*** Evorel Conti is a continuous combined HRT preparation. Patches are applied to the skin twice weekly. One Evorel Conti patch should be worn at all times, without interruptions. For initiation and continuation of treatment of menopausal symptoms, the lowest effective dose for the shortest duration should be used. ***Guidance on how to start therapy:*** Post-menopausal women currently not on HRT may start Evorel Conti at any time. ***Switching from other HRT:*** Women on a continuous combined regimen wishing to switch from another oestrogen to Evorel Conti may do so at any time. Women on a cyclic or continuous sequential regimen wishing to switch from a sequential combined HRT preparation to Evorel Conti may do so at the end of a cycle of the current therapy or after a 7-day hormone free interval. Unless there is a previous diagnosis of endometriosis, it is not recommended to add a progestogen in hysterectomised women. **Method of Administration:** The sachet containing one Evorel Conti patch should be opened and one part of the protective foil removed at the S- shaped incision. The patch should be applied to clean, dry, healthy, intact skin as soon as it is removed from the sachet. The patient should avoid contact between fingers and the adhesive part of the patch during application. Each application should be made to a different area of the skin, on the trunk below the waist. The patch should not be applied on or near the breasts and should remain in place during bathing and showering. Should a patch fall off, it should be replaced immediately with a new patch, however the usual day of changing Evorel Conti patches should be maintained. **Missed Dose**: If the patient forgets to change their patch, they should change it as soon as possible and apply the next one at the normal time. However, if it is almost time for the next patch, the patient should skip the missed one and go back to their regular schedule. Only one patch should be applied at a time. Wearing a patch for > 4 days by mistake or any period without a patch may increase the likelihood of breakthrough bleeding or spotting. ***Children*****:** Not indicated. ***Elderly:*** Data are insufficient in the elderly (>65 years old). ***Route of administration:*** Transdermal use. **Contraindications:** Known, past or suspected breast cancer. Known or suspected oestrogen-dependent malignant tumours or pre-malignant tumours. Undiagnosed genital bleeding. Untreated endometrial hyperplasia. Previous idiopathic or current venous thrombo-embolism (VTE). Active or recent past arterial thrombo-embolic (ATE) disease. Known thrombophilic conditions. Acute liver disease, or a history of liver disease if liver function tests have failed to return to normal. Known hypersensitivity to the active substances or to any of the excipients. Porphyria. **Special warnings and precautions for use:** For the treatment of menopausal symptoms, HRT should only be initiated for symptoms that adversely affect quality of life with careful appraisal of the risks and benefits at least annually. Evidence regarding the risks associated with HRT in the treatment of premature menopause is limited. Before initiating or re-instituting HRT, a complete personal and family medical history should be taken and together with contra-indications and warnings for use, should guide physical (including pelvic and breast) examination. ***Conditions which need supervision:*** If any of the following conditions are present, occurred previously, have been aggravated during pregnancy or previous hormone treatment, supervise patient closely. Conditions may recur or be aggravated during treatment, in particular: Leiomyoma or endometriosis, a history of, or risk factors for thrombo-embolic disorders, risk factors for oestrogen dependent tumours, hypertension, liver disorders, diabetes mellitus with or without vascular involvement, cholelithiasis, migraine or (severe) headache, systemic lupus erythematosus, history of endometrial hyperplasia, epilepsy, asthma, otosclerosis and mastopathy. ***Conditions which require monitoring while on oestrogen therapy:*** Oestrogens may cause fluid retention. Cardiac or renal dysfunction should be carefully observed. Disturbances or mild impairment of liver function. History of cholestatic jaundice. Pre-existing hypertriglyceridaemia. Rare cases of large increases of plasma triglycerides leading to pancreatitis have been reported with oestrogen therapy in this condition. ***Therapy should be discontinued if a contraindication is discovered and in the following situations:*** jaundice/deterioration in liver function, significant increase in blood pressure, new onset of migraine-type headache, pregnancy. ***Special warnings and precautions for use are also required in respect to:*** Endometrial hyperplasia and carcinoma, Breast cancer, Ovarian cancer, Venous thrombo-embolism, Coronary Artery disease, Ischaemic stroke, Hypothyroidism, Angioedema – please refer to the SmPC for full details. **Interactions:** The metabolism of oestrogens and progestogens may be increased by concomitant use of substances known to induce drug-metabolising enzymes, specifically cytochrome P450 enzymes, such as anticonvulsants, anti-infectives and bosentan. Ritonavir, telaprevir, nelfinavir and herbal preparations containing St. John's Wort may induce the metabolism of oestrogens and progestogens. Clinically, an increased metabolism of oestrogens and progestogens may lead to decreased effect and changes in the uterine bleeding profile. Oestrogen-containing oral contraceptives have been shown to significantly decrease plasma concentrations of lamotrigine when co-administered due to induction of lamotrigine glucuronidation. This may reduce seizure control. Therefore, dose adjustment of lamotrigine may be necessary. **Fertility**, **Pregnancy and lactation:** Not indicated, treatment should be withdrawn immediately. Data on a limited number of exposed pregnancies indicate adverse effects of norethisterone on the foetus. At doses higher than normally used in oral contraceptives and HRT formulations, masculinisation of female foetuses was observed. **Side effects:** Adverse reactions observed in clinical trials: **Very common** (≥1/10)**:** Application site erythema, Application site pruritus, Application site rash, Application site reaction, breast tenderness. **Common** (≥1/100 to <1/10)**:** Hypersensitivity**,** Depression, Insomnia, Anxiety, Nervousness, Paraesthesia, Headache, Palpitations, Hypertension, Varicose veins, Vasodilation, Abdominal pain, Diarrhoea, Nausea, Rash erythematous, Arthralgia, Back pain, Breast pain, Cervical polyp, Endometrial hyperplasia, Genital discharge, Dysmenorrhoea, Menorrhagia, Menstrual disorder, Metrorrhagia, Pain, Oedema, Application site oedema, Fatigue, Weight increased, Affect lability, Dyspepsia, Acne, Dry skin, Pain in extremity, Uterine spasms, Vaginal infection. **Uncommon** (≥1/1,000 to <1/100) **include:** Candidiasis, Migraine, Myalgia, Generalised Oedema, Oedema peripheral, Transaminases increase. **Rare** (≥1/10,000 to <1/1,000)**:** Epilepsy, Thrombosis, Gallbladder disorder, Myasthenia, Uterine leiomyoma, fallopian tube cysts. **Very rare** (<1/10,000): cholestatic jaundice **Frequency not known include** (cannot be estimated from the available clinical trial data)**:** Breast neoplasms, Endometrial cancer**,** Cerebrovascular accident, Deep vein thrombosis, Pulmonary embolism, Abdominal distension, Cholelithiasis, Stevens-Johnson syndrome. **Package Quantities & Cost:** Each carton box has 8 or 24 Transdermal Delivery Systems in individual foil-lined sachets. Cost – 1x8 £15.47; 1x24 £44.28. **Marketing authorisation number:** PL 49105/0009 **Marketing authorisation holder:** Theramex HQ UK Limited, 50 Broadway, 5th Floor, London, SW1H 0BL, UK. **Legal classification:** POM. **Date of Preparation:** October 2024: EVOR_UK_EN_20239_v1(v1.3).

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EVOREL® Sequi (estradiol hemihydrate norethisterone acetate) Abbreviated Prescribing Information

Please consult the Summary of Product Characteristics (SmPC) for other adverse reactions and full prescribing

Presentation: Evorel Sequi is a transdermal therapy comprising a) 4 Evorel 50 Transdermal Delivery Systems (TDSs), each containing: 3.2 mg of estradiol hemihydrate. b) 4 Evorel Conti TDSs, each containing: 3.2 mg of estradiol hemihydrate, 11.2 mg of norethisterone acetate. **Indication:** Hormone Replacement Therapy (HRT) for oestrogen deficiency symptoms in peri- and post-menopausal women. Prevention of osteoporosis in postmenopausal women at high risk of future fractures who are intolerant of, or contraindicated for, other medicinal products approved for the prevention of osteoporosis. **Dosage & administration:** ***Adults:*** Evorel Sequi is a continuous sequential HRT preparation. Patches are applied to the skin twice weekly. One Evorel Sequi patch should be worn at all times, without interruptions. For initiation and continuation of treatment of menopausal symptoms, the lowest effective dose for the shortest duration should be used. ***Guidance on how to start therapy:*** Any previous therapy with HRT must be stopped prior to starting Evorel Sequi. Post-menopausal women currently not on HRT may start Evorel Sequi at any time. Peri-menopausal women who are still having regular menstrual cycles and are not currently on HRT should start Evorel Sequi within 5 days of the start of bleeding. Peri-menopausal women with irregular menstrual cycles, for whom pregnancy has been excluded, can start Evorel Sequi at any time. ***Switching from other HRT:*** Women on a continuous combined regimen wishing to switch from another oestrogen to Evorel Sequi may do so at any time. Women on a cyclic or continuous sequential regimen wishing to switch from a sequential combined HRT preparation to Evorel Sequi may do so at the end of a cycle of the current therapy or after a 7-day hormone free interval. Unless there is a previous diagnosis of endometriosis, it is not recommended to add a progestogen in hysterectomised women. ***Method of Administration:*** A treatment cycle with Evorel Sequi is 28 days. During the first 14 days, one estradiol-only (Evorel 50) patch should be worn at all times without interruption. During days 15-28, one estradiol + norethisterone (Evorel Conti) patch should be worn and should remain in place during bathing and showering. A subsequent treatment cycle should follow immediately, without a treatment free interval. Patches should be applied to the trunk, below the waist. Patches should be changed twice a week, i.e. every three to four days. Application of a new patch should be to a site different from the previous application site. The patch should not be applied on or near the breasts. ***Missed dose:*** Change as soon as possible and apply the next one at normal time unless it is almost time for the next patch, then the patient should skip the missed one and return to regular schedule. Only one patch should be applied at a time. Wearing a patch for >4 days or any period without a patch may increase the likelihood of breakthrough bleeding or spotting. ***Children*****:** Not indicated. ***Elderly:*** Data are insufficient in the elderly (>65 years old). ***Route of administration:*** Transdermal use. **Contraindications:** Known, past or suspected breast cancer. Known or suspected oestrogen-dependent malignant tumours or pre-malignant tumours. Undiagnosed genital bleeding. Untreated endometrial hyperplasia, Previous idiopathic or current venous thrombo-embolism (VTE). Active or recent past arterial thrombo-embolic (ATE) disease. Acute liver disease, or a history of liver disease if liver function tests have failed to return to normal. Known thrombophilic conditions. Known hypersensitivity to the active substances or to any of the excipients. Porphyria. **Special warnings and precautions for use:** For the treatment of menopausal symptoms, HRT should only be initiated for symptoms that adversely affect quality of life with careful appraisal of the risks and benefits at least annually. Evidence regarding the risks associated with HRT in the treatment of premature menopause is limited. Before initiating or re-instituting HRT, a complete personal and family medical history should be taken and together with contra-indications and warnings for use, should guide physical (including pelvic and breast) examination. ***Conditions which need supervision:*** If any of the following conditions are present, occurred previously, have been aggravated during pregnancy or previous hormone treatment, supervise patient closely. Conditions may recur or be aggravated during treatment, in particular: Leiomyoma or endometriosis, a history of, or risk factors for, thrombo-embolic disorders or oestrogen dependent tumours, hypertension, liver disorders, diabetes mellitus, cholelithiasis, migraine or (severe) headache, systemic lupus erythematosus, history of endometrial hyperplasia, epilepsy, asthma, otosclerosis, hereditary angioedema and mastopathy. ***Conditions which require monitoring while on oestrogen therapy:*** Oestrogens may cause fluid retention. Cardiac or renal dysfunction should be carefully observed. Disturbances or mild impairment of liver function. History of cholestatic jaundice. Pre-existing hypertriglyceridaemia. Rare cases of large increases of plasma triglycerides leading to pancreatitis have been reported with oestrogen therapy in this condition. ***Therapy should be discontinued if a contraindication is discovered and in the following situations:*** jaundice/deterioration in liver function, significant increase in blood pressure, new onset of migraine-type headache, pregnancy. ***Special warnings and precautions for use are also required in respect to:*** Endometrial hyperplasia and carcinoma, Breast cancer, Ovarian cancer, Venous thrombo-embolism, Coronary Artery disease, Ischaemic stroke, Hypothyroidism, Angioedema – please refer to the SmPC for full details. **Interactions:** The metabolism of oestrogens and progestogens may be increased by concomitant use of substances known to induce drug-metabolising enzymes, specifically cytochrome P450 enzymes, such as anticonvulsants, anti-infectives and bosentan. Ritonavir, telaprevir, nelfinavir and herbal preparations containing St. John's Wort may induce the metabolism of oestrogens and progestogens. Clinically, an increased metabolism of oestrogens and progestogens may lead to decreased effect and changes in the uterine bleeding profile. Oestrogen-containing oral contraceptives have been shown to significantly decrease plasma concentrations of lamotrigine when co-administered due to induction of lamotrigine glucuronidation. This may reduce seizure control. Therefore, dose adjustment of lamotrigine may be necessary. **Fertility**, **Pregnancy and lactation:** Not indicated, treatment should be withdrawn immediately. Data on a limited number of exposed pregnancies indicate adverse effects of norethisterone on the foetus. At doses higher than normally used in oral contraceptives and HRT formulations, masculinisation of female foetuses was observed. **Side effects:** Adverse reactions observed in clinical trials: **Very common** (≥1/10)**:** Application site erythema, Application site pruritus, Application site rash, Application site reaction. Breast tenderness. **Common** (≥1/100 to <1/10)**:** Depression, Insomnia, Affect lability, Nervousness, Migraine, Headache, Hypertension, Abdominal pain, Gastrointestinal disorder, Diarrhoea, Flatulence, Nausea, Pruritus, Rash erythematous, Arthralgia, Back pain, Myalgia, Breast pain, Dysmenorrhoea, Menorrhagia, Menstrual disorder, Pain, Oedema, Malaise, Weight increased. Dyspepsia, Acne, Dry skin, Pain in extremity, Genital discharge, Uterine spasms, Vaginal infection. **Uncommon** (≥1/1,000 to <1/100) **include:** Candidiasis, Breast neoplasms, Fibroadenoma of breast, Hypersensitivity, Paraesthesia, Palpitations, Endometrial hyperplasia, Metrorrhagia, Generalised oedema, Transaminases increase. **Rare** (≥1/10,000 to <1/1,000) **include:** Gallbladder disorder, Myasthenia, **Very rare** (<1/10,000): Cholestatic jaundice **Frequency not known include:** Endometrial cancer**,** Cerebrovascular accident, Epilepsy, Deep Vein Thrombosis, Thrombosis, Pulmonary Embolism, Abdominal distension, Cholelithiasis, Rash, Stevens-Johnson syndrome, Oedema peripheral, Application site oedema. **Package Quantities & Cost:** Each carton box has 8 TDSs in individual foil-lined sachets. One Evorel Sequi box contains 4 Evorel 50 TDS and 4 Evorel Conti TDSs. Cost: £13.20. **Marketing authorisation number:** PL 49105/0010. **Marketing authorisation holder:** Theramex HQ UK Limited, 50 Broadway, 5th Floor, London, SW1H 0BL, UK. **Legal classification:** POM. **Date of Preparation:** October 2024: EVOR_UK_EN_20240_v1(v1.4).

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