

COURSE 014 MEDICATION REFERENCE

Estrogen, Progestogen, Testosterone, Genitourinary, and Nonhormonal Therapies; Package Inserts Accessed 7/25/26

Scope: Primary rows are U.S. FDA-approved products discussed in the presentation. Doses are FDA-labeled. Off-label female testosterone use, vaginal progesterone for menopausal endometrial protection, levonorgestrel IUS use with systemic estrogen, compounded products, non-U.S. brands, and nonstandard administration are identified only in Clinical Pearls.

SYSTEMIC ESTROGEN PRODUCTS

Generic / Class	Brand(s)	Strength / Form	Route	FDA-Approved Use	FDA-Labeled Dosing	Clinical Pearls
Estradiol	Estrace; generics [1]	Tablets: 0.5, 1, 2 mg	PO	Moderate to severe vasomotor symptoms; vulvar/vaginal atrophy; hypoestrogenism; prevention of postmenopausal osteoporosis	Use the lowest effective dose. Common labeled regimens are individualized within the 0.5 to 2 mg daily range, depending on indication.	*Oral administration undergoes first-pass hepatic metabolism and can increase SHBG. *Holding an oral tablet sublingually is off-label and is not supported by the oral tablet PI.
Estradiol	Vivelle-Dot, Dotti, Lyllana, Minivelle, Alora [2-6]	Twice-weekly transdermal systems, generally 0.025 to 0.1 mg/day; brand-specific strengths vary	Transdermal	Moderate to severe vasomotor symptoms; prevention of postmenopausal osteoporosis; some labels also include vulvar/vaginal atrophy	Apply one system twice weekly. Starting strength and titration vary by product and indication.	*Application sites and water-exposure instructions vary. *Cutting patches is not part of FDA labeling. *Patch adhesion and dermatitis can affect use.
Estradiol	Climara [7]	Once-weekly system: 0.025, 0.0375, 0.05, 0.06, 0.075, 0.1 mg/day	Transdermal	Moderate to severe vasomotor symptoms; vulvar/vaginal atrophy; prevention of postmenopausal osteoporosis	Apply one system once weekly.	*Once-weekly administration may be convenient but can produce end-of-week symptom recurrence in some patients. *Do not confuse with Climara Pro.
Estradiol	Menostar [8]	0.014 mg/day transdermal system	Transdermal	Prevention of postmenopausal osteoporosis	Apply one system once weekly.	*Lowest-dose branded estradiol patch. *Not labeled for vasomotor symptom treatment *A woman with a uterus still requires assessment of endometrial protection.
Estradiol	EstroGel [9]	0.06% gel; metered pump delivers 1.25 g gel containing 0.75 mg estradiol	Topical/ Transdermal	Moderate to severe vasomotor symptoms	Apply one pump once daily to the arm from wrist to shoulder.	*Allow to dry and follow product-specific washing and transfer precautions. *Compounded gels are not equivalent to this standardized product.
Estradiol	Divigel [10]	Single-dose packets containing 0.25, 0.5, 0.75, 1.0, or 1.25 mg estradiol	Topical/ Transdermal	Moderate to severe vasomotor symptoms	Apply one packet once daily to the upper thigh; select strength according to response.	*Small application area. *Do not apply to the face, breasts, or irritated skin. *Strengths are not interchangeable packet-for-packet.
Estradiol	Evamist [11]	1.53 mg estradiol per spray	Topical/ Transdermal spray	Moderate to severe vasomotor symptoms	Start with one spray once daily to the inner forearm; may increase to two or three sprays daily based on response.	*Flammable until dry. *Observe drying, washing, and secondary-transfer precautions. *Lenzetto is a non-U.S. brand and is not included as a separate FDA-approved product.
Estradiol	Elestrin [12]	0.06% metered gel; each actuation delivers 0.52 mg estradiol in 0.87 g gel	Topical/ Transdermal	Moderate to severe vasomotor symptoms due to menopause	Start with one pump applied once daily to the upper arm; adjust according to response	Product-specific application, drying, washing, and secondary-transfer precautions apply.
Estradiol	Estrasorb [13]	Topical emulsion; each 1.74 g pouch contains 2.5 mg estradiol per gram	Topical/ Transdermal	Moderate to severe vasomotor symptoms due to menopause	Apply one pouch to the left thigh and calf and one pouch to the right thigh and calf each morning	Two pouches constitute the labeled daily dose and provide nominal systemic delivery of 0.05 mg estradiol daily.
Estradiol acetate	Femring [14]	Vaginal ring delivering 0.05 or 0.1 mg estradiol/day	Vaginal, systemic	Moderate to severe vasomotor symptoms and vulvar/vaginal atrophy due to menopause	Insert one ring and replace every 3 months.	*Femring is systemic therapy, unlike Estring. *A woman with a uterus generally requires adequate progestogen protection.
Estradiol valerate; estradiol cypionate	Delestrogen; Depo-Estradiol [15,16]	Delestrogen: 10, 20, 40 mg/mL Depo-Estradiol: 5 mg/mL	IM	Moderate to severe vasomotor symptoms; selected hypoestrogenism indications	Delestrogen: labeled usual dose 10 to 20 mg every 4 weeks. Depo-Estradiol: labeled usual dose 1 to 5 mg every 3 to 4 weeks.	* Low-dose, high-frequency regimens differ from the PIs. *Compounded estradiol cypionate concentrations should not be treated as interchangeable with FDA-approved products.
Conjugated estrogens	Premarin [17]	Tablets: 0.3, 0.45, 0.625, 0.9, 1.25 mg	PO	Vasomotor symptoms; vulvar/vaginal atrophy; hypoestrogenism; selected cancer palliation; osteoporosis prevention	Dose is individualized by indication; one tablet daily using the lowest effective strength.	*This is conjugated estrogens, not 17 beta-estradiol. * Estrogen used in the WHI regimens 8

*Compounded Biest, Tri-est, estradiol troches, rapid-dissolve tablets, and combined multi-hormone vaginal preparations are not FDA-approved. Ratios, concentrations, absorption, and dosing vary by compounder and should not be treated as interchangeable with approved products.

LOCAL VAGINAL AND GENITOURINARY PRODUCTS

Generic / Class	Brand(s)	Strength / Form	Route	FDA-Approved Use	FDA-Labeled Dosing	Clinical Pearls
Estradiol	Estrace vaginal cream; generics [18]	0.01% cream, 0.1 mg estradiol per gram	Vaginal	Moderate to severe vulvar and vaginal atrophy due to menopause	Common labeled regimen: 2 to 4 g daily for 1 to 2 weeks, then gradual reduction to maintenance dosing.	*Cream permits internal and external application but can be messy and variably measured. *Use the minimum effective amount.
Estradiol	Vagifem; Yuvaferm [19,20]	10 mcg vaginal insert/tablet	Vaginal	Atrophic vaginitis due to menopause	One insert daily for 2 weeks, then one insert twice weekly.	*Measured local dose. *Systemic absorption is low but not zero. *Vagifem and Yuvaferm are not systemic MHT products.
Estradiol	Imvexxy [21]	Softgel vaginal inserts: 4 or 10 mcg	Vaginal	Moderate to severe dyspareunia due to vulvar and vaginal atrophy from menopause	One insert daily for 2 weeks, then one insert twice weekly.	*Applicator-free softgel *Not intended to treat vasomotor symptoms.
Estradiol	Estring [22]	Ring containing 2 mg estradiol, releasing about 7.5 mcg/day	Vaginal, local	Moderate to severe vulvar and vaginal atrophy due to menopause	Insert one ring and replace after 90 days.	*Local therapy. Do not confuse with systemic Femring. *The ring should be removed or replaced at 90 days.
Conjugated Estrogens	Premarin Vaginal Cream [23]	0.625 mg conjugated estrogens per gram	Vaginal	Atrophic vaginitis and kraurosis vulvae; moderate to severe dyspareunia due to vulvar and vaginal atrophy from menopause	Depending on indication, 0.5 to 2 g daily for 21 days followed by 7 days off, or 0.5 g twice weekly	Contains conjugated estrogens, not 17 β -estradiol.
Prasterone	Intrarosa [24]	6.5 mg vaginal insert	Vaginal	Moderate to severe dyspareunia due to vulvar and vaginal atrophy from menopause	Insert one vaginal insert once daily at bedtime.	Prasterone is DHEA. It is converted locally to active sex steroids. It is not systemic testosterone therapy.

PROGESTERONE, PROGESTINS, AND INTRAUTERINE PRODUCTS

Generic / Class	Brand(s)	Strength / Form	Route	FDA-Approved Use	FDA-Labeled Dosing	Clinical Pearls
Progesterone, micronized	Prometrium [25]	Capsules: 100, 200 mg	PO	Prevention of endometrial hyperplasia with conjugated estrogens; secondary amenorrhea	Endometrial protection label: 200 mg at bedtime for 12 days per 28-day cycle with conjugated estrogens 0.625 mg daily.	*Sedation and dizziness support bedtime dosing. *Prometrium contains peanut oil and is contraindicated in patients with peanut allergy. Excipients in generic progesterone products should be verified using the individual product labeling. *Continuous 100 mg and other MHT regimens may be guideline-supported but are not identical to the original PI regimen. *Piercing and inserting an oral capsule vaginally is off-label.
Medroxyprogesterone acetate	Provera [26]	Tablets: 2.5, 5, 10 mg	PO	Secondary amenorrhea; abnormal uterine bleeding; reduction of endometrial hyperplasia with estrogen therapy	For endometrial protection, 5 or 10 mg daily for 12 to 14 consecutive days per month with daily conjugated estrogens.	*Synthetic progestin used in WHI combination therapy. *It does not share the same neuroactive metabolite profile as micronized progesterone.
Norethindrone acetate	Aygestin; generics [27]	Tablet: 5 mg	PO	Secondary amenorrhea, endometriosis, and abnormal uterine bleeding	Dosing varies by labeled indication.	*Standalone norethindrone acetate 5 mg is not FDA-approved with estrogen for postmenopausal endometrial protection. *It is also a component of CombiPatch.
Drospirenone	Slynd [28]	4 mg tablets in a 24 active/4 inactive regimen	PO	Contraception	One tablet daily in sequence through the 28-day pack.	*Progestin-only contraceptive. *It is not FDA-approved as menopausal endometrial protection. *Monitor hyperkalemia risk in susceptible patients.
Progesterone	Crinone; Endometrin [29,30]	Crinone: 4% (45 mg) and 8% (90 mg) gel. Endometrin: 100 mg insert	Vaginal	Infertility and assisted reproductive technology indications; Crinone 4% also has a secondary amenorrhea indication	Product-specific fertility dosing applies. Endometrin is 100 mg two or three times daily in ART.	*These products are not FDA-approved for endometrial protection during menopausal estrogen therapy. *Vaginal progesterone use for that purpose is off-label and dose/schedule specific.
Progesterone	Progesterone injection, USP [31]	Commonly 50 mg/mL in oil	IM	Amenorrhea and abnormal uterine bleeding due to hormonal imbalance	Use the product-specific labeled regimen for the indicated condition.	*Not FDA-approved as a routine menopausal progestogen regimen. *Daily oil-based IM administration can be painful. *Compounded strengths and vehicles vary.
Levonorgestrel	Mirena; Liletta [32,33]	52 mg levonorgestrel-releasing intrauterine systems	Intrauterine	Contraception; Mirena and Liletta also have labeled heavy menstrual bleeding indications	Single device inserted by a trained clinician; duration depends on product and indication.	*Use for endometrial protection with systemic menopausal estrogen is off-label in the United States, although commonly discussed in menopause practice. *The device also provides contraception.

ESTROGEN-PROGESTOGEN AND TISSUE-SELECTIVE COMBINATIONS

Generic / Class	Brand(s)	Strength / Form	Route	FDA-Approved Use	FDA-Labeled Dosing	Clinical Pearls
Conjugated estrogens/ medroxyprogesterone acetate	Prempro; Premphase [34,35]	Prempro: CE/MPA 0.3/1.5, 0.45/1.5, 0.625/2.5, 0.625/5 mg. Premphase: CE 0.625 mg days 1-14, then CE/MPA 0.625/5 mg days 15-28	PO	Vasomotor symptoms; vulvar/vaginal atrophy; prevention of postmenopausal osteoporosis	Prempro: one tablet daily. Premphase: sequential 28-day pack.	*Prempro is continuous combined therapy. *Premphase is sequential and produces scheduled progestin exposure.
Estradiol/progesterone	Bijuva [36]	Capsules: 0.5 mg/100 mg and 1 mg/100 mg	PO	Moderate to severe vasomotor symptoms in postmenopausal women with a uterus	One capsule each evening with food; generally start with 0.5 mg/100 mg.	*Single-capsule bioidentical estradiol plus micronized progesterone product. *Not a contraceptive.
Drospirenone/estradiol	Angeliq [37]	Tablets: 0.25/0.5 mg and 0.5/1 mg	PO	Vasomotor symptoms; vulvar/vaginal atrophy	One tablet daily; select strength according to indication and response.	*Drospirenone has antimineralocorticoid activity. *Contraindicated with renal impairment, hepatic impairment, or adrenal insufficiency *Assess hyperkalemia risk.
Estradiol/ norethindrone acetate	Mimvey; Lopreeza [38,39]	1 mg/0.5 mg and 0.5 mg/0.1 mg, with brand-specific availability	PO	Moderate to severe vasomotor symptoms; selected strengths for vulvar/vaginal atrophy; prevention of postmenopausal osteoporosis in women with a uterus	One tablet once daily	*Continuous combined estradiol/progestin therapy. *Contains norethindrone acetate, not micronized progesterone. *Brand-specific strengths and indications should be verified.
Ethinyl estradiol/ norethindrone acetate	FemHRT; Jinteli [40,41]	FemHRT: 2.5 mcg/0.5 mg and 5 mcg/1 mg; Jinteli: 5 mcg/1 mg	PO	Moderate to severe vasomotor symptoms; prevention of postmenopausal osteoporosis in women with a uterus	One tablet once daily	*Contains ethinyl estradiol rather than 17 β -estradiol. *Continuous combined oral therapy. *Jinteli is available only as the 5 mcg/1 mg strength.
Estradiol/ norethindrone acetate	CombiPatch [42]	Systems delivering 0.05/0.14 or 0.05/0.25 mg/day	Transdermal	Moderate to severe vasomotor symptoms due to menopause; moderate to severe vulvar and vaginal atrophy due to menopause; hypoestrogenism due to hypogonadism, castration, or primary ovarian failure in women with a uterus	Apply one system twice weekly.	*Contains a synthetic progestin, not micronized progesterone. *Product-specific application instructions apply.
Estradiol/ levonorgestrel	Climara Pro [43]	System delivering 0.045 mg/day estradiol and 0.015 mg/day levonorgestrel	Transdermal	Vasomotor symptoms and prevention of postmenopausal osteoporosis in women with a uterus	Apply one system once weekly to the lower abdomen.	*Do not confuse with estrogen-only Climara. *Continuous combined systemic therapy.
Conjugated estrogens/ bazedoxifene	Duavee [44]	Tablet: 0.45 mg/20 mg	PO	Vasomotor symptoms and prevention of postmenopausal osteoporosis in women with a uterus	One tablet once daily.	*Bazedoxifene replaces a progestin for endometrial antagonism in this fixed product. *Do not add another estrogen or SERM. *Use in women with prior breast cancer or DCIS is not an FDA- approved indication.

TESTOSTERONE AND ANABOLIC ANDROGEN PRODUCTS

Generic / Class	Brand(s)	Strength / Form	Route	FDA-Approved Use	FDA-Labeled Dosing	Clinical Pearls
Testosterone	AndroGel 1%, AndroGel 1.62%, Testim 1% [45-47]	Male-formulated gels and pumps; product- specific packet/pump strengths	Topical	Testosterone replacement in adult males with confirmed hypogonadism	No FDA labeled dosing for women.	*No systemic testosterone product is FDA- approved for women or HSDD. *Female use is off-label and should use a precisely measured fraction of a male dose under specialty guidance. *Secondary transfer precautions are essential.
Testosterone cypionate; testosterone enanthate	Depo-Testosterone; Delatestryl [48,49]	Depo-Testosterone: 100 or 200 mg/mL Enanthate: 200 mg/mL	IM, SubQ, product- specific	Testosterone replacement in adult males with confirmed hypogonadism	No FDA labeled dosing for women.	*Female use is off-label. *High concentrations make small volume errors clinically important. *Consensus guidance favors transdermal testosterone for female HSDD rather than routine injectable use.
Testosterone	Testopel [50]	75 mg pellet	SubQ implantation	Androgen replacement in males with qualifying hypogonadal conditions	No FDA labeled dosing for women.	*Not FDA-approved for women. *Pellets are difficult to titrate or reverse. *BioTE and EvexiPEL are not FDA-approved testosterone products.

- Compounded testosterone troches are not FDA-approved. Absorption and exposure may be variable, and the dosing ranges promoted by individual compounding practices are not established FDA-labeled female regimens.

NONHORMONAL AND CONTEXTUAL MEDICATIONS DISCUSSED

Generic / Class	Brand(s)	Strength / Form	Route	FDA-Approved Use	FDA-Labeled Dosing	Clinical Pearls
Fezolinetant	Veozah [51]	Tablet: 45 mg	PO	Moderate to severe vasomotor symptoms due to menopause	45 mg once daily.	*Nonhormonal NK3 receptor antagonist. Requires LFTs baseline and follow-up monitoring per current PI. *It treats vasomotor symptoms but does not provide estrogen effects in bone or genitourinary tissue.
Elinzanetant	Lynkuet [52]	Capsules: 60 mg	PO	Moderate to severe vasomotor symptoms due to menopause	120 mg, two capsules, once daily at bedtime.	*Nonhormonal NK1/NK3 receptor antagonist. *Follow the PI for drug interactions and dose modifications.
Paroxetine	Brisdelle [53]	Capsule: 7.5 mg	PO	Moderate to severe vasomotor symptoms associated with menopause	7.5 mg once daily at bedtime.	*Not indicated for psychiatric treatment at this dose. *Generally avoid with tamoxifen because CYP2D6 inhibition may reduce active tamoxifen metabolite formation.
Zuranolone	Zurzuvae [54]	Capsules: 20, 25, 30 mg	PO	Postpartum depression in adults	50 mg once daily in the evening for 14 days with a fatty meal; reduce when indicated by the PI.	*Synthetic neuroactive steroid used in the presentation to contextualize allopregnanolone biology. *not approved for menopausal insomnia or progesterone intolerance.
Oxandrolone, historical product	Oxandrin; former generic products [55]	Former tablets: 2.5 and 10 mg	PO	No current FDA-approved use. Previously approved for selected catabolic conditions and relief of bone pain associated with osteoporosis.	No current FDA-approved dosing. Historical labeling only.	*FDA withdrew approval of Oxandrin and four generic oxandrolone applications effective June 28, 2023. *FDA subsequently determined that the products were withdrawn for reasons of safety or effectiveness. *Oxandrolone is not menopausal hormone replacement and carries hepatic, lipid, reproductive, and virilizing risks. *Not menopausal hormone replacement. *Schedule III anabolic steroid with hepatic, lipid, reproductive, and virilizing risks. *Nandrolone esters and stanozolol were discussed as other inappropriate substitutes but are not included as menopause therapies.
Flibanserin	Addyi [56]	Tablet: 100 mg	PO	Acquired, generalized HSDD in women younger than 65 years	100 mg once daily at bedtime. Discontinue after 8 weeks if symptoms do not improve.	*Now labeled for women younger than 65 years, including qualifying postmenopausal women, not only premenopausal women. *Boxed warning for hypotension and syncope associated with alcohol use, moderate or strong CYP3A4 inhibitors, and hepatic impairment. *Wait at least 2 hours after one or two alcoholic drinks before the bedtime dose; skip the dose after three or more drinks. *Not indicated to enhance sexual performance.
Bremelanotide	Vyleesi [57]	Prefilled autoinjector: 1.75 mg/0.3 mL	SubQ	Acquired, generalized HSDD in premenopausal women	Inject 1.75 mg into the abdomen or thigh at least 45 minutes before anticipated sexual activity. Maximum one dose per 24 hours; more than 8 doses per month is not recommended.	*As-needed melanocortin receptor agonist. *Not indicated for postmenopausal women or to enhance sexual performance. *Contraindicated with uncontrolled hypertension or known cardiovascular disease. *Can cause transient blood-pressure increases, nausea, and focal hyperpigmentation.

Generic / Class	Brand(s)	Strength / Form	Route	FDA-Approved Use	FDA-Labeled Dosing	Clinical Pearls
Ospemifene (SERM)	Osphena [58]	Tablet: 60 mg	PO	Moderate to severe dyspareunia and moderate to severe vaginal dryness, symptoms of vulvar and vaginal atrophy due to menopause	60 mg once daily with food	*Nonhormonal selective estrogen receptor modulator with tissue-specific estrogen agonist and antagonist effects. *Boxed warning for endometrial cancer and cardiovascular disorders. *Has estrogen agonist effects in the endometrium. *Do not use concomitantly with estrogens or other estrogen agonists/antagonists. *Contraindicated in women with undiagnosed abnormal genital bleeding, estrogen-dependent neoplasia, or active or prior thromboembolic disease. Benefits: Improves vaginal epithelium thickness and maturation, Lowers vaginal pH, Reduces dyspareunia and dryness, May improve lubrication and sexual comfort, Useful for women who prefer an oral therapy rather than vaginal estrogen

PACKAGE INSERT REFERENCES

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1. Estrace (estradiol tablets, USP) [prescribing information]. U.S. Food and Drug Administration.
2. Vivelle-Dot (estradiol transdermal system) [prescribing information]. U.S. Food and Drug Administration.
3. Dotti (estradiol transdermal system) [prescribing information]. DailyMed.
4. Lyllana (estradiol transdermal system) [prescribing information]. DailyMed.
5. Minivelle (estradiol transdermal system) [prescribing information]. DailyMed.
6. Alora (estradiol transdermal system) [prescribing information]. U.S. Food and Drug Administration.
7. Climara (estradiol transdermal system) [prescribing information]. U.S. Food and Drug Administration.
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9. EstroGel (estradiol gel) [prescribing information]. U.S. Food and Drug Administration.
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13. Estrasorb (estradiol topical emulsion) [prescribing information]. U.S. Food and Drug Administration.
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17. Premarin (conjugated estrogens tablets, USP) [prescribing information]. U.S. Food and Drug Administration.
18. Estrace Vaginal Cream (estradiol vaginal cream, USP 0.01%) [prescribing information]. U.S. Food and Drug Administration.
19. Vagifem (estradiol vaginal inserts) [prescribing information]. U.S. Food and Drug Administration.
20. Yuvaferm (estradiol vaginal insert) [prescribing information]. DailyMed.
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22. Estring (estradiol vaginal system) [prescribing information]. U.S. Food and Drug Administration.
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24. Intrarosa (prasterone vaginal inserts) [prescribing information]. U.S. Food and Drug Administration.
25. Prometrium (progesterone, USP capsules) [prescribing information]. U.S. Food and Drug Administration.
26. Provera (medroxyprogesterone acetate tablets, USP) [prescribing information]. U.S. Food and Drug Administration.

27. Norethindrone acetate tablets, USP [prescribing information]. DailyMed.
28. Slynd (drospirenone tablets) [prescribing information]. U.S. Food and Drug Administration.
29. Crinone (progesterone gel) [prescribing information]. U.S. Food and Drug Administration.
30. Endometrin (progesterone vaginal insert) [prescribing information]. U.S. Food and Drug Administration.
31. Progesterone injection, USP in sesame oil [prescribing information]. U.S. Food and Drug Administration.
32. Mirena (levonorgestrel-releasing intrauterine system) [prescribing information]. U.S. Food and Drug Administration.
33. Liletta (levonorgestrel-releasing intrauterine system) [prescribing information]. U.S. Food and Drug Administration.
34. Prempro (conjugated estrogens/medroxyprogesterone acetate tablets) [prescribing information]. U.S. Food and Drug Administration.
35. Premphase (conjugated estrogens/medroxyprogesterone acetate tablets) [prescribing information]. U.S. Food and Drug Administration.
36. Bijuva (estradiol and progesterone capsules) [prescribing information]. U.S. Food and Drug Administration.
37. Angeliq (drospirenone and estradiol tablets) [prescribing information]. U.S. Food and Drug Administration.
38. Mimvey (estradiol and norethindrone acetate tablets) [prescribing information]. DailyMed.
39. Lopreeza (estradiol and norethindrone acetate tablets) [prescribing information]. DailyMed.
40. FemHRT (norethindrone acetate and ethinyl estradiol tablets) [prescribing information]. DailyMed.
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