Conjugated Estrogens and Medroxyprogeste Tablets, Prempro

Prempro 2.5 mg—Each peach tablet for oral administration contains 0.625 mg conjugated estrogens, 2.5 mg of medroxyprogesterone acetate, and the following inactive ingredients: calcium phosphate tribasic, calcium sulfate, carnauba wax, cellulose, glyceryl monooleate, lactose, magnesium stearate, methylcellulose, pharmaceutical glaze, polyethylene glycol, sucrose, povidone, titanium dioxide, and red ferric oxide.

Prempro 5 mg—Each light-blue tablet for oral administration contains 0.625 mg of conjugated estrogens, 5 mg of medroxyprogesterone acetate, and the following inactive ingredients: calcium phosphate tribasic, calcium sulfate, carnauba wax, cellulose, glyceryl monooleate, lactose, magnesium stearate, methylcellulose, pharmaceutical glaze, polyethylene glycol, sucrose, povidone, titanium dioxide, and FD&C Blue No. 2.

Premphase—Each maroon Premarin tablet for oral administration contains 0.625 mg of conjugated estrogens and the following inactive ingredients: calcium phosphate tribasic, calcium sulfate, carnauba wax, cellulose, glyceryl monooleate, lactose, magnesium stearate, methylcellulose, pharmaceutical glaze, polyethylene glycol, stearic acid, sucrose, titanium dioxide, FD&C Blue No. 2, D&C Red No. 27, FD&C Red No. 40. These tablets comply with USP Drug Release Test 1. Each light-blue tablet for oral administration contains 0.625 mg of conjugated estrogens and 5 mg of medroxyprogesterone acetate and the following inactive ingredients: calcium phosphate tribasic, calcium sulfate, carnauba wax, cellulose, glyceryl monooleate, lactose, magnesium stearate, methylcellulose, pharmaceutical glaze, polyethylene glycol, sucrose, povidone, titanium dioxide, and FD&C Blue No. 2.

Conjugated Estrogens (0.3–2.50 mg) Prematin

Tablets are available in 0.3-, 0.625-, 0.9-, 1.25-, and 2.5-mg strengths of conjugated estrogens. Premarin tablets contain the following inactive ingredients: calcium phosphate tribasic, calcium sulfate anhydrous (white tablet), calcium sulfate, carnauba wax, cellulose, glyceryl monooleate, lactose, magnesium stearate, methylcellulose, pharmaceutical glaze, polyethylene glycol, stearic acid, sucrose, talc, and titanium dioxide. The 0.3-mg tablets also contain D&C Yellow No. 10, FD&C Blue No. 1, FD&C Blue No. 2, FD&C Yellow No. 6. The 0.625-mg tablets also contain FD&C Blue No. 2, D&C Red No. 27, and FD&C Red No. 40. The 0.9-mg tablets also contain D&C Red No. 6, D&C Red No. 7. The 1.25-mg tablets contain black iron oxide, D&C Yellow No. 10, and FD&C Yellow No. 6. The 2.5-mg tablets contain: FD&C Blue No. 2 and D&C Red No. 7.

Coumadin Tablets

Coumadin tablets also contain (all strengths) lactose, starch, and magnesium stearate; 1 mg of D&C Red No. 6; 2 mg of FD&C Blue No. 2 and FD&C Red No. 40; 2 1/2 mg of FD&C Blue No. 1, and D&C Yellow No. 10; 4 mg of FD&C Blue No. 1 Lake; 5 mg of FD&C Yellow No. 6; 7 1/2 mg of D&C Yellow No. 10, and FD&C Yellow No. 6; 10 mg of dye free.

Crospovidone Effervescent Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
1000.00	1	Crospovidone (micronized)	1000.00
150.00	2	Citric acid	150.00
25.00	3	Aerosil® 200	25.00
100.00	4	Sucrose (crystalline)	100.00
1.00	5	Saccharin sodium	1.00
QS	6	Water	QS
5.00	7	Magnesium stearate	5.00
125.00	8	Sodium bicarbonate	125.00
65.00	9	Flavor mixture	65.00

Manufacturing Directions

1. Granulate mixture of items 1 to 5 with item 6, dry, and pass through a sieve.
2. Mix the dry granules with items 7 to 9, and press with medium-compression force.
3. The dosage may be increased to 2000 mg crospovidone by increasing the tablet weight to 3200 mg.
4. Compress 1590-mg tablets, using 20-mm-diameter biplanar punches.