

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL:

USAN SYNTHETIC CONJUGATED ESTROGENS, B

PRONUNCIATION (es' troe jens)

THERAPEUTIC CLAIM hormone replacement therapy

CHEMICAL DESCRIPTION

Synthetic conjugated estrogens, B, contains the sodium sulfate forms of estrone, equilin, 17 α -estradiol, 17 α -dihydroequilin, 17 β -dihydroequilin, 17 α -dihydroequilenin, 17 β -dihydroequilenin, equilenin, 17 β -estradiol, and $\Delta^{8,9}$ -dehydroestrone. The total percent label claim for the sum of estrone, equilin, and 17 α -dihydroequilin is 90 to 110%. The individual levels for each component are: estrone 53.0% to 61.5%, equilin 19.0% to 29.0%, 17 α -estradiol 3.0% to 7.0%, 17 α -dihydroequilenin 0.3% to 3.0%, 17 β -dihydroequilenin 0.2% to 1.8%, equilenin 0.2% to 4.0%, 17 β -estradiol 0.5% to 2.5%, and $\Delta^{8,9}$ -dehydroestrone 2.5% to 6.0%.

TRADEMARK ENJUVIA™

MANUFACTURER ORGANICS/LaGrange, Inc.

SPONSOR Endeavor Pharmaceuticals, Inc.

CODE DESIGNATION CE-10

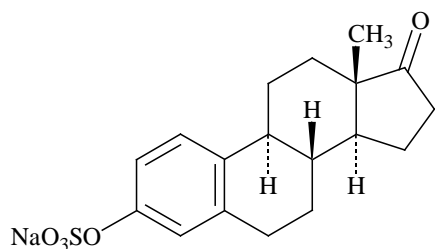
NOTE: The chemical names, structures, molecular formulas, molecular weights, and CAS Registry numbers for each of the components are attached.

Component A

CHEMICAL NAMES

- (1) estra-1,3,5(10)-trien-17-one, 3-(sulfooxy)-, sodium salt
- (2) 17-oxoestra-1,3,5(10)-trien-3-yl sodium sulfate
- (3) estrone sodium sulfate

STRUCTURAL FORMULA



MOLECULAR FORMULA $C_{18}H_{21}NaO_5S$

MOLECULAR WEIGHT 372.41

CAS REGISTRY NUMBER 438-67-5

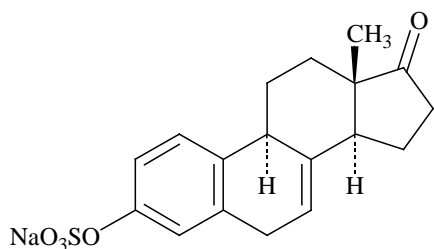
Component B

CHEMICAL NAMES

- (1) estra-1,3,5(10),7-tetraen-17-one, 3-(sulfooxy)-, sodium salt
- (2) 17-oxoestra-1,3,5(10),7-tetraen-3-yl sodium sulfate
- (3) equilin sodium sulfate

Component B (continued)

STRUCTURAL FORMULA



MOLECULAR FORMULA $C_{18}H_{19}NaO_5S$

MOLECULAR WEIGHT 370.40

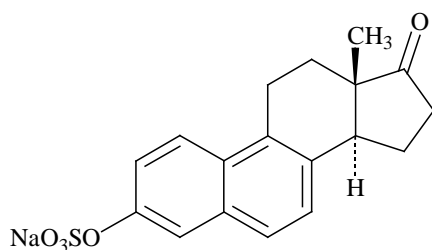
CAS REGISTRY NUMBER 16680-47-0

Component C

CHEMICAL NAMES

- (1) estra-1,3,5,7,9-pentaen-17-one, 3-(sulfooxy)-, sodium salt
- (2) 17-oxoestra-1,3,5,7,9-pentaen-3-yl sodium sulfate
- (3) equilenin sodium sulfate

STRUCTURAL FORMULA



MOLECULAR FORMULA $C_{18}H_{17}NaO_5S$

MOLECULAR WEIGHT 368.38

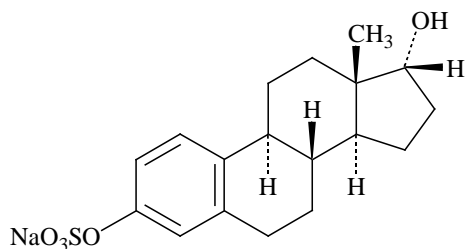
CAS REGISTRY NUMBER 16680-48-1

Component D

CHEMICAL NAMES

- (1) estra-1,3,5(10)-triene-3,17-diol, 3-(hydrogen sulfate), monosodium salt, (17 α)-
- (2) 17 α -hydroxyestra-1,3,5(10)-trien-3-yl sodium sulfate
- (3) estradiol sodium 3-sulfate

STRUCTURAL FORMULA



MOLECULAR FORMULA $C_{18}H_{23}NaO_5S$

MOLECULAR WEIGHT 374.43

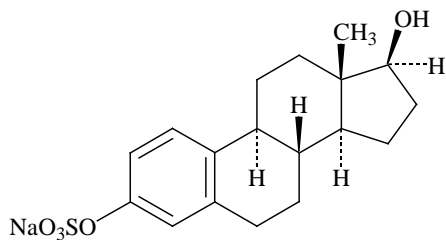
CAS REGISTRY NUMBER 56050-04-5

Component E

CHEMICAL NAMES

- (1) estra-1,3,5(10)-triene-3,17-diol (17 β)-, 3-(hydrogen sulfate), monosodium salt
- (2) 17 β -hydroxyestra-1,3,5(10)-trien-3-yl sodium sulfate
- (3) 17 β -estradiol sodium 3-sulfate

STRUCTURAL FORMULA



Component E (continued)MOLECULAR FORMULA $C_{18}H_{23}NaO_5S$

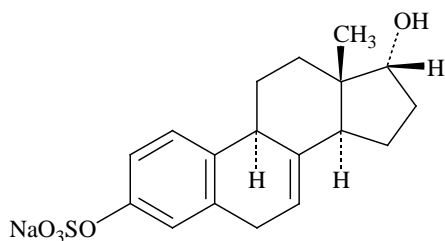
MOLECULAR WEIGHT 374.43

CAS REGISTRY NUMBER 4999-79-5**Component F**

CHEMICAL NAMES

- (1) estra-1,3,5(10),7-tetraene-3,17-diol, 3-(hydrogen sulfate), monosodium salt, (17 α)-
- (2) 17 α -hydroxyestra-1,3,5(10),7-tetraen-3-yl sodium sulfate
- (3) 17 α -dihydroequilin sodium 3-sulfate

STRUCTURAL FORMULA

MOLECULAR FORMULA $C_{18}H_{21}NaO_5S$

MOLECULAR WEIGHT 372.41

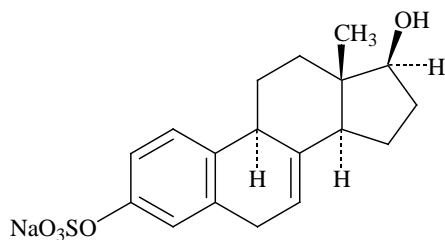
CAS REGISTRY NUMBER 56050-05-6**Component G**

CHEMICAL NAMES

- (1) estra-1,3,5(10),7-tetraene-3,17-diol, 3-(hydrogen sulfate), monosodium salt, (17 β)-
- (2) 17 β -hydroxyestra-1,3,5(10),7-tetraen-3-yl sodium sulfate
- (3) 17 β -dihydroequilin sodium 3-sulfate

Component G (continued)

STRUCTURAL FORMULA



MOLECULAR FORMULA $C_{18}H_{21}NaO_5S$

MOLECULAR WEIGHT 372.41

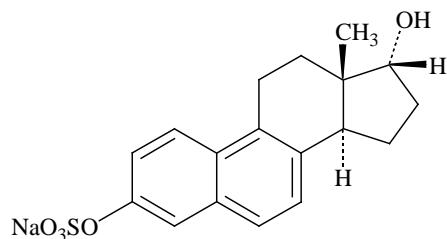
CAS REGISTRY NUMBER 16680-49-2

Component H

CHEMICAL NAMES

- (1) *estra-1,3,5,7,9-pentaene-3,17-diol, 3-(hydrogen sulfate), monosodium salt, (17 α)-*
- (2) *17 α -hydroxyestra-1,3,5,7,9-pentaen-3-yl sodium sulfate*
- (3) *17 α -dihydroequilenin sodium 3-sulfate*

STRUCTURAL FORMULA



MOLECULAR FORMULA $C_{18}H_{19}NaO_5S$

MOLECULAR WEIGHT 370.40

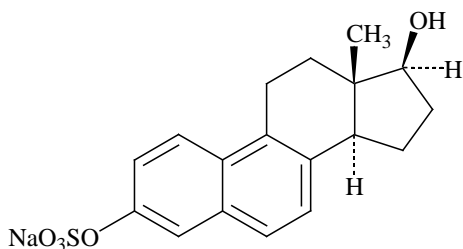
CAS REGISTRY NUMBER 56086-66-9

Component I

CHEMICAL NAMES

- (1) estra-1,3,5,7,9-pentaene-3,17-diol, 3-(hydrogen sulfate), monosodium salt, (17 β)-
- (2) 17 β -hydroxyestra-1,3,5,7,9-pentaen-3-yl sodium sulfate
- (3) 17 β -dihydroequilenin sodium 3-sulfate

STRUCTURAL FORMULA



MOLECULAR FORMULA $C_{18}H_{19}NaO_5S$

MOLECULAR WEIGHT 370.40

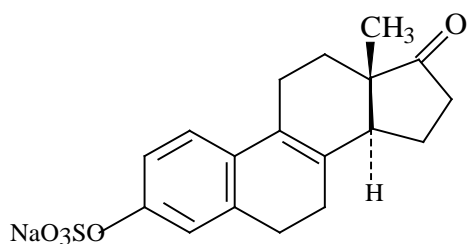
CAS REGISTRY NUMBER 16680-50-5

Component J

CHEMICAL NAMES

- (1) estra-1,3,5(10),8-tetraen-17-one, 3-hydroxy, monosodium salt
- (2) 3-hydroxyestra-1,3,5(10),8-tetraen-17-one sodium salt
- (3) 8,9-dehydroestrone sodium sulfate

STRUCTURAL FORMULA



SYNTHETIC CONJUGATED ESTROGENS, B

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Component J (continued)

MOLECULAR FORMULA $C_{18}H_{19}NaO_5S$

MOLECULAR WEIGHT 370.40

CAS REGISTRY NUMBER none as yet