

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL:

USAN	SYNTHETIC CONJUGATED ESTROGENS, B
PRONUNCIATION	es' troe jens
THERAPEUTIC CLAIM	estrogen 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 and equilin, is 79.5% - 88.0%. The individual levels for each component are: estrone 52.5% - 61.5%, equilin 22.5% - 30.5%, 17 α -estradiol 2.5% - 9.5%, 17 α -dihydroequilin 13.5% - 19.5%, 17 β -dihydroequilin 0.5% - 4.0%, 17 α -dihydroequilenin 0.2% - 3.25%, 17 β -dihydroequilenin 0.2% - 2.75%, equilenin 0.2% - 5.5%, 17 β -estradiol 0.2% - 2.25%, and $\Delta^{8,9}$ -dehydroestrone 0.2% - 6.25%.

TRADEMARK	Unknown as yet
MANUFACTURER	Organics LaGrange, Inc.
SPONSOR	Duramed Pharmaceutical 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.

SYNTHETIC CONJUGATED ESTROGENS, B

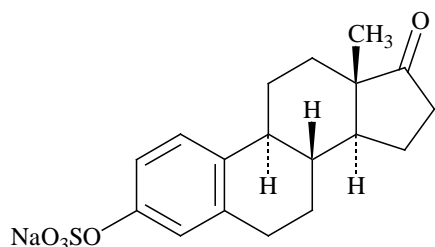
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Component A

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

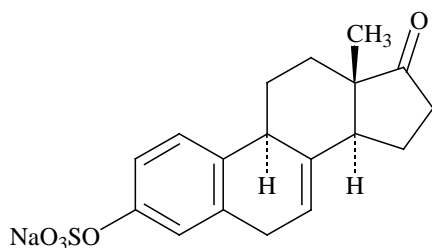
CAS REGISTRY NUMBER 438-67-5

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

STRUCTURAL FORMULA



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

MOLECULAR WEIGHT 370.40

CAS REGISTRY NUMBER 16680-47-0

SYNTHETIC CONJUGATED ESTROGENS, B

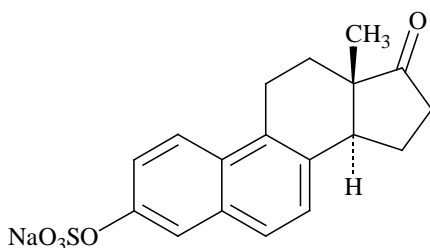
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Component C

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 $\text{C}_{18}\text{H}_{17}\text{NaO}_5\text{S}$

MOLECULAR WEIGHT 368.38

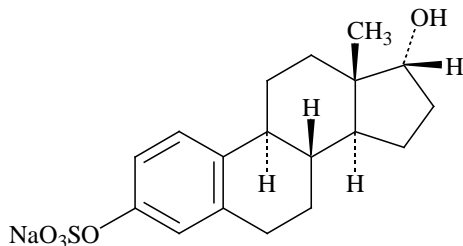
CAS REGISTRY NUMBER 16680-48-1

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 $\text{C}_{18}\text{H}_{23}\text{NaO}_5\text{S}$

MOLECULAR WEIGHT 374.43

Component D (continued)

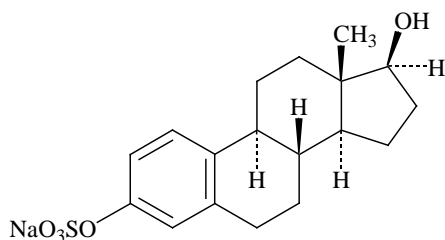
CAS REGISTRY NUMBER 56050-04-5

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



MOLECULAR FORMULA C₁₈H₂₃NaO₅S

MOLECULAR WEIGHT 374.43

CAS REGISTRY NUMBER 4999-79-5

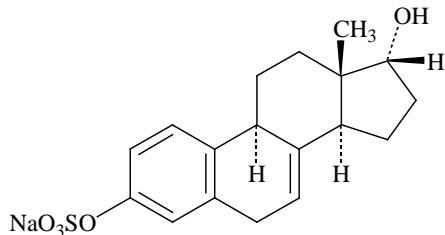
Component F

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

Component F (continued)

STRUCTURAL FORMULA



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

MOLECULAR WEIGHT 372.41

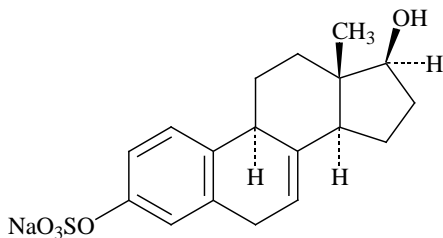
CAS REGISTRY NUMBER 56050-05-6

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

STRUCTURAL FORMULA



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

MOLECULAR WEIGHT 372.41

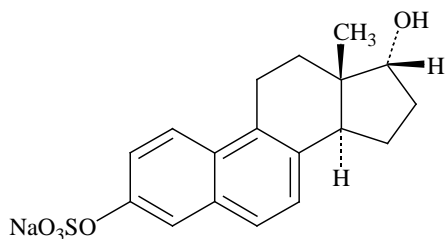
CAS REGISTRY NUMBER 16680-49-2

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

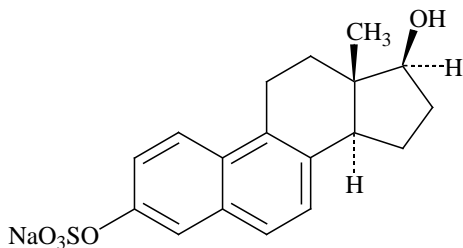
CAS REGISTRY NUMBER 56086-66-9

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

SYNTHETIC CONJUGATED ESTROGENS, B

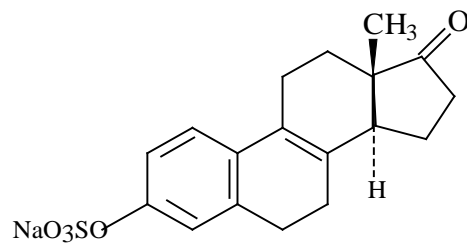
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Component J

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



MOLECULAR FORMULA	C ₁₈ H ₁₉ NaO ₅ S
MOLECULAR WEIGHT	370.40
<u>CAS</u> REGISTRY NUMBER	none as yet