

**HORMONE BALANCE- salsolinol hydrochloride, dhea (dehydroepiandrosterone), 7-oxo-dehydroepiandrosterone-3b-acetate, folliculinum, oophorinum (suis), cholesterinum, progesterone, testosterone, cortisone aceticum, aldosterone, androsterone, follicle stimulating hormone liquid
Dr. Donna Restivo DC**

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Drug Facts:

ACTIVE INGREDIENTS:

Salsolinol (Hydrochloride) 6X, 12X, 30X, 200X, DHEA (Dehydroepiandrosterone) 6X, 12X, 30X, 200X, 12C, 30C, 60C, 200C, 7-Oxo-Dehydroepiandrosterone 3-Acetate 8X, 12X, 30X, 60X, 200X, 12C, 30C, 60C, 200C, Folliculinum 8X, 12X, 30X, 60X, 200X, 12C, 30C, 60C, 200C, Oophorinum (Suis) 8X, 12X, 30X, 60X, 200X, 12C, 30C, 60C, 200C, Cholesterinum 8X, 12X, 30X, 200X, 12C, 30C, 60C, 200C, Progesterone 8X, 12X, 30X, 200X, 12C, 30C, 60C, 200C, Testosterone 8X, 12X, 30X, 200X, 12C, 30C, 60C, 200C, Cortisone Aceticum 12X, 30X, 200X, 12C, 30C, 60C, 200C, Aldosterone 12C, 30C, 60C, 200C, Androsterone 12C, 30C, 60C, 200C, Follicle Stimulating Hormone 12C, 30C, 60C, 200C.

HOMEOPATHIC INDICATIONS:

Temporary relief of symptoms related to hormone imbalances or insufficiencies in men and women, including low energy, inability to handle stress, trouble focusing, changes in mood, infertility, irregular menstrual cycles (females) and lack of libido.**

**These statements are based upon traditional homeopathic principles. They have not been reviewed by the Food and Drug Administration.

WARNINGS:

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

If pregnant or breast-feeding, ask a health professional before use.

Tamper seal: "Sealed for Your Protection." Do not use if seal is broken or missing.

KEEP OUT OF REACH OF CHILDREN:

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

10 drops under the tongue, 3 to 6 times per day or as directed by a health professional. Consult a physician for use in children under 12 years of age.

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INACTIVE INGREDIENTS:

demineralized water, 25% ethanol.

QUESTIONS:

Distributed by Dr. Donna Restivo DC, Wellness Consultant
822 South Lake Blvd, Mahopac, New York 10541
www.mahopacmassage.com • (845) 628-6286

PACKAGE LABEL DISPLAY:

DR. DONNA RESTIVO DC
WELLNESS CONSULTANT
NDC 62185-0041-1
HOMEOPATHIC
Hormone Balance
1 FL OZ (30 ml)

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DR. DONNA RESTIVO DC
—WELLNESS CONSULTANT—

NDC 62185-0041-1

HOMEOPATHIC

Hormone Balance

1 FL OZ (30 ml)

INACTIVE INGREDIENTS: demineralized water, 25% ethanol

ACTIVE INGREDIENTS:

Salsolinol 6X, 12X, 30X, 200X, DHEA 6X, 12X, 30X, 200X, 12C, 30C, 60C, 200C, 7-oxo-dehydroepiandrosterone-3 β -acetate 8X, 12X, 30X, 60X, 200X, 12C, 30C, 60C, 200C, Folliculinum 8X, 12X, 30X, 60X, 200X, 12C, 30C, 60C, 200C, Oophorium 8X, 12X, 30X, 60X, 200X, 12C, 30C, 60C, 200C, Cholesterinum 8X, 12X, 30X, 200X, 12C, 30C, 60C, 200C, Progesterone 8X, 12X, 30X, 200X, 12C, 30C, 60C, 200C, Testosterone 8X, 12X, 30X, 200X, 12C, 30C, 60C, 200C, Cortisone Aceticum 12X, 30X, 200X, 12C, 30C, 60C, 200C, Aldosterone 12C, 30C, 60C, 200C, Androsterone 12C, 30C, 60C, 200C, Follicle Stimulating Hormone 12C, 30C, 60C, 200C.

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LOT: XXXXXX

HORMONE BALANCE

salsolinol hydrochloride, dhea (dehydroepiandrosterone), 7-oxo-dehydroepiandrosterone-3b-acetate, folliculinum, oophorinum (suis), cholesterinum, progesterone, testosterone, cortisone aceticum, aldosterone, androsterone, follicle stimulating hormone liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62185-0041
Route of Administration	ORAL	DEA Schedule	CIII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALSOLINOL HYDROCHLORIDE, (+/-)- (UNII: 1C0F27WEAL) (SALSOLINOL HYDROCHLORIDE, (+/-)- - UNII:1C0F27WEAL)	SALSOLINOL HYDROCHLORIDE, (+/-)-	6 [hp_X] in 1 mL
PRASTERONE (UNII: 459AG36T1B) (PRASTERONE - UNII:459AG36T1B)	PRASTERONE	6 [hp_X] in 1 mL
7-OXODEHYDROEPIANDROSTERONE 3-ACETATE (UNII: 84RQ0XOM11) (7-OXODEHYDROEPIANDROSTERONE 3-ACETATE - UNII:84RQ0XOM11)	7- OXODEHYDROEPIANDROSTERONE 3-ACETATE	8 [hp_X] in 1 mL
ESTRONE (UNII: 2DI9HA706A) (ESTRONE - UNII:2DI9HA706A)	ESTRONE	8 [hp_X] in 1 mL
SUS SCROFA OVARY (UNII: S7YTV04R8O) (SUS SCROFA OVARY - UNII:S7YTV04R8O)	SUS SCROFA OVARY	8 [hp_X] in 1 mL
CHOLESTEROL (UNII: 97C5T2UQ7J) (CHOLESTEROL - UNII:97C5T2UQ7J)	CHOLESTEROL	8 [hp_X] in 1 mL
PROGESTERONE (UNII: 4G7DS2Q64Y) (PROGESTERONE - UNII:4G7DS2Q64Y)	PROGESTERONE	8 [hp_X] in 1 mL
TESTOSTERONE (UNII: 3XMK78S47O) (TESTOSTERONE - UNII:3XMK78S47O)	TESTOSTERONE	8 [hp_X] in 1 mL
CORTISONE ACETATE (UNII: 883WKN7W8X) (CORTISONE - UNII:V27W9254FZ)	CORTISONE ACETATE	12 [hp_X] in 1 mL
ALDOSTERONE (UNII: 4964P6T9RB) (ALDOSTERONE - UNII:4964P6T9RB)	ALDOSTERONE	12 [hp_C] in 1 mL
ANDROSTERONE (UNII: C24W7J5D5R) (ANDROSTERONE - UNII:C24W7J5D5R)	ANDROSTERONE	12 [hp_C] in 1 mL
FOLLITROPIN (UNII: 076WHW89TW) (FOLLITROPIN - UNII:076WHW89TW)	FOLLITROPIN	12 [hp_C] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62185-0041-1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	11/30/2018	02/08/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		11/30/2018	02/08/2024

Labeler - Dr. Donna Restivo DC (790796940)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(62185-0041) , api manufacture(62185-0041) , label(62185-0041) , pack(62185-0041)

Revised: 12/2021

Dr. Donna Restivo DC