

DISTRESS DROPS 2121- distress drops liquid

Professional Complementary Health Formulas

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.

C121

ACTIVE INGREDIENTS

Avena sativa 1X
Asafoetida 3X
Corydalis canadensis 3X
Hyoscyamus niger 3X
Sumbul 6X
Valeriana officinalis 3X
Cicuta virosa 4X
Ignatia amara 4X
Olei gaultheria procumbens 4X
Staphysagria 4X

QUESTIONS

Professional Formulas

PO Box 2034 Lake Oswego, OR 97035

INDICATIONS

For the temporary relief of feeling distressed or a tendency towards overreaction.*

*Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

WARNINGS

In case of overdose, get medical help or contact a poison control center right away.

Keep out of the reach of children.

If pregnant or breastfeeding, ask a healthcare professional before use.

DIRECTIONS

Place drops under tongue 30 minutes before/after meals. Adults and children 12 years and over: Take 10 drops up to 3 times per day. Consult a physician for use in children under 12 years of age.

OTHER INFORMATION

Tamper resistant. If seal is broken, do not use. After opening, close container tightly and store at room temperature away from heat.

INACTIVE INGREDIENTS

20% ethanol, purified water.

LABEL

Est 1985
Professional Formulas
Complementary Health
Distress Drops
Homeopathic Remedy
2 FL. OZ. (59 mL)



DISTRESS DROPS 2121			
distress drops liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63083-2121
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength

AVENA SATIVA FLOWERING TOP (UNII: MA9CQJ3F7F) (AVENA SATIVA FLOWERING TOP - UNII:MA9CQJ3F7F)	AVENA SATIVA FLOWERING TOP	1 [hp_X] in 59 mL
FERULA ASSA-FOETIDA RESIN (UNII: W9FZA51AS1) (FERULA ASSA-FOETIDA RESIN - UNII:W9FZA51AS1)	FERULA ASSA-FOETIDA RESIN	3 [hp_X] in 59 mL
DICENTRA CANADENSIS ROOT (UNII: Y5JS7YM46F) (DICENTRA CANADENSIS ROOT - UNII:Y5JS7YM46F)	DICENTRA CANADENSIS ROOT	3 [hp_X] in 59 mL
HYOSCYAMUS NIGER (UNII: 4WRK2153H3) (HYOSCYAMUS NIGER - UNII:4WRK2153H3)	HYOSCYAMUS NIGER	3 [hp_X] in 59 mL
FERULA SUMBUL ROOT (UNII: GLA4808EHQ) (FERULA SUMBUL ROOT - UNII:GLA4808EHQ)	FERULA SUMBUL ROOT	6 [hp_X] in 59 mL
VALERIAN (UNII: JWF5YAW3QW) (VALERIAN - UNII:JWF5YAW3QW)	VALERIAN	3 [hp_X] in 59 mL
CICUTA VIROSA WHOLE (UNII: 3E698BL84C) (CICUTA VIROSA WHOLE - UNII:3E698BL84C)	CICUTA VIROSA WHOLE	4 [hp_X] in 59 mL
STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K)	STRYCHNOS IGNATII SEED	4 [hp_X] in 59 mL
GAULTHERIA PROCUMBENS TOP (UNII: 830295X963) (GAULTHERIA PROCUMBENS TOP - UNII:830295X963)	GAULTHERIA PROCUMBENS TOP	4 [hp_X] in 59 mL
DELPHINIUM STAPHISAGRIA SEED (UNII: 00543AP1JV) (DELPHINIUM STAPHISAGRIA SEED - UNII:00543AP1JV)	DELPHINIUM STAPHISAGRIA SEED	4 [hp_X] in 59 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63083-2121-2	59 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	08/15/1985	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		08/15/1984	

Labeler - Professional Complementary Health Formulas (167339027)

Registrant - Natural Pharmaceutical Manufacturing LLC (015624923)

Establishment

Name	Address	ID/FEI	Business Operations
Natural Pharmaceutical Manufacturing LLC		015624923	manufacture(63083-2121)