HELONIAS DIOICA- helonias dioica pellet Hahnemann Laboratories, INC.

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.

Hahnemann Labs Inc. 1940 Fourth St. San Rafael, CA 94901

HELONIAS DIOICA 6C

Min. net wt: 5g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: • If pregnant or breast-feeding, ask a

health professional before use.

• If symptoms

persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



Min. net wt: 30g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a

health professional before use.

If symptoms persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



Min. net wt: 100g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms

persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



Min. net wt: 5g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms

persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



Min. net wt: 30g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



Min. net wt: 100g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms

persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



Hahnemann Labs Inc.

HELONIAS DIOICA 30C

Min. net wt: 1g
HOMEOPATHIC
MEDICINE HPUS
Active ingredient:
Listed above
Use:Traditional use
such as headache.
Keep out of reach
of children
Directions: Take 5
pellets orally once

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sucrose

Inactive ingredients:

nemann Labs Inc. 1940 Fourth St. San Rafael, (

Min. net wt: 5g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



Min. net wt: 30g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



Min. net wt: 100g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms

persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



Hahnemann Labs Inc.

HELONIAS DIOICA 100C

Min. net wt: 1g **HOMEOPATHIC** MEDICINE HPUS Active ingredient: Listed above Use: Traditional use such as headache. Keep out of reach of children Directions: Take 5 pellets orally once

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sucrose

Inactive ingredients:

HELONIAS DIOICA 100C

Min. net wt: 5g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms

persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



HELONIAS DIOICA 100C

Min. net wt: 30g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms

persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



HELONIAS DIOICA 100C

Min. net wt: 100g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms

persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



Hahnemann Labs Inc.

HELONIAS DIOICA 200C

Min. net wt: 1g **HOMEOPATHIC** MEDICINE HPUS Active ingredient: Listed above Use: Traditional use such as headache. Keep out of reach of children Directions: Take 5 pellets orally once

sucrose 00000

Inactive ingredients:

HELONIAS DIOICA 200C

Min. net wt: 5g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a

health professional before use.

If symptoms persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



HELONIAS DIOICA 200C

Min. net wt: 30g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms

persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



HELONIAS DIOICA 200C

Min. net wt: 100g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms

health professional before use.

If symptoms persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



Hahnemann Labs Inc.

HELONIAS DIOICA 500C

Min. net wt: 1g **HOMEOPATHIC** MEDICINE HPUS Active ingredient: Listed above Use: Traditional use such as headache. Keep out of reach of children Directions: Take 5 pellets orally once

sucrose 00000

Inactive ingredients:

HELONIAS DIOICA 500C

Min. net wt: 5g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



HELONIAS DIOICA 500C

Min. net wt: 30g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms

persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



HELONIAS DIOICA 500C

Min. net wt: 100g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms

persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



Hahnemann Labs Inc.

HELONIAS DIOICA 1M

Min. net wt: 1g
HOMEOPATHIC
MEDICINE HPUS
Active ingredient:
Listed above
Use:Traditional use
such as headache.
Keep out of reach
of children
Directions: Take 5
pellets orally once

sucrose

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Inactive ingredients:

emann Labs Inc. 1940 Fourth St. San Rafael,

Min. net wt: 5g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms

persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



Min. net wt: 30g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



Min. net wt: 100g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms

persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



Hahnemann Labs Inc.

HELONIAS DIOICA 10M

Min. net wt: 1g
HOMEOPATHIC
MEDICINE HPUS
Active ingredient:
Listed above
Use:Traditional use
such as headache.
Keep out of reach
of children
Directions: Take 5

pellets orally once Inactive ingredients: sucrose

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memann Labs Inc. 1940 Fourth St. San Rafael, CA
TWIST TO OPEN - USE ONLY IF SEALEI

Min. net wt: 5g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms

persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



Min. net wt: 30g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms

persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



Hahnemann Labs Inc. 1940 Fourth St. San Rafael, CA 94901

HELONIAS DIOICA 10M

Min. net wt: 100g of pellets

HOMEOPATHIC MEDICINE HPUS

Drug Facts: Active ingredients: Listed above

Uses: This product is intended for traditional

homeopathic uses such as for headache.

Warnings: ■ If pregnant or breast-feeding, ask a health professional before use. ■ If symptoms

persist beyond 3 days, consult a health professional.

Keep out of reach of children.

Directions: Take 5 pellets orally once, or as

directed by a health professional

Inactive ingredients: sucrose

Questions? Call toll free 888-427-6422

Do not use if safety seal is broken.



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HELONIAS DIOICA

helonias dioica pellet

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Product Type HUMAN OTC D

HUMAN OTC DRUG Item Code (Source)

NDC:37662-1500

Route of Administration

ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHAMAELIRIUM LUTEUM ROOT (UNII: DQV54Y5H3U) (CHAMAELIRIUM LUTEUM ROOT - UNII:DQV54Y5H3U)	CHAMAELIRIUM LUTEUM ROOT	100 [hp_C]

Inactive Ingredients	
Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	

Product Characteristics						
Color	white	Score	no score			
Shape	ROUND	Size	2mm			
Flavor		Imprint Code				
Contains						

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:37662- 1500-1	200 in 1 VIAL, GLASS; Type 0: Not a Combination Product	09/13/2022				
2	NDC:37662- 1500-2	500 in 1 VIAL, GLASS; Type 0: Not a Combination Product	09/13/2022				
3	NDC:37662- 1500-3	3000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/13/2022				
4	NDC:37662- 1500-4	10000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/13/2022				

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
unapproved homeopathic		09/13/2022					

helonias dioica pellet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37662-1504
Route of Administration	ORAL		

	Active Ingredient/Active Moiety				
ı		Basis of Strength			
	CHAMAELIRIUM LUTEUM ROOT (UNII: DQV54Y5H3U) (CHAMAELIRIUM LUTEUM ROOT - UNII:DQV54Y5H3U)	CHAMAELIRIUM LUTEUM ROOT	10 [hp_M]		

Inactive Ingredients

	Inc	ırediei	nt Name
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Strength

SUCROSE (UNII: C151H8M554)

Product Characteristics							
Color	white	Score	no score				
Shape	ROUND	Size	2mm				
Flavor		Imprint Code					
Contains							

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:37662- 1504-1	200 in 1 VIAL, GLASS; Type 0: Not a Combination Product	09/13/2022				
2	NDC:37662- 1504-2	500 in 1 VIAL, GLASS; Type 0: Not a Combination Product	09/13/2022				
3	NDC:37662- 1504-3	3000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/13/2022				
4	NDC:37662- 1504-4	10000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/13/2022				

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
unapproved homeopathic		09/13/2022					

HELONIAS DIOICA

helonias dioica pellet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37662-1502	
Route of Administration	ORAL			

l	Active Ingredient/Active Moiety				
l	Ingredient Name	Basis of Strength			
	CHAMAELIRIUM LUTEUM ROOT (UNII: DQV54Y5H3U) (CHAMAELIRIUM LUTEUM ROOT - UNII:DQV54Y5H3U)	CHAMAELIRIUM LUTEUM ROOT	500 [hp_C]		

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	

Product Characteristics					
Color	white	Score	no score		
Shape	ROUND	Size	2mm		
Flavor		Imprint Code			
Contains					

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:37662- 1502-1	200 in 1 VIAL, GLASS; Type 0: Not a Combination Product	09/13/2022			
2	NDC:37662- 1502-2	500 in 1 VIAL, GLASS; Type 0: Not a Combination Product	09/13/2022			
3	NDC:37662- 1502-3	3000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/13/2022			
4	NDC:37662- 1502-4	10000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/13/2022			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved homeopathic		09/13/2022		

helonias dioica pellet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37662-1501	
Route of Administration	ORAL			

I	Active Ingredient/Active Moiety				
I	Ingredient Name	Basis of Strength			
l	CHAMAELIRIUM LUTEUM ROOT (UNII: DQV54Y5H3U) (CHAMAELIRIUM LUTEUM ROOT - UNII:DQV54Y5H3U)	CHAMAELIRIUM LUTEUM ROOT	200 [hp_C]		

Inactive Ingredients				
Ingredient Name	Strength			
SUCROSE (UNII: C151H8M554)				

Product Characteristics					
Color	white	Score	no score		
Shape	ROUND	Size	2mm		
Flavor		Imprint Code			
Contains					

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:37662- 1501-1	200 in 1 VIAL, GLASS; Type 0: Not a Combination Product	09/13/2022			
2	NDC:37662- 1501-2	500 in 1 VIAL, GLASS; Type 0: Not a Combination Product	09/13/2022			
3	NDC:37662- 1501-3	3000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/13/2022			
4	NDC:37662- 1501-4	10000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/13/2022			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved homeopathic		09/13/2022			

helonias dioica pellet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37662-1503	
Route of Administration	ORAL			

l	Active Ingredient/Active Moiety				
l	Ingredient Name	Basis of Strength			
	CHAMAELIRIUM LUTEUM ROOT (UNII: DQV54Y5H3U) (CHAMAELIRIUM LUTEUM ROOT - UNII:DQV54Y5H3U)	CHAMAELIRIUM LUTEUM ROOT	1 [hp_M]		

Inactive Ingredients	
Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	2mm
Flavor		Imprint Code	
Contains			

ı	Packaging					
4	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:37662- 1503-1	200 in 1 VIAL, GLASS; Type 0: Not a Combination Product	09/13/2022			
2	NDC:37662- 1503-2	500 in 1 VIAL, GLASS; Type 0: Not a Combination Product	09/13/2022			
3	NDC:37662- 1503-3	3000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/13/2022			
4	NDC:37662- 1503-4	10000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/13/2022			

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
	09/13/2022			
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date		

helonias dioica pellet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37662-1497	
Route of Administration	ORAL			

l	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength		
	CHAMAELIRIUM LUTEUM ROOT (UNII: DQV54Y5H3U) (CHAMAELIRIUM LUTEUM ROOT - UNII:DQV54Y5H3U)	CHAMAELIRIUM LUTEUM ROOT	6 [hp_C]	

Inactive Ingredients			
Ingredient Name	Strength		
SUCROSE (UNII: C151H8M554)			

Product Characteristics				
Color	white	Score	no score	
Shape	ROUND	Size	3mm	
Flavor		Imprint Code		

Contains

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:37662- 1497-1	200 in 1 VIAL, GLASS; Type 0: Not a Combination Product	09/13/2022				
2	NDC:37662- 1497-2	1200 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/13/2022				
3	NDC:37662- 1497-3	4000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/13/2022				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved homeopathic		09/13/2022		

HELONIAS DIOICA

helonias dioica pellet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37662-1498
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	
	CHAMAELIRIUM LUTEUM ROOT (UNII: DQV54Y5H3U) (CHAMAELIRIUM LUTEUM ROOT - UNII:DQV54Y5H3U)	CHAMAELIRIUM LUTEUM ROOT	12 [hp_C]

Inactive Ingredients	
Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	

Product Characteristics			
Color white		Score	no score
Shape	ROUND	Size	3mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37662- 1498-1	200 in 1 VIAL, GLASS; Type 0: Not a Combination Product	09/13/2022	
2	NDC:37662- 1498-2	1200 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/13/2022	
3	NDC:37662- 1498-3	4000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/13/2022	

keting Start Marketing End Date Date
2022

helonias dioica pellet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:37662-1499	
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	
	CHAMAELIRIUM LUTEUM ROOT (UNII: DQV54Y5H3U) (CHAMAELIRIUM LUTEUM ROOT - UNII:DQV54Y5H3U)	CHAMAELIRIUM LUTEUM ROOT	30 [hp_C]

Inactive Ingredients			
Ingredient Name	Strength		
SUCROSE (UNII: C151H8M554)			

Product Characteristics			
Color white		Score	no score
Shape	ROUND	Size	3mm
Flavor		Imprint Code	
Contains			

P	Packaging				
#	# Item Code Package Description		Marketing Start Date	Marketing End Date	
1	NDC:37662- 1499-1	80 in 1 VIAL, GLASS; Type 0: Not a Combination Product	09/13/2022		
2	NDC:37662-	200 in 1 VIAL, GLASS; Type 0: Not a Combination	00/12/2022		

4	1499-2	Product	U3/13/2022	
3	NDC:37662- 1499-3	1200 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/13/2022	
4	NDC:37662- 1499-4	4000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/13/2022	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved homeopathic		09/13/2022			
		09/13/2022			

Labeler - Hahnemann Laboratories, INC. (147098081)

Establishment				
Name	Address	ID/FEI	Business Operations	
Hahnemann Laboratories, INC.		147098081	manufacture(37662-1497, 37662-1498, 37662-1499, 37662-1500, 37662-1501, 37662-1502, 37662-1503, 37662-1504)	

Revised: 9/2022 Hahnemann Laboratories, INC.