HELLEBORUS NIGER- helleborus niger 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

HELLEBORUS NIGER 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.

HELLEBORUS NIGER 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

sucrose

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Inactive ingredients:

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.

HELLEBORUS NIGER 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 Inactive ingredients: sucrose

HELLEBORUS NIGER 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.



HELLEBORUS NIGER 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.



HELLEBORUS NIGER 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.

HELLEBORUS NIGER 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 Inactive ingredients: sucrose

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emann Labs Inc. 1940 Fourth St. San Rafael,
TWIST TO OPEN - USE ONLY IF SEAI

HELLEBORUS NIGER 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.



HELLEBORUS NIGER 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

■ 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.



HELLEBORUS NIGER 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 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.

HELLEBORUS NIGER 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 Inactive ingredients: sucrose

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emann Labs Inc. 1940 Fourth St. San Rafael, C.
TWIST TO OPEN - USE ONLY IF SEALE

HELLEBORUS NIGER 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.



HELLEBORUS NIGER 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

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.



HELLEBORUS NIGER 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.

HELLEBORUS NIGER 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
Inactive ingredients:

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sucrose

emann Labs Inc. 1940 Fourth St. San Rafael, C

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.

HELLEBORUS NIGER 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

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Inactive ingredients:

sucrose

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

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. 1940 Fourth St. San Rafael, CA 94901

HELLEBORUS NIGER LM1

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.



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HELLEBORUS NIGER

helleborus niger pellet

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Product Type HUMAN OTC DRUG

Item Code (Source)

NDC:37662-1662

Route of Administration

ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HELLEBORUS NIGER ROOT (UNII: 608DGJ6815) (HELLEBORUS NIGER ROOT - UNII: 608DGJ6815)	HELLEBORUS NIGER 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				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:37662- 1662-1	200 in 1 VIAL, GLASS; Type 0: Not a Combination Product	10/03/2022			
2	NDC:37662- 1662-2	500 in 1 VIAL, GLASS; Type 0: Not a Combination Product	10/03/2022			
3	NDC:37662- 1662-3	3000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/03/2022			
4	NDC:37662- 1662-4	10000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/03/2022			

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
unapproved homeopathic		10/03/2022		

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37662-1663	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
HELLEBORUS NIGER ROOT (UNII: 608DGJ6815) (HELLEBORUS NIGER ROOT - UNII:608DGJ6815)	HELLEBORUS NIGER ROOT	10 [hp_M]		

Inactive Ingredients

Ingredient Name	Strength
Ingredient Name	Strength

SUCROSE (UNII: C151H8M554)

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

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:37662- 1663-1	200 in 1 VIAL, GLASS; Type 0: Not a Combination Product	10/03/2022			
2	NDC:37662- 1663-2	500 in 1 VIAL, GLASS; Type 0: Not a Combination Product	10/03/2022			
3	NDC:37662- 1663-3	3000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/03/2022			
4	NDC:37662- 1663-4	10000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/03/2022			

Marketing Information				
Marketing Application Number or Monograph Marketing Start Market Category Citation Date Date				
unapproved homeopathic		10/03/2022		

HELLEBORUS NIGER

helleborus niger pellet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37662-1657	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
HELLEBORUS NIGER ROOT (UNII: 608DGJ6815) (HELLEBORUS NIGER ROOT - UNII: 608DGJ6815)	HELLEBORUS NIGER 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					

P	Packaging					
# Item Code		Package Description	Marketing Start Date	Marketing End Date		
1	NDC:37662- 1657-1	200 in 1 VIAL, GLASS; Type 0: Not a Combination Product	10/03/2022			
2	NDC:37662- 1657-2	1200 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/03/2022			
3	NDC:37662- 1657-3	4000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/03/2022			

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing Category Citation Date Date				
	10/03/2022			
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date		

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37662-1658	
Route of Administration	ORAL			

l	Active Ingredient/Active Moiety					
l	Ingredient Name	Basis of Strength	Strength			
	HELLEBORUS NIGER ROOT (UNII: 608DGJ6815) (HELLEBORUS NIGER ROOT - UNII: 608DGJ6815)	HELLEBORUS NIGER 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					

F	Packaging					
#	# Item Code Package Description		Marketing Start Date	Marketing End Date		
1	NDC:37662- 1658-1	80 in 1 VIAL, GLASS; Type 0: Not a Combination Product	10/03/2022			
2	NDC:37662- 1658-2	200 in 1 VIAL, GLASS; Type 0: Not a Combination Product	10/03/2022			
3	NDC:37662- 1658-3	1200 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/03/2022			
4	NDC:37662- 1658-4	4000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/03/2022			

Marketing Information				
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date	
unapproved homeopathic		10/03/2022		

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37662-1659	
Route of Administration	ORAL			

I	Active Ingredient/Active Moiety			
I	Ingredient Name	Basis of Strength	Strength	
	HELLEBORUS NIGER ROOT (UNII: 608DGJ6815) (HELLEBORUS NIGER ROOT - UNII: 608DGJ6815)	HELLEBORUS NIGER 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		

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
NDC:37662- 1659-1	200 in 1 VIAL, GLASS; Type 0: Not a Combination Product	10/03/2022			
NDC:37662- 1659-2	500 in 1 VIAL, GLASS; Type 0: Not a Combination Product	10/03/2022			
NDC:37662- 1659-3	3000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/03/2022			
NDC:37662- 1659-4	10000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/03/2022			

Marketing Information				
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date	
unapproved homeopathic		10/03/2022		
homeopathic		10/03/2022		

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37662-1660	
Route of Administration	ORAL			

I	Active Ingredient/Active Moiety				
I	Ingredient Name	Basis of Strength	Strength		
	HELLEBORUS NIGER ROOT (UNII: 608DGJ6815) (HELLEBORUS NIGER ROOT - UNII:608DGJ6815)	HELLEBORUS NIGER ROOT	200 [hp_C]		

Inactive Ingredients	
Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	

Color white Score no score			
DUND	Size	2mm	
	Imprint Code		
	JND	500.0	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:37662- 1660-1	200 in 1 VIAL, GLASS; Type 0: Not a Combination Product	10/03/2022			
2	NDC:37662- 1660-2	500 in 1 VIAL, GLASS; Type 0: Not a Combination Product	10/03/2022			
3	NDC:37662- 1660-3	3000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/03/2022			
4	NDC:37662- 1660-4	10000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/03/2022			

Marketing Information				
Marketing Application Number or Monograph Marketing Start Ma Category Citation Date				
	10/03/2022			
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date		

helleborus niger pellet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37662-1656	
Route of Administration	ORAL			

l	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
	HELLEBORUS NIGER ROOT (UNII: 608DGJ6815) (HELLEBORUS NIGER ROOT - UNII:608DGJ6815)	HELLEBORUS NIGER 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				

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37662- 1656-1	200 in 1 VIAL, GLASS; Type 0: Not a Combination Product	10/03/2022	
2	NDC:37662- 1656-2	1200 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/03/2022	
3	NDC:37662- 1656-3	4000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/03/2022	

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing I Category Citation Date Date				
unapproved homeopathic		10/03/2022		
homeopathic		10/03/2022		

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37662-1661	
Route of Administration	ORAL			

l	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
	HELLEBORUS NIGER ROOT (UNII: 608DGJ6815) (HELLEBORUS NIGER ROOT - UNII: 608DGJ6815)	HELLEBORUS NIGER 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- 1661-1	200 in 1 VIAL, GLASS; Type 0: Not a Combination Product	10/03/2022		
7	NDC:37662-	500 in 1 VIAL, GLASS; Type 0: Not a Combination	10/02/2022		

1	_	1661-2	Product	10/03/2022	
	3		3000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/03/2022	
	4	NDC:37662- 10000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		10/03/2022	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved homeopathic		10/03/2022		

helleborus niger pellet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37662-1664	
Route of Administration	ORAL			

Active Ingredient/Active Moiety Ingredient Name Basis of Strength HELLEBORUS NIGER ROOT (UNII: 608DGJ6815) (HELLEBORUS NIGER ROOT - UNII: 608DGJ6815) HELLEBORUS NIGER ROOT | 1 [hp_Q]

Inactive Ingredients		
Ingredient Name	Strength	
SUCROSE (UNII: C151H8M554)		

Product Characteristics				
Color	white	Score	no score	
Shape	ROUND	Size	1mm	
Flavor		Imprint Code		
Contains				

	Packaging					
# Item Code		Package Description	Marketing Start Date	Marketing End Date		
	1 NDC:37662-1664-1	10000 in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	10/03/2022			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/03/2022	

Labeler - Hahnemann Laboratories, INC. (147098081)

Establishment			
Name	Address	ID/FEI	Business Operations
Hahnemann Laboratories, INC.		147098081	manufacture(37662-1656, 37662-1657, 37662-1658, 37662-1659, 37662-1660, 37662-1661, 37662-1662, 37662-1663, 37662-1664)

Revised: 10/2022 Hahnemann Laboratories, INC.