PLACENTA COMPOSITUM - horse chestnut and lactic acid, l- and claviceps purpurea sclerotium and cupric sulfate and melilotus officinalis top and sus scrofa placenta and solanum nigrum whole and strophanthus hispidus seed and sus scrofa embryo and sodium pyruvate and sus scrofa vein and sus scrofa artery and sus scrofa umbilical cord and tobacco leaf and vipera berus venom and barium carbonate and lead iodide injection
Heel 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.

Placenta Compositum 2.2 ml Injection

DESCRIPTION
Injection Solution Ingredient Information: Each 2.2 ml ampule contains: Aesculus hippocastanum 4X, Sarcolacticum acidum 4X, Secale cornutum 4X, Cuprum sulphuricum 6X, Melilotus officinalis 6X, Placenta suis 6X, Solanum nigrum 6X, Strophanthus hispidus 6X, Embryo suis 8X, Natrum pyruvicum 8X, Vena suis 8X, Arteria suis 10X, Funiculus umbilicalis suis 10X, Tabacum 10X, Vipera berus 10X, Baryta carbonica 13X, Plumbum iodatum 18X 22 mcl each. Inactive ingredient: Sterile isotonic sodium chloride
solution

INDICATION AND USAGE
Placenta compositum Injection Solution is indicated for stimulation of metabolic functions of the peripheral circulation of the blood as well as for a revitalizing and stimulating effect on the liver and peripheral vascular system.

Placenta compositum Injection Solution is classified as a homeopathic combination drug.

Botanical ingredients:
- Aesculus hippocastanum (horse chestnut)
- Melilotus officinalis (yellow sweet clover)
- Secale cornutum (rye ergot)
- Solanum nigrum (black nightshade)
- Strophanthus hispidus (Strophanthus)
- Tabacum (tobacco)

Mineral ingredients:
- Baryta carbonica (barium carbonate)
- Cuprum sulphuricum (copper sulfate)
- Natrum pyruvicum (sodium pyruvate)
- Plumbum iodatum (lead iodide)
- Sarcolacticum acidum (L-lactic acid)

Animal-derived ingredients
- Arteria suis (porcine artery)
- Embryo suis (porcine embryo)
- Funiculus umbilicalis suis (porcine umbilical cord)
- Placenta suis (porcine placenta)
- Vena suis (porcine vein)
- Vipera berus (common viper)

DOSAGE AND ADMINISTRATION

The dosage schedules listed below can be used as a general guide for the administration of Placenta compositum Injection Solution. Placenta compositum Injection Solution shows individual differences in clinical response. Therefore, the dosage for each patient should be individualized according to the patient's response to therapy.

Adults and children 7 years and older: in acute disorders, 1 ampule per day, otherwise 1 ampule, 1 to 3 times per week IM/SC/IV/ID. *Children ages 2 to 6* receive ½ the adult dosage.

Discard unused solution.

WARNINGS

Warnings and Precautions

If pain persists or worsens, if new symptoms occur, or if redness or swelling is present, the patient should be carefully re-evaluated because these could be signs of a serious condition.

Pregnancy Category C. Animal reproduction studies have not been conducted with this drug. It is also not known whether this drug can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. This drug should be given to a pregnant woman only if clearly needed.

To report SUSPECTED ADVERSE REACTIONS, contact Heel Inc. at 1.800.920.9203 or info@heelusa.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

PLACENTA COMPOSITUM

horse chestnut and lactic acid, l- and claviceps purpurea sclerotium and cupric sulfate and melilotus officinalis top and sus scrofa placenta and solanum nigrum whole and strophanthus hispidus seed and sus scrofa embryo and sodium pyruvate and sus scrofa vein and sus scrofa artery and sus scrofa umbilical cord and tobacco leaf and vipera berus venom and barium carbonate and lead iodide injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:50114-7055
Route of Administration	INTRADERMAL, INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		

Ingredient Name	Basis of Strength	Strength
HORSE CHESTNUT (UNII: 3C18L6RJAZ) (HORSE CHESTNUT - UNII:3C18L6RJAZ)	HORSE CHESTNUT	4 [hp_X] in 2.2 mL
LACTIC ACID, L- (UNII: F9S9FFU82N) (LACTIC ACID, L- - UNII:F9S9FFU82N)	LACTIC ACID, L-	4 [hp_X] in 2.2 mL
CLAVICEPS PURPUREA SCLEROTIUM (UNII: 01G9XEA93N) (CLAVICEPS PURPUREA SCLEROTIUM - UNII:01G9XEA93N)	CLAVICEPS PURPUREA SCLEROTIUM	4 [hp_X] in 2.2 mL
CUPRIC SULFATE (UNII: LRX7AJ16DT) (CUPRIC CATION - UNII:8CBV67279L, SULFATE ION - UNII:7IS9N8KPMG)	CUPRIC SULFATE	6 [hp_X] in 2.2 mL
MELILOTUS OFFICINALIS TOP (UNII: GM6P02J2DX) (MELILOTUS OFFICINALIS TOP - UNII:GM6P02J2DX)	MELILOTUS OFFICINALIS TOP	6 [hp_X] in 2.2 mL
SUS SCROFA PLACENTA (UNII: C8CV8867O8) (SUS SCROFA PLACENTA - UNII:C8CV8867O8)	SUS SCROFA PLACENTA	6 [hp_X] in 2.2 mL
SOLANUM NIGRUM WHOLE (UNII: 0FMD6WV47M) (SOLANUM NIGRUM WHOLE - UNII:0FMD6WV47M)	SOLANUM NIGRUM WHOLE	6 [hp_X] in 2.2 mL
STROPHANTHUS HISPIDUS SEED (UNII: MO892VI77K) (STROPHANTHUS HISPIDUS SEED - UNII:MO892VI77K)	STROPHANTHUS HISPIDUS SEED	6 [hp_X] in 2.2 mL
SUS SCROFA EMBRYO (UNII: 9928MC12VO) (SUS SCROFA EMBRYO - UNII:9928MC12VO)	SUS SCROFA EMBRYO	8 [hp_X] in 2.2 mL
SODIUM PYRUVATE (UNII: POD38AIF08) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PYRUVATE	8 [hp_X] in 2.2 mL
SUS SCROFA VEIN (UNII: 2510RH3I89) (SUS SCROFA VEIN - UNII:2510RH3I89)	SUS SCROFA VEIN	8 [hp_X] in 2.2 mL
SUS SCROFA ARTERY (UNII: 63O327782Q) (SUS SCROFA ARTERY - UNII:63O327782Q)	SUS SCROFA ARTERY	10 [hp_X] in 2.2 mL
SUS SCROFA UMBILICAL CORD (UNII: 118OYG6W3H) (SUS SCROFA UMBILICAL CORD - UNII:118OYG6W3H)	SUS SCROFA UMBILICAL CORD	10 [hp_X] in 2.2 mL
TOBACCO LEAF (UNII: 6YR2608RSU) (TOBACCO LEAF - UNII:6YR2608RSU)	TOBACCO LEAF	10 [hp_X] in 2.2 mL
VIPERA BERUS VENOM (UNII: 0ORO6NCA4M) (VIPERA BERUS VENOM - UNII:0ORO6NCA4M)	VIPERA BERUS VENOM	10 [hp_X] in 2.2 mL
BARIUM CARBONATE (UNII: 6P669D8HQ8) (BARIUM CATION - UNII:V645272HLN, CARBONATE ION - UNII:7UJQ5OPE7D)	BARIUM CARBONATE	13 [hp_X] in 2.2 mL
LEAD IODIDE (UNII: OTL90F2GLT) (LEAD IODIDE - UNII:OTL90F2GLT)	LEAD IODIDE	18 [hp_X] in 2.2 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50114-7055-1	10 in 1 CARTON		
1		2.2 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		04/30/2009	

Labeler - Heel Inc (102783016)

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