

MENS PLATINUM- calcarea carbonica, capsicum annuum, ferrum metallicum, glandula suprarenalis, graphites, hepar suis, hypothalamus, kali carbonicum, lycopodium clavatum, natrum muriaticum, nux vomica, pancreatinum, phytolacca decandra, orchitinum. liquid Breakthrough M2 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.

Breakthrough M2 Men's PLATINUM

Active ingredients (HPUS*)

equal amounts of: Calcarea Carbonica 12X, Capsicum Annuum 6X, Ferrum Metallicum 12X, Glandula Suprarenalis 8X, Graphites 12X, Hepar Suis 10X, Hypothalamus 18X, Kali Carbonicum 6X, Lycopodium Clavatum 12X, Natrum Muriaticum 12X, Nux Vomica 30X, Pancreatinum 12X, Phytolacca Decandra 12X, Orchitinum 8X.

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

*The letters "HPUS" indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.

Uses:

Temporarily gives support during weight management program.

Warnings:

- This product is not intended for use by children under 18 years of age.
- **IF PREGNANT OR NURSING** or taking any medication, ask a healthcare professional before use.
- **KEEP OUT OF REACH OF CHILDREN** . In case of accidental overdose, get medical help or contact a Poison Control Center immediately. (800-222-1222).

KEEP OUT OF REACH OF CHILDREN.

Directions:

Use only as directed. Shake well before use. Take 12 drops, 3 times a day, 30 minutes before meals. Place drops under the tongue and hold for 10-15 seconds before swallowing. Consult a physician before starting any diet/exercise program.

Other Information:

- Store at room temperature away from heat and sunlight.
- Do not use if tamper evident neck seal is missing or broken.

Inactive ingredients:

Ethyl Alcohol, Purified Water.

DISTRIBUTED BY

Breakthrough M2 Inc.

2308 St Rte 208, Montgomery, NY 12549

(845) 713-4320

Visit www.breakthroughM2.com

Made in USA in FDA inspected facility.

NDC 70965-001-02

Breakthrough M2

Homeopathic PLATINUM®

MEN

2 fl oz (60 ml)

Ethyl Alcohol 20%

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DRUG FACTS

Active Ingredients (HPUS*) equal amounts of: Calcarea Carbonica 12X, Capsicum Annum 6X, Ferrum Metallicum 12X, Glandula Suprarenalis 8X, Graphites 12X, Hepar Suis 10X, Hypothalamus 18X, Kali Carbonicum 6X, Lycopodium Clavatum 12X, Natrum Muriaticum 12X, Nux Vomica 30X, Pancreatinum 12X, Phytolacca Decandra 12X, Orchitimum 8X.

Purpose: Supports healthy sleep, stable mood, lower stress levels, body processes and organ support while following a healthy weight management diet and exercise regimen.†

Uses: Temporarily gives support during weight management program.†

Warnings:
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MENS PLATINUM

calcarea carbonica, capsicum annuum, ferrum metallicum, glandula suprarenalis, graphites, hepar suis, hypothalamus, kali carbonicum, lycopodium clavatum, natrum muriaticum, nux vomica, pancreatinum, phytolacca decandra, orchitimum. liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70965-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OYSTER SHELL CALCIUM CARBONATE, CRUDE (UNII: 2E32821G6I) (OYSTER SHELL CALCIUM CARBONATE, CRUDE - UNII:2E32821G6I)	OYSTER SHELL CALCIUM CARBONATE, CRUDE	12 [hp_X] in 59 mL
CAPSICUM (UNII: 00 UK7646FG) (CAPSICUM - UNII:00 UK7646FG)	CAPSICUM	6 [hp_X] in 59 mL
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	12 [hp_X] in 59 mL
SUS SCROFA ADRENAL GLAND (UNII: 398IYQ16YV) (SUS SCROFA ADRENAL GLAND - UNII:398IYQ16YV)	SUS SCROFA ADRENAL GLAND	8 [hp_X] in 59 mL

GRAPHITE (UNII: 4QQN74LH4O) (GRAPHITE - UNII:4QQN74LH4O)	GRAPHITE	12 [hp_X] in 59 mL
PORK LIVER (UNII: 6EC706HI7F) (PORK LIVER - UNII:6EC706HI7F)	PORK LIVER	10 [hp_X] in 59 mL
BOS TAURUS HYPOTHALAMUS (UNII: S6G2NLH4Y7) (BOS TAURUS HYPOTHALAMUS - UNII:S6G2NLH4Y7)	BOS TAURUS HYPOTHALAMUS	18 [hp_X] in 59 mL
POTASSIUM CARBONATE (UNII: BQN1B9B9HA) (CARBONATE ION - UNII:7UJQ5OPE7D)	POTASSIUM CARBONATE	6 [hp_X] in 59 mL
LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	12 [hp_X] in 59 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	12 [hp_X] in 59 mL
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	30 [hp_X] in 59 mL
PANCRELIPASE (UNII: FQ3DRG0N5K) (PANCRELIPASE LIPASE - UNII:8MYC33932O)	PANCRELIPASE LIPASE	12 [hp_X] in 59 mL
PHYTOLACCA AMERICANA ROOT (UNII: 11E6VI8VEG) (PHYTOLACCA AMERICANA ROOT - UNII:11E6VI8VEG)	PHYTOLACCA AMERICANA ROOT	12 [hp_X] in 59 mL
SUS SCROFA TESTICLE (UNII: KM02613O28) (SUS SCROFA TESTICLE - UNII:KM02613O28)	SUS SCROFA TESTICLE	8 [hp_X] in 59 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:70965-001-02	59 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	10/10/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/10/2016	

Labeler - Breakthrough M2 Inc (039423774)

Registrant - OHM PHARMA INC. (030572478)

Establishment

Name	Address	ID/FEI	Business Operations
OHM PHARMA INC.		030572478	manufacture(70965-001)