# HYDRATE II- coffea tosta, avena sativa, equisetum hyemale, hypericum perforatum, ginkgo biloba, germanium sesquioxide, silicea liquid Maplewood Company

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.

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#### **DRUG FACTS:**

#### **ACTIVE INGREDIENTS:**

Coffea Tosta 2X, Avena Sativa 3X, Equisetum Hyemale 3X, Hypericum Perforatum 3X, Ginkgo Biloba 6X, Germanium Sesquioxide 8X, Silicea 8X.

#### **INDICATIONS:**

For temporary relief of dry mouth, dyspepsia, infrequent urination, constipation alternating with diarrhea, chronic myalgia, headache and low back pain.

#### **WARNINGS:**

□**If pregnant or breast-feeding**,□ ask a health care professinal before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

Do not use if tamper evident seal is broken or missing.

Store in a cool, dry place.

#### **DIRECTIONS:**

Mix 3 parts water to one part juice, add 6 drops Hydrate II to 8 oz. mixture. Drink 4 eight oz glasses daily in between meals. Drink hydrate/water mixture for 6 days and then only water for one day. Repeat. After eight weeks begin drinking more pure water and less hydrate/water mixture. Consult a physician for use in children under 12 years of age.

#### **INACTIVE INGREDIENTS:**

Celandine, Beet, Blessed Thistle, Boldo, Dandelion, Parsley, Demineralized Water, 25% Ethanol

#### KEEP OUT OF REACH OF CHILDREN:

**□Keep out of reach of children.** □ In case of overdose, get medical help or contact a Poison Control Center right away.

#### **INDICATIONS:**

For temporary relief of dry mouth, dyspepsia, infrequent urination, constipation alternating with diarrhea, chronic myalgia, headache and low back pain.

#### **QUESTIONS:**

Manufactured For:

Maplewood Company 7334 S. Alton Way Building #14, Ste. A Centennial, CO 80112

#### **PACKAGE DISPLAY LABEL:**

HYDRATE II
HOMEOPATHIC
1 FL OZ (30 mL)

ACTIVE INGREDIENTS:
Coffea Tosta 2X, Avena Sativa 3X,
Equisetum Hyemale 3X,
Hypericum Perforatum 3X,
Ginkgo Biloba 6X, Germanium
Sesquioxide 8X, Silicea 8X,
INACTIVE INGREDIENTS:
Demineralized Water, 25% Ethanol,
Hydrate II Herbal Base:
Celandine (Aerial Parts)
Chelidonium Majus, Beet (Root)
Beta Vulgaris, Blessed Thistle
(Aerial Parts) Cnicus Benedictus,
Boldo (Leaf) Peumus Boldus,
Dandelion (Root) Taraxacum
Officinale, Parsley (Leaf)
Petroselinum Crispum.

WARNINGS: If pregnant or breast-feeding, ask a health care professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Do not use if tamper evident seal is broken or missing. Store in a cool, dry place.

LOT: XXXXXXXXXX



#### HOMEOPATHIC



25% Ethanol 1 FL OZ (30 ml)

#### INDICATIONS:

For temporary relief of dry mouth, dyspepsia, infrequent urination, constipation alternating with diarrhea, chronic myalgia, headache and low back pain.

#### DIRECTIONS:

Mix 3 parts water to one part juice, add 6 drops Hydrate II to 8 oz. mixture or add 30 drops to a quart mixture. Drink 4 eight oz glasses daily in between meals. Drink hydrate/water mixture for 6 days and then only water for one day. Repeat. After eight weeks begin drinking more pure water and less hydrate/water mixture. Consult a physician for use in children under 12 years of age.

Manufactured For: Maplewood Company 7334 S. Alton Way Building #14, Ste. A Centennial, CO 80112

#### HYDRATE II

coffea tosta, avena sativa, equisetum hyemale, hypericum perforatum, ginkgo biloba, germanium sesquioxide, silicea liquid

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:51987-0002 Route of Administration ORAL

| Active Ingredient/Active Moiety  |                                 |                     |  |
|--|---------------------------------|---------------------|--|
| Ingredient Name  | Basis of Strength               | Strength            |  |
| COFFEA ARABICA SEED, ROASTED (UNII: 9H58JRT35E) (COFFEA ARABICA SEED, ROASTED - UNII:9H58JRT35E)     | COFFEA ARABICA SEED,<br>ROASTED | 2 [hp_X]<br>in 1 mL |  |
| <b>AVENA SATIVA FLOWERING TOP</b> (UNII: MA9CQJ3F7F) (AVENA SATIVA FLOWERING TOP - UNII: MA9CQJ3F7F) | AVENA SATIVA<br>FLOWERING TOP   | 3 [hp_X]<br>in 1 mL |  |
| <b>EQ UISETUM HYEMALE</b> (UNII: 59677RXH25) (EQUISETUM HYEMALE - UNII:59677RXH25)                   | EQUISETUM HYEMALE               | 3 [hp_X]<br>in 1 mL |  |
| <b>HYPERICUM PERFORATUM</b> (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)              | HYPERICUM PERFORATUM            | 3 [hp_X]<br>in 1 mL |  |

| GINKGO (UNII: 19FUJ2C58T) (GINKGO - UNII:19FUJ2C58T)   | GINKGO                    | 6 [hp_X] in 1 mL    |
|--|---------------------------|---------------------|
| <b>GERMANIUM SESQUIO XIDE</b> (UNII: 96 WE9 1N25T) (GERMANIUM SESQUIO XIDE - UNII: 96 WE9 1N25T) | GERMANIUM<br>SESQUIO XIDE | 8 [hp_X]<br>in 1 mL |
| SILICON DIO XIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)                          | SILICON DIOXIDE           | 8 [hp_X]<br>in 1 mL |

| Inactive Ingredients                                 |          |  |
|--|----------|--|
| Ingredient Name                                      | Strength |  |
| CHELIDO NIUM MAJUS (UNII: 7E889U5RNN)                |          |  |
| BEET (UNII: N487KM8COK)                              |          |  |
| CENTAUREA BENEDICTA FLOWERING TOP (UNII: NJN80GZ34N) |          |  |
| PEUMUS BOLDUS LEAF (UNII: Q4EWM09M3O)                |          |  |
| TARAXACUM OFFICINALE (UNII: 39981FM375)              |          |  |
| PETRO SELINUM CRISPUM (UNII: 1WZA4Y92EX)             |          |  |
| WATER (UNII: 059QF0KO0R)                             |          |  |
| ALCOHOL (UNII: 3K9958V90M)                           |          |  |

| Packaging |                      |   |                         |                       |
|-----------|----------------------|---|-------------------------|-----------------------|
| #         | Item Code            | Package Description   | Marketing Start<br>Date | Marketing End<br>Date |
| 1         | NDC:51987-<br>0002-1 | 30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | 08/22/2013              |                       |

| Marketing Information  |  |                      |                    |
|------------------------|--|----------------------|--------------------|
| Marketing Category     | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| unapproved homeopathic |  | 08/22/2013           |                    |
|                        |  |                      |                    |

## Labeler - Maplewood Company (022963389)

### Registrant - Apotheca Company (844330915)

| Establishment       |         |           |   |
|---------------------|---------|-----------|---|
| Name                | Address | ID/FEI    | Business Operations   |
| Apotheca<br>Company |         | 844330915 | manufacture(51987-0002), api manufacture(51987-0002), label(51987-0002), pack(51987-0002) |

Revised: 11/2019 Maplewood Company