

# **COLOCYNTHIS HOMACCORD - gnaphalium and citrullus colocynthis fruit without seed injection**

**JENAHEXAL PHARMA GMBH**

*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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## **Colocynthis Homaccord**

### **Description:**

- Injection Solution Ingredient Information: Each 1.1ml ampule contains: Gnaphalium polycephalum 3X,10X,30X,200X 2.2mcl each; Colocynthis 4X,10X,30X,200X 8.8mcl each. Inactive ingredient: Sterile isotonic sodium chloride solution.

### **Indications and Usage:**

- Colocynthis-Homaccord® Injection Solution is indicated for neuralgia of various origins and locations, especially sciatic neuralgia, intercostal neuralgia and intervertebral disc disorders.

### **Dosage and Administration:**

- 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. (2.1)

### **Dosage Form and Strength:**

- Injections: 1.1ml ampule

### **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

### **1. Indications and Usage**

1.1 Colocynthis-Homaccord® Injection Solution is classified as a homeopathic combination drug.

1.2 Botanical ingredients: Colocynthis (bitter cucumber) Gnaphalium polycephalum (common everlasting)

1.3 Colocynthis-Homaccord® Injection Solution is indicated for neuralgia of various origins and locations, especially sciatic neuralgia, intercostal neuralgia and intervertebral disc disorders.

### **2. Dosage and Administration**

2.1 The dosage schedules listed below can be used as a general guide for the administration of Colocynthis-Homaccord® Injection Solution. Colocynthis-Homaccord® 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.

Colocynthis-Homaccord® Injection Solution may be administered intravenously, intramuscularly, subcutaneously, or intradermally. The required dose of Colocynthis-Homaccord® Injection Solution is first withdrawn from the ampule into the syringe, and the syringe is then shaken briefly. Colocynthis-Homaccord® Injection Solution should be administered using a narrow gauge needle (e.g. 22 to 30

gauge). Note: Parental drug products like Colocynthis-Homaccord® Injection Solution should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Colocynthis-Homaccord® Injection Solution is a clear, colorless solution. Discolored solutions should be discarded.

### 3. Warnings and Precautions

3.1 Colocynthis-Homaccord® Injection Solution exhibits no known adverse renal, hepatic, cardiovascular, gastrointestinal or central nervous system effects.

3.2 No harmful or potentially harmful side effects such as central nervous system depression are known. Colocynthis-Homaccord® Injection Solution is generally well-tolerated, however, if symptoms persist or worsen discontinue use.

3.3 Teratogenic effects: In general, homeopathic drugs are not known to cause direct or indirect harm to the fetus. 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.

3.4 Drug Interactions: None known

3.5 Drug / Laboratory Test Interaction: None known

3.6 Carcinogenesis, mutagenesis, impairment of fertility: Not applicable

### 4. Use in Specific Populations

4.1 Pediatric Use: Colocynthis-Homaccord® Injection Solution can be safely administered to children as young as 2 years. (see Dosage and Administration)

4.2 Nursing Mothers: It is not known whether any of the ingredients in Colocynthis-Homaccord® Injection Solution are excreted in human milk. However, because many drugs are excreted in human milk, Colocynthis-Homaccord® Injection Solution should be administered with caution to nursing mothers.

4.3 Geriatric use: Colocynthis-Homaccord® Injection Solution is safe to use in adults 12 years and older. (see Dosage and Administration)

### 5. Clinical Pharmacology

5.1 The exact mechanism of action of Colocynthis-Homaccord® Injection Solution is not fully understood.

### 6. Drug Abuse and Dependence

6.1 Not applicable for homeopathic drugs

### 7. Overdosage

7.1 Due to the low concentration of active ingredients in homeopathic preparations such as Colocynthis-Homaccord® Injection Solution, adverse reactions following over dosage are extremely unlikely. However, care must be taken not to exceed the recommended dosage.

### 8. How Supplied

8.1 Colocynthis-Homaccord® Injection Solution 1.1ml ampules: Packs of 10 ampules: NDC 50114-7065-1

### 9. Storage Conditions

9.1 Avoid freezing and excessive heat. Store at room temperature. Protect from light.

ColocynthisHoma\_Inj\_Box.jpg



ColocynthisHoma\_Inj insert\_Rx2.jpg

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- 3.5 Drug / Laboratory Test Interaction: None known
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ColocynthisHoma\_Inj insert\_Rx.jpg

**Rx  
Only**

## Package Insert Information for Colocynthis-Homaccord® Injection Solution

*Homeopathic Medicine*

### HIGHLIGHTS OF PRESCRIBING INFORMATION

#### Description:

- Injection Solution Ingredient Information: Each 1.1 ml ampule contains: Gnaphalium polycephalum 3X, 10X, 30X, 200X 2.2 mcl each; Colocynthis 4X, 10X, 30X, 200X 8.8 mcl each. Inactive ingredient: Sterile isotonic sodium chloride solution.

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#### Dosage and Administration:

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#### Dosage Form and Strength:

- *Injections: 1.1 ml ampule*

#### Warnings and Precautions

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Revised 06/2009

### FULL PRESCRIBING INFORMATION

#### 1. Indications and Usage

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#### 1.2 Botanical ingredients:

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Gnaphalium polycephalum (common everlasting)

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# COLOCYNTHIS HOMACCORD

gnaphalium and citrullus colocynthis fruit without seed injection

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:68275-320
<b>Route of Administration</b>	INTRAMUSCULAR, SUBCUTANEOUS, INTRAVENOUS, INTRADERMAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GNAPHALIUM</b> (UNII: BGI20Z6M57) (GNAPHALIUM - UNII:BGI20Z6M57)	GNAPHALIUM	3 [hp_X] in 1.1 mL
<b>GNAPHALIUM</b> (UNII: BGI20Z6M57) (GNAPHALIUM - UNII:BGI20Z6M57)	GNAPHALIUM	10 [hp_X] in 1.1 mL
<b>GNAPHALIUM</b> (UNII: BGI20Z6M57) (GNAPHALIUM - UNII:BGI20Z6M57)	GNAPHALIUM	30 [hp_X] in 1.1 mL
<b>GNAPHALIUM</b> (UNII: BGI20Z6M57) (GNAPHALIUM - UNII:BGI20Z6M57)	GNAPHALIUM	200 [hp_X] in 1.1 mL
<b>CITRULLUS COLOCYNTHIS FRUIT WITHOUT SEED</b> (UNII: 23H32AOH17) (CITRULLUS COLOCYNTHIS FRUIT WITHOUT SEED - UNII:23H32AOH17)	CITRULLUS COLOCYNTHIS FRUIT WITHOUT SEED	4 [hp_X] in 1.1 mL
<b>CITRULLUS COLOCYNTHIS FRUIT WITHOUT SEED</b> (UNII: 23H32AOH17) (CITRULLUS COLOCYNTHIS FRUIT WITHOUT SEED - UNII:23H32AOH17)	CITRULLUS COLOCYNTHIS FRUIT WITHOUT SEED	10 [hp_X] in 1.1 mL
<b>CITRULLUS COLOCYNTHIS FRUIT WITHOUT SEED</b> (UNII: 23H32AOH17) (CITRULLUS COLOCYNTHIS FRUIT WITHOUT SEED - UNII:23H32AOH17)	CITRULLUS COLOCYNTHIS FRUIT WITHOUT SEED	30 [hp_X] in 1.1 mL
<b>CITRULLUS COLOCYNTHIS FRUIT WITHOUT SEED</b> (UNII: 23H32AOH17) (CITRULLUS COLOCYNTHIS FRUIT WITHOUT SEED - UNII:23H32AOH17)	CITRULLUS COLOCYNTHIS FRUIT WITHOUT SEED	200 [hp_X] in 1.1 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68275-320-10	1.1 mL in 1 AMPULE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		09/09/2009	

**Labeler** - JENAHEXAL PHARMA GMBH (344282590)

## Establishment

Name	Address	ID/FEI	Business Operations
JENAHEXAL PHARMA GMBH		344282590	manufacture

Revised: 9/2009

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