

**PSEUDOEPHEDRINE HCL UNIT DOSE- pseudoephedrine hcl tablet, film coated**  
**Major Pharmaceuticals**

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**Major 44-112-DSP**

***Active ingredient (in each tablet)***

Pseudoephedrine HCl 30 mg

***Purpose***

Nasal decongestant

***Uses***

- temporarily relieves sinus congestion and pressure
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies

***Warnings***

**Do not use**

if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if you have**

- diabetes
- heart disease
- thyroid disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland

**When using this product**

**do not exceed recommended dosage.**

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with fever

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away.

### ***Directions***

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; do not take more than 8 tablets in 24 hours
children ages 6 to 11 years	take 1 tablet every 4 to 6 hours; do not take more than 4 tablets in 24 hours
children under 6 years	do not use

### ***Other information***

- **each tablet contains:** calcium 15 mg
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

### ***Inactive ingredients***

croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, silicon dioxide, titanium dioxide, triacetin

### ***Questions or comments?***

**1-800-426-9391**

### ***Principal Display Panel***

**MAJOR®**

NDC 0904-6990-61

**Unit Dose**

**PSEUDOEPHEDRINE HCl**

**NASAL DECONGESTANT**

**30 mg each**

**Institutional Dispensing only**

**100 TABLETS**

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER**

**UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

50844 REV0619C11212

Distributed by:

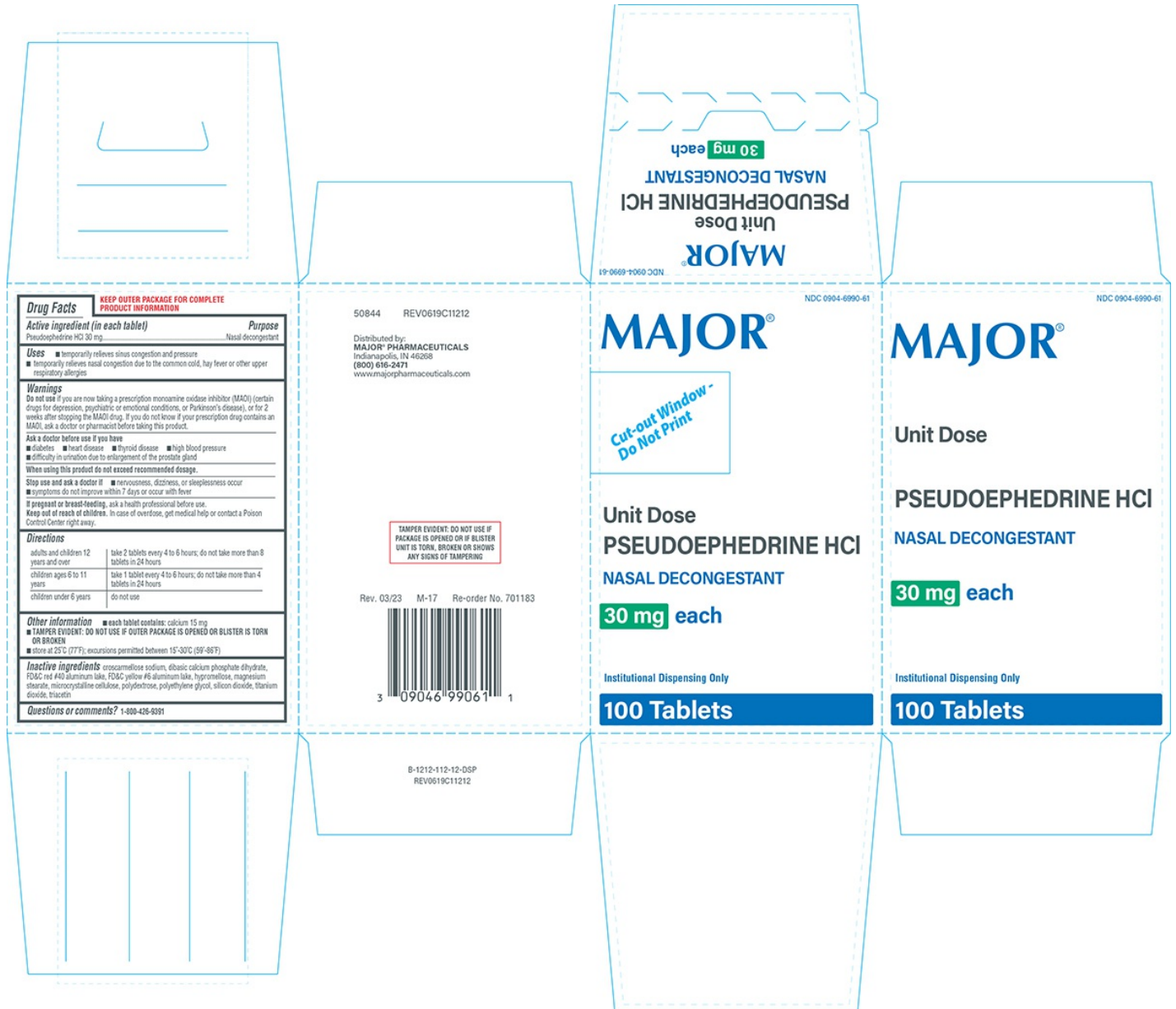
**MAJOR® PHARMACEUTICALS**

Indianapolis, IN 46268

(800) 616-2471

www.majorpharmaceuticals.com

Rev. 03/23 M-17 Re-order No. 701183



**Major 44-112**

**PSEUDOEPHEDRINE HCL UNIT DOSE**

pseudoephedrine hcl tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-6990
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>FD&amp;C RED NO. 40 ALUMINUM LAKE</b> (UNII: 6T47AS764T)	
<b>FD&amp;C YELLOW NO. 6 ALUMINUM LAKE</b> (UNII: GYP6Z2JR6Q)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRACETIN</b> (UNII: XHX3C3X673)	

**Product Characteristics**

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	44;112
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6990-61	10 in 1 CARTON	08/12/2019	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M012	08/12/2019	

**Labeler - Major Pharmaceuticals (191427277)****Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		038154464	pack(0904-6990)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		832867837	manufacture(0904-6990) , pack(0904-6990)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(0904-6990)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		868734088	manufacture(0904-6990)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		967626305	pack(0904-6990)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		117025878	manufacture(0904-6990)

Revised: 4/2024

Major Pharmaceuticals