

## Safety Data Sheet



### Section 1: Identification

#### Product identifier

**Product Name**

- **NIFedipine extended-release tablets (Nifediac CC)**

**Product Code**

- NDC 68682-105-10; NDC 68682-105-30; NDC 68682-106-10; NDC 68682-106-30; NDC 68682-107-10

#### Relevant identified uses of the substance or mixture and uses advised against

**Recommended use**

- Nifedipine extended release tablets are indicated for treatment of hypertension.

**Restrictions on use**

- Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

#### Details of the supplier of the safety data sheet

**Manufacturer**

- Valeant Pharmaceuticals International, Inc.  
100 LifeSciences Parkway  
Steinbach R5G 1Z7  
Canada  
valeant.com

**Supplier**

- Oceanside Pharmaceuticals, a division of Valeant Pharmaceuticals N. America, LLC  
400 Somerset Corporate Blvd.  
Bridgewater, NJ 08807  
United States  
valeant.com

**Telephone (General)** • 1-800-321-4576

#### Emergency telephone number

**Supplier**

- 1-800-535-5053 - US - Infotrac

**Supplier**

- +1 352-323-3500 - International - Infotrac

*This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.*

### Section 2: Hazard Identification

#### UN GHS Revision 3

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS): Third Revised Edition

#### Classification of the substance or mixture

**UN GHS**

- Acute Toxicity Oral 4  
Reproductive Toxicity 2  
Specific Target Organ Toxicity Single Exposure 1  
Skin Irritation 2  
Eye Irritation 2A  
Effects on or via Lactation

#### Label elements

**UN GHS**

**DANGER**

- Hazard statements** • Harmful if swallowed  
 Causes skin irritation  
 Causes serious eye irritation  
 Suspected of damaging fertility or the unborn child.  
 Causes damage to organs.  
 May cause harm to breast-fed children

**Precautionary statements**

- Prevention** • Do not handle until all safety precautions have been read and understood.  
 Do not breathe dust, fume, gas, mist, vapours and/or spray.  
 Wash thoroughly after handling.  
 Use personal protective equipment as required.
- Response** • IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician if you feel unwell.  
 IF ON SKIN: Wash with plenty of soap and water.  
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 IF exposed or concerned: Get medical advice/attention.

- Storage/Disposal** • Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

**Other hazards**

- UN GHS** • No data available

## Section 3 - Composition/Information on Ingredients

**Substances**

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

**Mixtures**

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Nifedipine	CAS:21829-25-4 EINECS:244-598-3	9% TO 30%	UN GHS Revision 3: NDA
Microcrystalline cellulose	CAS:9004-34-6 EINECS:232-674-9	N/A	UN GHS Revision 3: Skin Irrit. 2; Eye Irrit. 2A
Ethylcellulose	CAS:9004-57-3	N/A	UN GHS Revision 3: NDA
Amino methacrylate copolymer	CAS:25086-15-1	N/A	UN GHS Revision 3: NDA
Hydroxypropyl methylcellulose	CAS:9004-65-3	N/A	UN GHS Revision 3: NDA
Hydroxyethyl cellulose	CAS:9004-62-0	N/A	UN GHS Revision 3: Skin Irrit. 2; Eye Irrit. 2A
Titanium dioxide*	CAS:13463-67-7 EINECS:236-675-5	N/A	UN GHS Revision 3: STOT RE 2; Carc. 2

Colloidal silicon dioxide	CAS:112945-52-5	N/A	UN GHS Revision 3: Acute Tox. Oral 5
Talc*	CAS:14807-96-6 EINECS:238-877-9	N/A	UN GHS Revision 3: Skin Irrit. 3; STOT RE 1
Sodium lauryl sulfate	CAS:151-21-3 EINECS:205-788-1	N/A	UN GHS Revision 3: Skin Irrit. 2; Eye Irrit. 2; Acute Tox. Oral 4; Aquatic Acute 2
Polyethylene glycol #600 *	CAS:25322-68-3	N/A	UN GHS Revision 3: NDA
Lactose	CAS:63-42-3 EINECS:200-559-2	N/A	UN GHS Revision 3: Skin Irrit. 2; Skin Irrit. 3; Eye Irrit. 2A; Eye Irrit. 2B
Magnesium stearate	CAS:557-04-0 EINECS:209-150-3	N/A	UN GHS Revision 3: NDA
Iron oxide Yellow	CAS:51274-00-1 EINECS:257-098-5	N/A	UN GHS Revision 3: NDA

\* Note - The 90 mg tablet does not contain these ingredients.

N/A - Designates that the chemical percentage of composition is not available as it is considered a trade secret.

## Section 4: First-Aid Measures

### Description of first aid measures

#### Inhalation

- Normal use of this product does not pose an inhalation hazard. However, during bulk handling should respiratory tract irritation develop, discontinue use and remove to fresh air. Get medical attention if irritation or other symptoms develop or persist.

#### Skin

- IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.

#### Eye

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately if symptoms occur.

#### Ingestion

- If swallowed, seek medical advice immediately and show this container or label.

### Most important symptoms and effects, both acute and delayed

- Events observed following overdose included hypotension, heart rhythm disturbances, loss of consciousness, and cardiac failure.

### Indication of any immediate medical attention and special treatment needed

#### Notes to Physician

- Treat according to accepted protocols. For additional guidance, refer to the current prescribing information.

## Section 5: Fire-Fighting Measures

### Extinguishing media

**Suitable Extinguishing Media** • Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

**Unsuitable Extinguishing Media** • No data available

### Special hazards arising from the substance or mixture

**Unusual Fire and Explosion Hazards** • No data available

**Hazardous Combustion** • No data available.

**Products****Advice for firefighters**

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

**Section 6 - Accidental Release Measures****Personal precautions, protective equipment and emergency procedures****Personal Precautions**

- No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

**Emergency Procedures**

- Keep unauthorized personnel away. Clean up spilled tablets and place in sealed container. Avoid breaking tablets or creating dust during clean up.

**Environmental precautions**

- No data available on the environmental impact of this product.

**Methods and material for containment and cleaning up****Containment/Clean-up Measures**

- LARGE SPILLS: Use HEPA vacuum to clean up spill. If HEPA vacuum is not available, dampen spilled tablets with water prior to cleaning up to prevent dust cloud.

**Section 7 - Handling and Storage****Precautions for safe handling****Handling**

- Minimize dust generation and accumulation. Use good safety and industrial hygiene practices. Avoid breaking capsules.

**Conditions for safe storage, including any incompatibilities****Storage**

- Keep tightly closed. Store at controlled room temperature 25°C/77°F (excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before date marked on carton and/or container. Protect from light.

**Section 8 - Exposure Controls/Personal Protection****Control parameters****Exposure Limits/Guidelines**

- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines						
	Result	ACGIH	Canada Quebec	NIOSH	OSHA	Other Agency Information
Polyethylene glycol #600 * (25322-68-3)	TWAs	Not established	Not established	Not established	Not established	10 mg/m3 TWA (MW>200, aerosol)
Talc* (14807-96-6)	TWAs	2 mg/m3 TWA (particulate matter containing no asbestos and <1% crystalline silica, respirable fraction)	3 mg/m3 TWAEV (respirable dust)	2 mg/m3 TWA (containing no Asbestos and <1% Quartz, respirable dust)	Not established	Not established
Titanium dioxide* (13463-67-7)	TWAs	10 mg/m3 TWA	10 mg/m3 TWAEV (containing no Asbestos and <1% Crystalline silica, total)	Not established	15 mg/m3 TWA (total dust)	Not established

			dust)			
Microcrystalline cellulose (9004-34-6)	TWAs	10 mg/m3 TWA	10 mg/m3 TWAEV (containing no Asbestos and <1% Crystalline silica, total dust)	10 mg/m3 TWA (total dust); 5 mg/m3 TWA (respirable dust)	15 mg/m3 TWA (total dust); 5 mg/m3 TWA (respirable fraction)	Not established

### Exposure Control Notations

#### ACGIH

- Titanium dioxide\* (13463-67-7): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen)
- Talc\* (14807-96-6): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen (containing no asbestos fibers))

### Exposure Limits Supplemental

#### OSHA

- Talc\* (14807-96-6): **Mineral Dusts:** (20 mppcf TWA (if 1% Quartz or more, use Quartz limit))

#### ACGIH

- Microcrystalline cellulose (9004-34-6): **TLV Basis - Critical Effects:** (upper respiratory tract irritation)
- Titanium dioxide\* (13463-67-7): **TLV Basis - Critical Effects:** (lower respiratory tract irritation)
- Talc\* (14807-96-6): **TLV Basis - Critical Effects:** (pulmonary fibrosis (containing no asbestos fibers); pulmonary function (containing no asbestos fibers))

### Exposure controls

#### Engineering Measures/Controls

- NO SPECIAL CONTROLS ARE REQUIRED UNDER CONDITIONS OF INTENDED USE. Local exhaust ventilation should be provided when handling bulk product.

#### Personal Protective Equipment

##### Respiratory

- For bulk handling, the personal breathing protection should be determined based upon a risk assessment and in accordance with local regulations. Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or symptoms are experienced.

##### Eye/Face

- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging.

##### Hands

- Wear protective gloves when handling bulk product before closed in final packaging.

##### Skin/Body

- Avoid contact with skin.

#### General Industrial Hygiene Considerations

- Handle in accordance with good industrial hygiene and safety practice. Wash thoroughly with soap and water after handling.

#### Environmental Exposure Controls

- No data available

## Section 9 - Physical and Chemical Properties

### Information on Physical and Chemical Properties

Material Description			
Physical Form	Solid	Appearance/Description	Not relevant
Color	Yellow	Odor	Not relevant
General Properties			
Boiling Point	No data available	Melting Point/Freezing Point	172 to 174 °C(341.6 to 345.2 °F)
Decomposition Temperature	No data available	pH	Not relevant
Specific Gravity/Relative Density	Not relevant	Water Solubility	Insoluble
Viscosity	Not relevant		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		

**Flammability**

Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		

**Environmental**

Octanol/Water Partition coefficient	No data available		
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**Section 10: Stability and Reactivity****Reactivity**

- Stable under normal temperatures and pressures.

**Chemical stability**

- Hazardous polymerization will not occur.

**Possibility of hazardous reactions**

- No data available

**Conditions to avoid**

- Light, heat and humidity.

**Incompatible materials**

- Strong oxidizing agents.

**Hazardous decomposition products**

- Nitric oxides and carbon monoxides.

**Section 11 - Toxicological Information****Information on toxicological effects**

Components		
Nifedipine (9% TO 30%)	21829-25-4	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 1022 mg/kg; <i>Behavioral:</i> <b>Changes in motor activity (specific assay); Lungs, Thorax, or Respiration:Dyspnea; Lungs, Thorax, or Respiration:Respiratory stimulation;</b> <b>Reproductive:</b> Ingestion/Oral-Rat TDLo • 10 mg/kg (21D preg); <i>Reproductive Effects:</i> <b>Specific Developmental Abnormalities:Cardiovascular (circulatory) system;</b> Ingestion/Oral-Rat TDLo • 40 mg/kg (14D preg); <i>Reproductive Effects:</i> <b>Specific Developmental Abnormalities:Musculoskeletal system</b>

GHS Properties	Classification
<b>Acute toxicity</b>	UN GHS 3 • Acute Toxicity - Oral 4
<b>Skin corrosion/Irritation</b>	UN GHS 3 • Skin Irritation 2
<b>Serious eye damage/Irritation</b>	UN GHS 3 • Eye Irritation 2A
<b>Skin sensitization</b>	UN GHS 3 • Classification criteria not met
<b>Respiratory sensitization</b>	UN GHS 3 • Classification criteria not met
<b>Aspiration Hazard</b>	UN GHS 3 • Classification criteria not met
<b>Carcinogenicity</b>	UN GHS 3 • Classification criteria not met
<b>Germ Cell Mutagenicity</b>	UN GHS 3 • Classification criteria not met
<b>Toxicity for Reproduction</b>	UN GHS 3 • Additional category for effects on or via lactation; Toxic to Reproduction 2
<b>STOT-SE</b>	UN GHS 3 • Specific Target Organ Toxicity Single Exposure 1

STOT-RE

UN GHS 3 • Classification criteria not met

**Potential Health Effects****Inhalation**

- Acute (Immediate)**
  - Under normal conditions of use, no health effects are expected. Exposure to dust from broken capsules may cause irritation.
- Chronic (Delayed)**
  - Repeated and prolonged exposure may cause irritation.

**Skin**

- Acute (Immediate)**
  - May cause skin irritation.
- Chronic (Delayed)**
  - Repeated and prolonged exposure may cause sensitization.

**Eye**

- Acute (Immediate)**
  - May cause mild eye irritation with direct contact to eye.
- Chronic (Delayed)**
  - Under normal conditions of use, no health effects are expected.

**Ingestion**

- Acute (Immediate)**
  - Toxic if ingested in excess of prescription dose. May affect the heart and/or cardiovascular system. Symptoms may include hypotension, heart rhythm disturbances and cardiac failure.
- Chronic (Delayed)**
  - No data available

Carcinogenic Effects			
	CAS	IARC	NTP
Talc*	14807-96-6	Group 3-Not Classifiable	Evidence of Carcinogenicity
Titanium dioxide*	13463-67-7	Group 2B-Possible Carcinogen	Evidence of Carcinogenicity
Colloidal silicon dioxide	112945-52-5	Group 3-Not Classifiable	Not Listed

**Reproductive Effects**

- There are no adequate and well-controlled studies in humans. In rodents, rabbits, and monkeys, nifedipine has been shown to have a variety of embryotoxic, placentotoxic, and fetotoxic effects. Nifedipine is excreted in human milk.

**Section 12 - Ecological Information****Toxicity**

- This material has not been tested for environmental effects.

**Persistence and degradability**

- No data available

**Bioaccumulative potential**

- No data available

**Mobility in Soil**

- No data available

**Other adverse effects****Section 13 - Disposal Considerations****Waste treatment methods****Product waste**

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

**Packaging waste**

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

## Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
TDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IMO/IMDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IATA/ICAO	Not Applicable	Not Regulated	Not Applicable	Not Applicable	

**Special precautions for user** • No data available

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** • No data available

## Section 15 - Regulatory Information

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

**SARA Hazard Classifications** • No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Amino methacrylate copolymer	25086-15-1	Yes	No	Yes
Nifedipine	21829-25-4	Yes	Yes	No
Microcrystalline cellulose	9004-34-6	Yes	Yes	Yes
Hydroxyethyl cellulose	9004-62-0	Yes	No	Yes
Ethylcellulose	9004-57-3	Yes	No	Yes
Hydroxypropyl methylcellulose	9004-65-3	Yes	No	Yes
Iron oxide Yellow	51274-00-1	Yes	Yes	Yes
Lactose	63-42-3	Yes	Yes	Yes
Polyethylene glycol #600 *	25322-68-3	Yes	No	Yes
Colloidal silicon dioxide	112945-52-5	Yes	No	No
Sodium lauryl sulfate	151-21-3	Yes	Yes	Yes
Magnesium stearate	557-04-0	Yes	Yes	Yes
Talc*	14807-96-6	Yes	Yes	Yes
Titanium dioxide*	13463-67-7	Yes	Yes	Yes

## Canada

### Labor

Canada - WHMIS - Classifications of Substances

Uncontrolled product



• Hydroxypropyl methylcellulose	9004-65-3	according to WHMIS classification criteria
• Magnesium stearate	557-04-0	Not Listed
• Ethylcellulose	9004-57-3	Uncontrolled product according to WHMIS classification criteria
• Microcrystalline cellulose	9004-34-6	Uncontrolled product according to WHMIS classification criteria (including microcrystalline and paper fibers)
• Talc*	14807-96-6	D2A D2A (In certain cases, this classification does not apply. For more information, consult the section Substance Specific Issues - Titanium dioxide, mixture containing on Health Canada's WHMIS Division website.)
• Titanium dioxide*	13463-67-7	
• Sodium lauryl sulfate	151-21-3	D2B
• Hydroxyethyl cellulose	9004-62-0	Uncontrolled product according to WHMIS classification criteria
• Amino methacrylate copolymer	25086-15-1	Not Listed
• Lactose	63-42-3	Uncontrolled product according to WHMIS classification criteria
• Colloidal silicon dioxide	112945-52-5	Not Listed
• Nifedipine	21829-25-4	Not Listed
• Polyethylene glycol #600 *	25322-68-3	Not Listed
• Iron oxide Yellow	51274-00-1	Uncontrolled product according to WHMIS classification criteria

**Canada - WHMIS - Ingredient Disclosure List**

• Hydroxypropyl methylcellulose	9004-65-3	Not Listed
• Magnesium stearate	557-04-0	Not Listed
• Ethylcellulose	9004-57-3	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• Talc*	14807-96-6	Not Listed
• Titanium dioxide*	13463-67-7	Not Listed
• Sodium lauryl sulfate	151-21-3	1 %
• Hydroxyethyl cellulose	9004-62-0	Not Listed
• Amino methacrylate copolymer	25086-15-1	Not Listed
• Lactose	63-42-3	Not Listed
• Colloidal silicon dioxide	112945-52-5	Not Listed
• Nifedipine	21829-25-4	Not Listed
• Polyethylene glycol #600 *	25322-68-3	Not Listed
• Iron oxide Yellow	51274-00-1	Not Listed

**United States - California****Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Hydroxypropyl methylcellulose	9004-65-3	Not Listed
• Magnesium stearate	557-04-0	Not Listed

• Ethylcellulose	9004-57-3	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• Talc*	14807-96-6	Not Listed
• Titanium dioxide*	13463-67-7	carcinogen, 9/2/2011 (airborne, unbound particles of respirable size)
• Sodium lauryl sulfate	151-21-3	Not Listed
• Hydroxyethyl cellulose	9004-62-0	Not Listed
• Amino methacrylate copolymer	25086-15-1	Not Listed
• Lactose	63-42-3	Not Listed
• Colloidal silicon dioxide	112945-52-5	Not Listed
• Nifedipine	21829-25-4	Not Listed
• Polyethylene glycol #600 *	25322-68-3	Not Listed
• Iron oxide Yellow	51274-00-1	Not Listed
<b>U.S. - California - Proposition 65 - Developmental Toxicity</b>		
• Hydroxypropyl methylcellulose	9004-65-3	Not Listed
• Magnesium stearate	557-04-0	Not Listed
• Ethylcellulose	9004-57-3	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• Talc*	14807-96-6	Not Listed
• Titanium dioxide*	13463-67-7	Not Listed
• Sodium lauryl sulfate	151-21-3	Not Listed
• Hydroxyethyl cellulose	9004-62-0	Not Listed
• Amino methacrylate copolymer	25086-15-1	Not Listed
• Lactose	63-42-3	Not Listed
• Colloidal silicon dioxide	112945-52-5	Not Listed
• Nifedipine	21829-25-4	developmental toxicity, 1/29/1999
• Polyethylene glycol #600 *	25322-68-3	Not Listed
• Iron oxide Yellow	51274-00-1	Not Listed
<b>U.S. - California - Proposition 65 - Reproductive Toxicity - Female</b>		
• Hydroxypropyl methylcellulose	9004-65-3	Not Listed
• Magnesium stearate	557-04-0	Not Listed
• Ethylcellulose	9004-57-3	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• Talc*	14807-96-6	Not Listed
• Titanium dioxide*	13463-67-7	Not Listed
• Sodium lauryl sulfate	151-21-3	Not Listed
• Hydroxyethyl cellulose	9004-62-0	Not Listed
• Amino methacrylate copolymer	25086-15-1	Not Listed
• Lactose	63-42-3	Not Listed
• Colloidal silicon dioxide	112945-52-5	Not Listed
• Nifedipine	21829-25-4	female reproductive toxicity 1/29/99
• Polyethylene glycol #600 *	25322-68-3	Not Listed
• Iron oxide Yellow	51274-00-1	Not Listed
<b>U.S. - California - Proposition 65 - Reproductive Toxicity - Male</b>		
• Hydroxypropyl methylcellulose	9004-65-3	Not Listed
• Magnesium stearate	557-04-0	Not Listed
• Ethylcellulose	9004-57-3	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• Talc*	14807-96-6	Not Listed

• Titanium dioxide*	13463-67-7	Not Listed
• Sodium lauryl sulfate	151-21-3	Not Listed
• Hydroxyethyl cellulose	9004-62-0	Not Listed
• Amino methacrylate copolymer	25086-15-1	Not Listed
• Lactose	63-42-3	Not Listed
• Colloidal silicon dioxide	112945-52-5	Not Listed
• Nifedipine	21829-25-4	male reproductive toxicity, 1/29/99
• Polyethylene glycol #600 *	25322-68-3	Not Listed
• Iron oxide Yellow	51274-00-1	Not Listed

## Section 16 - Other Information

<b>Revision Date</b>	• 07/October/2016
<b>Last Revision Date</b>	• 08/March/2016
<b>Preparation Date</b>	• 08/March/2016
<b>Disclaimer/Statement of Liability</b>	<ul style="list-style-type: none"> <li>To the best of our knowledge, the information contained herein is accurate. However, neither Valeant Pharmaceuticals International, Inc. nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. NO WARRANTY, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS OR OTHERWISE IS MADE. In no event shall Valeant Pharmaceuticals International, Inc. or any of its subsidiaries be liable for any special, incidental or consequential damages.</li> </ul>