

**ACETAMINOPHEN EXTENDED-RELEASE TABLETS, 650 MG -  
acetaminophen tablet, extended release  
MARKSANS PHARMA LIMITED**

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**Arthritis Pain Relief  
Acetaminophen Extended-Release Tablets USP, 650 mg**

**Active ingredient (in each caplet)**

Acetaminophen 650 mg

**Purpose**

Pain reliever/fever reducer

**Uses**

**Acetaminophen Extended-Release Tablets USP, 650 mg - Arthritis Pain**

- temporarily relieves minor aches and pains due to:
  - minor pain of arthritis
  - muscular aches
  - backache
  - premenstrual and menstrual cramps
  - the common cold
  - headache
  - toothache
- temporarily reduces fever.

**Acetaminophen Extended-Release Tablets USP, 650 mg - Muscle Aches and Pain**

- temporarily relieves minor aches and pains due to:
  - muscular aches
  - backache
  - minor pain of arthritis
  - toothache
  - premenstrual and menstrual cramps
  - headache
  - the common cold
- temporarily reduces fever

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product.

**Allergy alert:** acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product.

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

liver disease.

**Ask a doctor or pharmacist before use if you are** taking the blood thinning drug warfarin.

**Stop use and ask a doctor if**

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

**If pregnant or breast-feeding**

ask a health professional before use.

**Keep out of reach of children.**

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

## Directions

**Do not take more than directed. See overdose warning**

adults and children 12 years and over	<ul style="list-style-type: none"><li>• take 2 caplets every 8 hours with water</li><li>• swallow whole; do not crush, chew, split, or dissolve</li><li>• do not take more than 6 caplets in 24 hours</li><li>• do not use for more than 10 days unless directed by a doctor</li></ul>
children under 12 years	<ul style="list-style-type: none"><li>• ask a doctor.</li></ul>

## Other information

- store between 20-25°C (68-77°F)
- The FDA approved Dissolution methods differ from USP
- **do not use if carton is opened. Do not use if foil inner seal is broken or missing**

## Inactive ingredients

carnauba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

## Questions or comments ?

Call at 1-877-376-4271 Mon-Fri 9.00am - 6.00pm EST

## PRINCIPAL DISPLAY PANEL

NDC 25000-071-02

Acetaminophen Extended-Release Tablets USP, 650 mg - Arthritis Pain  
24 count carton label



NDC 25000-071-02

Acetaminophen Extended-Release Tablets USP, 650 mg- Arthritis Pain  
24 count bottle label

<p><b>DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN</b>  <small>*Compare to Tylenol® for Arthritis Pain active ingredient NDC 25000-071-02</small></p> <p><b>Arthritis Pain Relief</b></p> <p><b>Acetaminophen</b>  <b>Extended-Release Tablets USP, 650 mg</b>  <b>Pain Reliever / Fever Reducer</b></p> <p><small>Lasts up to 8 hours  For the temporary relief of minor arthritis pain</small></p> <p><b>Marksans</b></p> <p><small>*Caplets Shaped 8-Layer Tablets</small> <b>24 Caplets*</b></p>		<p><b>IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USE.</b></p> <p><b>Active ingredient (in each caplet) Purpose</b>  Acetaminophen 650 mg.....Pain reliever/fever reducer</p> <p><b>Uses</b> ■ temporarily relieves minor aches and pains due to: ■ minor pain of arthritis</p>	<p>LOT :  EXP :  R56/21</p>
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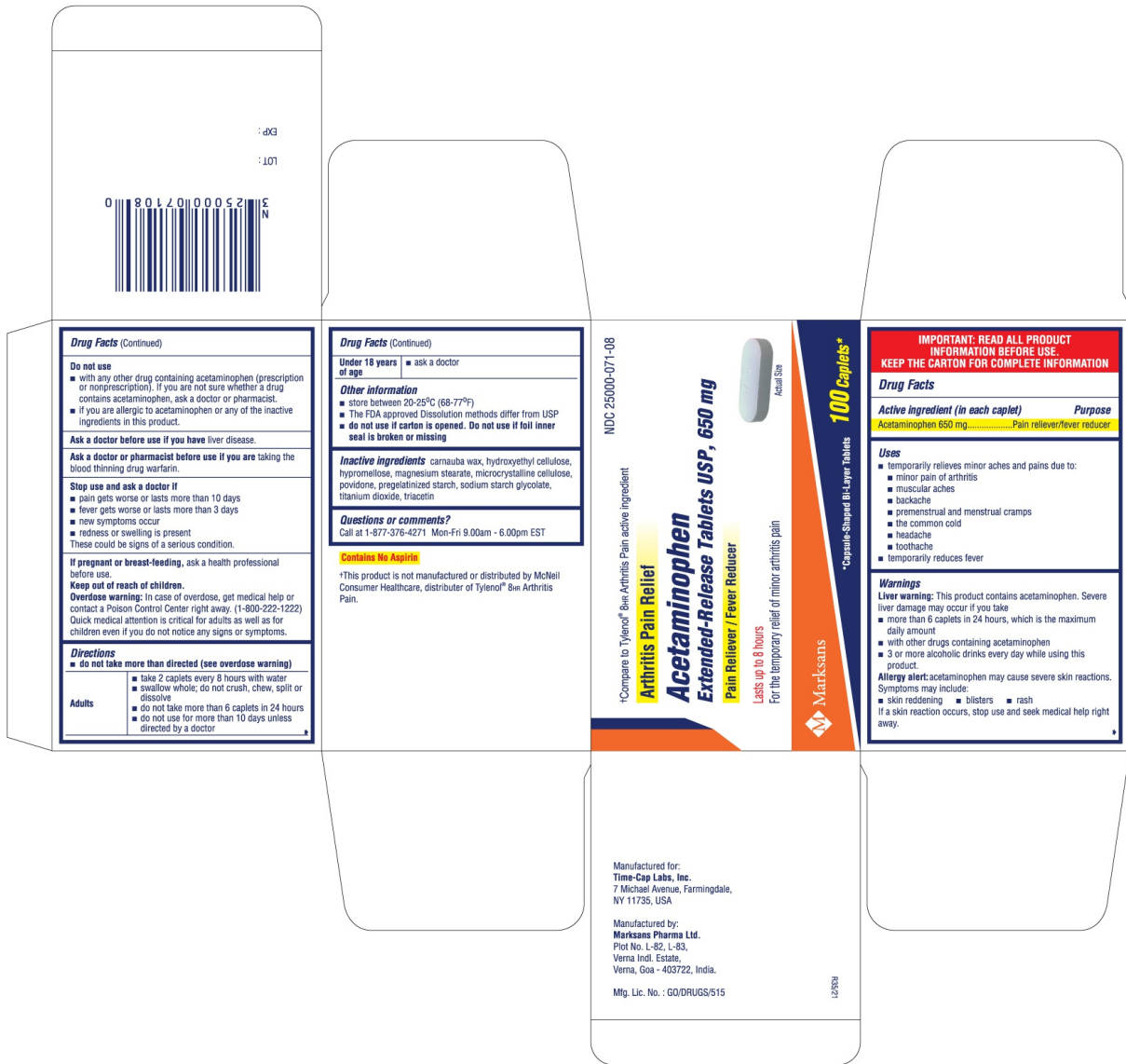
<ul style="list-style-type: none"> <li>■ muscular aches ■ backache</li> <li>■ premenstrual and menstrual cramps ■ the common cold ■ headache ■ toothache ■ temporarily reduces fever</li> </ul> <p><b>Warnings Liver warning:</b> This product contains acetaminophen.</p>	<p>Severe liver damage may occur if you take ■ more than 6 caplets in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product. <b>Allergy</b></p>	<p><b>alert:</b> acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash. If a skin reaction occurs, stop use and seek medical help right away. <b>Do not use</b> ■ with any other drug containing</p>
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<p>acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ if you are allergic to acetaminophen or any of the inactive ingredients in this</p>	<p>product. <b>Ask a doctor before use if you have liver disease. Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin. Stop use and ask a doctor if</b> ■ pain gets worse or lasts more than 10 days ■ fever</p>	<p>gets worse or lasts more than 3 days ■ new symptoms occur ■ redness or swelling is present. These could be signs of a serious condition. <b>If pregnant or breastfeeding</b>, ask a health professional before use. <b>Keep out of reach of</b></p>
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<p><b>children. Overdose warning:</b> In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs</p>	<p>or symptoms. <b>Directions</b> ■ do not take more than directed (see overdose warning). <b>Adults:</b> ■ take 2 caplets every 8 hours with water ■ swallow whole; do not crush, chew, split or dissolve ■ do not take more than 6 caplets in 24</p>	<p>hours ■ do not use for more than 10 days unless directed by a doctor <b>Under 18 years of age:</b> ■ ask a doctor <b>Other information</b> ■ store between 20-25°C (68-77°F) ■ The FDA approved Dissolution methods differ from</p>
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<p>USP ■ <b>Do not use if foil inner seal is broken or missing</b>  <b>Inactive ingredients</b> carnauba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized</p>	<p>starch, sodium starch glycolate, titanium dioxide, triacetin</p> <p><b>Questions or comments?</b>  Call at 1-877-376-4271  Mon-Fri 9.00am-6.00pm EST</p> <p><b>Contains No Aspirin</b>  †This product is not manufactured</p>	<p>or distributed by McNeil Consumer Healthcare, distributor of Tylenol® 8hr Arthritis Pain.  Manufactured for: <b>Time-Cap Labs, Inc.</b>  7 Michael Avenue, Farmingdale, NY 11735, USA  Manufactured by: <b>Marksans Pharma Ltd.</b>  Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa - 403722, India.  Mfg. Lic. No. : GO/DRUGS/515</p>
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NDC 25000-071-08  
Acetaminophen Extended-Release Tablets USP, 650 mg- Arthritis Pain  
100 count carton label



NDC 25000-071-08

Acetaminophen Extended-Release Tablets USP, 650 mg- Arthritis Pain

100 count bottle label

**DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN**

†Compare to Tylenol® 8HR Arthritis Pain active ingredient

NDC 25000-071-08

**Arthritis Pain Relief**

**Acetaminophen**  
**Extended-Release Tablets USP, 650 mg**

**Pain Reliever / Fever Reducer**

Lasts up to 8 hours  
For the temporary relief of minor arthritis pain

LOT :  
EXP :  
R35/21



\*Capsule-Shaped Bi-Layer Tablets **100 Caplets\***



IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USE.		Drug Facts (Continued)	
<b>Drug Facts</b>		<ul style="list-style-type: none"> <li>3 or more alcoholic drinks every day while using this product.</li> <li><b>Allergy alert:</b> acetaminophen may cause severe skin reactions. Symptoms may include:                             <ul style="list-style-type: none"> <li>skin reddening</li> <li>blisters</li> <li>rash</li> </ul>                             If a skin reaction occurs, stop use and seek medical help right away.                         </li> </ul>	
<b>Active ingredient (in each caplet)</b>	<b>Purpose</b>	<b>Do not use</b>	
Acetaminophen 650 mg	Pain reliever/fever reducer	<ul style="list-style-type: none"> <li>with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>if you are allergic to acetaminophen or any of the inactive ingredients in this product.</li> </ul>	
<b>Uses</b>		<b>Ask a doctor before use if you have liver disease.</b>	
<ul style="list-style-type: none"> <li>temporarily relieves minor aches and pains due to:                             <ul style="list-style-type: none"> <li>minor pain of arthritis</li> <li>muscular aches</li> <li>backache</li> <li>premenstrual and menstrual cramps</li> <li>the common cold</li> <li>headache</li> <li>toothache</li> </ul> </li> <li>temporarily reduces fever</li> </ul>		<b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</b>	
<b>Warnings</b>		<b>Stop use and ask a doctor if</b>	
<p><b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take</p> <ul style="list-style-type: none"> <li>more than 6 caplets in 24 hours, which is the maximum daily amount</li> <li>with other drugs containing acetaminophen</li> </ul>		<ul style="list-style-type: none"> <li>pain gets worse or lasts more than 10 days</li> <li>fever gets worse or lasts more than 3 days</li> <li>new symptoms occur</li> <li>redness or swelling is present</li> </ul> These could be signs of a serious condition.	

<b>Drug Facts (Continued)</b>		<b>Drug Facts (Continued)</b>	
<p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.</p> <p><b>Overdose warning:</b> In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p>		<p><b>Inactive ingredients</b> carnauba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin</p> <p><b>Questions or comments?</b> Call at 1-877-376-4271 Mon-Fri 9:00am - 6:00pm EST</p>	
<b>Directions</b>		<b>Contains No Aspirin</b>	
<ul style="list-style-type: none"> <li>do not take more than directed (see overdose warning)</li> </ul>		†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® 8HR Arthritis Pain.	
<b>Adults</b>	<ul style="list-style-type: none"> <li>take 2 caplets every 8 hours with water</li> <li>swallow whole; do not crush, chew, split or dissolve</li> <li>do not take more than 6 caplets in 24 hours</li> <li>do not use for more than 10 days unless directed by a doctor</li> </ul>	<p>Manufactured for: <b>Time-Cap Labs, Inc.</b> 7 Michael Avenue, Farmingdale, NY 11735, USA</p>	
<b>Under 18 years of age</b>	<ul style="list-style-type: none"> <li>ask a doctor</li> </ul>	<p>Manufactured by: <b>Marksans Pharma Ltd.</b> Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa - 403722, India.</p> <p>Mfg. Lic. No.: GO/DRUGS/515</p>	
<b>Other information</b>			
<ul style="list-style-type: none"> <li>store between 20-25°C (68-77°F)</li> <li>The FDA approved Dissolution methods differ from USP</li> <li>do not use if carton is opened. Do not use if foil inner seal is broken or missing</li> </ul>			

NDC 25000-071-10

Acetaminophen Extended-Release Tablets USP, 650 mg- Arthritis Pain  
225 count carton label

LOT:  
EXP:

3 25000 107 110 3  
N



<p><b>Drug Facts (Continued)</b></p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>if you are allergic to acetaminophen or any of the inactive ingredients in this product.</li> </ul> <p><b>Ask a doctor before use if you have liver disease.</b></p> <p><b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</b></p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>pain gets worse or lasts more than 10 days</li> <li>fever gets worse or lasts more than 3 days</li> <li>new symptoms occur</li> <li>redness or swelling is present</li> </ul> <p>These could be signs of a serious condition.</p> <p><b>If pregnant or breast-feeding, ask a health professional before use.</b></p> <p><b>Keep out of reach of children.</b></p> <p><b>Overdose warning:</b> In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> <p><b>Directions</b></p> <p><b>do not take more than directed (see overdose warning)</b></p> <p><b>Adults</b></p> <ul style="list-style-type: none"> <li>take 2 caplets every 8 hours with water</li> <li>swallow whole; do not crush, chew, split or dissolve</li> <li>do not take more than 6 caplets in 24 hours</li> <li>do not use for more than 10 days unless directed by a doctor.</li> </ul>	<p><b>Drug Facts (Continued)</b></p> <p><b>Under 18 years of age</b> ■ ask a doctor</p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>store between 20-25°C (68-77°F)</li> <li>The FDA approved Dissolution methods differ from USP</li> <li>do not use if carton is opened. Do not use if foil inner seal is broken or missing</li> </ul> <p><b>Inactive ingredients</b> carnauba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin</p> <p><b>Questions or comments?</b> Call at 1-877-376-4271 Mon-Fri 9.00am - 6.00pm EST</p> <p><b>Contains No Aspirin</b></p> <p>*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® 8hr Arthritis Pain.</p>
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NDC 25000-071-10

\*Compare to Tylenol® 8hr Arthritis Pain active ingredient

**Arthritis Pain Relief**

Acetaminophen

**Extended-Release Tablets USP, 650 mg**

**Pain Reliever / Fever Reducer**

Lasts up to 8 hours  
For the temporary relief of minor arthritis pain



Actual Size

\* Capsule-Shaped Bi-Layer Tablets

225 Caplets\*

Markksans

Manufactured for:  
**Time-Cap Labs, Inc.**  
7 Michael Avenue, Farmingdale,  
NY 11735, USA

Manufactured by:  
**Markksans Pharma Ltd.**  
Plot No. L-82, L-83,  
Verna Indl. Estate,  
Verna, Goa - 403722, India.

Mfg. Lic. No. : GO/DRUGS/515

L28281

IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USE.  
KEEP THE CARTON FOR COMPLETE INFORMATION

**Drug Facts**

Active Ingredient (in each caplet)	Purpose
Acetaminophen 650 mg	Pain reliever/fever reducer

**Uses**

- temporarily relieves minor aches and pains due to:
  - minor pain of arthritis
  - muscular aches
  - backache
  - premenstrual and menstrual cramps
  - the common cold
  - headache
  - toothache
- temporarily reduces fever

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product.

**Allergy alert:** acetaminophen may cause severe skin reactions. Symptoms may include:

- skin redness
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

NDC 25000-071-10

Acetaminophen Extended-Release Tablets USP, 650 mg- Arthritis Pain  
225 count bottle label



**DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN**

†Compare to Tylenol® 8HR Arthritis Pain active ingredient

NDC 25000-071-10

**Arthritis Pain Relief**

**Acetaminophen**  
**Extended-Release Tablets USP, 650 mg**

**Pain Reliever / Fever Reducer**

Lasts up to 8 hours  
For the temporary relief of minor arthritis pain

LOT :  
EXP :  
R35/21



\*Capsule-Shaped Bi-Layer Tablets

**225 Caplets\***



IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USE.	
<b>Drug Facts</b>	<b>Drug Facts</b> (Continued)
<b>Active ingredient (in each caplet)</b> Acetaminophen 650 mg	<b>Purpose</b> Pain reliever/fever reducer
<b>Uses</b> temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> <li>minor pain of arthritis</li> <li>muscular aches</li> <li>backache</li> <li>premenstrual and menstrual cramps</li> <li>the common cold</li> <li>headache</li> <li>toothache</li> <li>temporarily reduces fever</li> </ul>	<b>Do not use</b> <ul style="list-style-type: none"> <li>with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>if you are allergic to acetaminophen or any of the inactive ingredients in this product.</li> </ul>
<b>Warnings</b> <b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take <ul style="list-style-type: none"> <li>more than 6 caplets in 24 hours, which is the maximum daily amount</li> <li>with other drugs containing acetaminophen</li> </ul>	<b>Ask a doctor before use if you have liver disease.</b> <b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</b> <b>Stop use and ask a doctor if</b> <ul style="list-style-type: none"> <li>pain gets worse or lasts more than 10 days</li> <li>fever gets worse or lasts more than 3 days</li> <li>new symptoms occur</li> <li>redness or swelling is present</li> </ul> These could be signs of a serious condition.
<b>Drug Facts</b> (Continued) If pregnant or breast-feeding, ask a health professional before use. <b>Keep out of reach of children.</b> <b>Overdose warning:</b> In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.	<b>Drug Facts</b> (Continued) <b>Inactive ingredients</b> carnauba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin <b>Questions or comments?</b> Call at 1-877-376-4271 Mon-Fri 9:00am - 6:00pm EST
<b>Directions</b> do not take more than directed (see overdose warning)	<b>Contains No Aspirin</b> †This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® 8HR Arthritis Pain.
<b>Adults</b> <ul style="list-style-type: none"> <li>take 2 caplets every 8 hours with water</li> <li>swallow whole; do not crush, chew, split or dissolve</li> <li>do not take more than 6 caplets in 24 hours</li> <li>do not use for more than 10 days unless directed by a doctor</li> </ul>	<b>Manufactured for:</b> <b>Time-Cap Labs, Inc.</b> 7 Michael Avenue, Farmingdale, NY 11735, USA
<b>Under 18 years of age</b> ask a doctor	<b>Manufactured by:</b> <b>Marksans Pharma Ltd.</b> Plot No. L-62, L-83, Verna Indl. Estate, Verna, Goa - 403722, India. Mfg. Lic. No. : G0/DRUGS/515
<b>Other information</b> <ul style="list-style-type: none"> <li>store between 20-25°C (68-77°F)</li> <li>The FDA approved Dissolution methods differ from USP</li> <li>do not use if carton is opened. Do not use if foil inner seal is broken or missing</li> </ul>	

<b>Drug Facts</b> (Continued) If pregnant or breast-feeding, ask a health professional before use. <b>Keep out of reach of children.</b> <b>Overdose warning:</b> In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.	<b>Drug Facts</b> (Continued) <b>Inactive ingredients</b> carnauba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin <b>Questions or comments?</b> Call at 1-877-376-4271 Mon-Fri 9:00am - 6:00pm EST
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NDC 25000-071-11

Acetaminophen Extended-Release Tablets USP, 650 mg- Arthritis Pain  
290 count carton label

**Drug Facts (Continued)**

**Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product.

**Ask a doctor before use if you have liver disease.**

**Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.**

**Stop use and ask a doctor if**

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

**If pregnant or breast-feeding, ask a health professional before use.**

**Keep out of reach of children.**

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

**do not take more than directed (see overdose warning)**

- take 2 caplets every 8 hours with water
- swallow whole; do not crush, chew, split or dissolve
- do not take more than 6 caplets in 24 hours
- do not use for more than 10 days unless directed by a doctor

**Adults**

**Drug Facts (Continued)**

**Under 18 years of age** ■ ask a doctor of age

**Other information**

- store between 20-25°C (68-77°F)
- The FDA approved Dissolution methods differ from USP
- do not use if carton is opened. Do not use if foil inner seal is broken or missing

**Inactive ingredients** carnauba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

**Questions or comments?**  
Call at 1-877-376-4271 Mon-Fri 9:00am - 6:00pm EST

**Contains No Aspirin**

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® 8hr Arthritis Pain.

**IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USE. KEEP THE CARTON FOR COMPLETE INFORMATION**

**Drug Facts**

**Active Ingredient (in each caplet)** ■ Acetaminophen 650 mg. ■ Pain reliever/fever reducer

**Uses**

- temporarily relieves minor aches and pains due to:
  - minor pain of arthritis
  - muscular aches
  - backache
  - premenstrual and menstrual cramps
  - the common cold
  - headache
  - toothache
- temporarily reduces fever

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product.

**Allergy alert:** acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening ■ blisters ■ rash

If a skin reaction occurs, stop use and seek medical help right away.

NDC 25000-071-11

Arthritis Pain Relief  
**Acetaminophen**  
Extended-Release Tablets USP, 650 mg  
Pain Reliever / Fever Reducer

Actual Size

290 Caplets\*

Capsule-Shaped Bi-Layer Tablets

Marksans

For the temporary relief of minor arthritis pain  
Lasts up to 8 hours

Manufactured for:  
Time-Cap Labs, Inc.  
7 Michael Avenue, Farmingdale,  
NY 11735, USA

Manufactured by:  
Marksans Pharma Ltd.  
Plot No. L-82, L-83,  
Verna Indl. Estate,  
Verna, Goa - 403722, India.

Mfg. Lic. No. : GQ/DRUGS/515

RS/01

NDC 25000-071-11

Acetaminophen Extended-Release Tablets USP, 650 mg- Arthritis Pain  
290 count bottle label

**DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN**

†Compare to Tylenol® 8HR Arthritis Pain active ingredient

NDC 25000-071-11

**Arthritis Pain Relief**

**Acetaminophen**  
**Extended-Release Tablets USP, 650 mg**

**Pain Reliever / Fever Reducer**

Lasts up to 8 hours

For the temporary relief of minor arthritis pain

LOT :  
EXP :  
R3521



\*Capsule-Shaped Bi-Layer Tablets **290 Caplets\***



IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USE.		Drug Facts (Continued)
<b>Drug Facts</b>		<ul style="list-style-type: none"> <li>3 or more alcoholic drinks every day while using this product.</li> <li><b>Allergy alert:</b> acetaminophen may cause severe skin reactions. Symptoms may include:                             <ul style="list-style-type: none"> <li>skin reddening</li> <li>blisters</li> <li>rash</li> </ul> </li> <li>If a skin reaction occurs, stop use and seek medical help right away.</li> </ul>
<b>Active ingredient (in each caplet)</b>	<b>Purpose</b>	
Acetaminophen 650 mg.....	Pain reliever/fever reducer	<p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>if you are allergic to acetaminophen or any of the inactive ingredients in this product.</li> </ul> <p><b>Ask a doctor before use if you have liver disease.</b></p> <p><b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</b></p>
<b>Uses</b>		
<ul style="list-style-type: none"> <li>temporarily relieves minor aches and pains due to:                             <ul style="list-style-type: none"> <li>minor pain of arthritis</li> <li>muscular aches</li> <li>backache</li> <li>premenstrual and menstrual cramps</li> <li>the common cold</li> <li>headache</li> <li>toothache</li> </ul> </li> <li>temporarily reduces fever</li> </ul>		<p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>pain gets worse or lasts more than 10 days</li> <li>fever gets worse or lasts more than 3 days</li> <li>new symptoms occur</li> <li>redness or swelling is present</li> </ul> <p>These could be signs of a serious condition.</p>
<b>Warnings</b>		
<p><b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take</p> <ul style="list-style-type: none"> <li>more than 6 caplets in 24 hours, which is the maximum daily amount</li> <li>with other drugs containing acetaminophen</li> </ul>		

<b>Drug Facts (Continued)</b>		<b>Drug Facts (Continued)</b>
<p><b>If pregnant or breast-feeding,</b> ask a health professional before use. <b>Keep out of reach of children.</b></p> <p><b>Overdose warning:</b> In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p>		<p><b>Inactive ingredients</b> carnauba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin</p>
<b>Directions</b>		<b>Questions or comments?</b>
<p><b>do not take more than directed (see overdose warning)</b></p>		<p><b>Contains No Aspirin</b></p> <p>*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® 8hr Arthritis Pain.</p> <p>Manufactured for: <b>Time-Cap Labs, Inc.</b> 7 Michael Avenue, Farmingdale, NY 11735, USA</p> <p>Manufactured by: <b>Marksans Pharma Ltd.</b> Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa - 403722, India.</p> <p>Mfg. Lic. No. : GO/DRUGS/515</p>
<b>Adults</b>	<ul style="list-style-type: none"> <li>take 2 caplets every 8 hours with water</li> <li>swallow whole; do not crush, chew, split or dissolve</li> <li>do not take more than 6 caplets in 24 hours</li> <li>do not use for more than 10 days unless directed by a doctor</li> </ul>	
<b>Under 18 years of age</b>	<ul style="list-style-type: none"> <li>ask a doctor</li> </ul>	
<b>Other information</b>		
<ul style="list-style-type: none"> <li>store between 20-25°C (68-77°F)</li> <li>The FDA approved Dissolution methods differ from USP</li> <li><b>do not use if carton is opened. Do not use if foil inner seal is broken or missing</b></li> </ul>		

NDC 25000-071-45

Acetaminophen Extended-Release Tablets USP, 650 mg- Arthritis Pain

400 count bottle label

**DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN**

NDC 25000-071-45

<sup>†</sup>Compare to Tylenol<sup>®</sup> 8-hr Arthritis Pain active ingredient


**Arthritis Pain Relief**

# Acetaminophen

## Extended-Release Tablets USP, 650 mg

**Pain Reliever / Fever Reducer**

Lasts up to 8 hours  
For the temporary relief of minor arthritis pain



Actual Size

**IMPORTANT - READ ALL PRODUCT INFORMATION BEFORE USE.**

**Drug Facts**

Active ingredient (in each caplet)	Purpose
Acetaminophen 650 mg	Pain reliever/fever reducer

**Uses**

- temporarily relieves minor aches and pains due to:
  - minor pain of arthritis
  - muscular aches
  - backache
  - premenstrual and menstrual cramps
  - the common cold
  - headache
  - toothache
- temporarily reduces fever

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy alert:** acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure

**Drug Facts (continued)**

whether a drug contains acetaminophen, ask a doctor or pharmacist.

- if you are allergic to acetaminophen or any of the inactive ingredients in this product

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

**Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin**

**Stop use and ask a doctor if**

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.**

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

**Do not take more than directed.** See overdose warning

**adults**

- take 2 caplets every 8 hours with water
- swallow whole; do not crush, chew, split

**Drug Facts (continued)**

or dissolve

- do not take more than 6 caplets in 24 hours
- do not use for more than 10 days unless directed by a doctor

**under 18 years of age**

- ask a doctor

**Other information**

- store between 20-25°C (68-77°F)
- The FDA approved Dissolution methods differ from USP
- **do not use if carton is opened. Do not use if foil inner seal is broken or missing**

**Inactive ingredients** carnauba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

**Questions or comments?**  
Call 1-877-376-4271 Mon-Fri 9:00am - 6:00pm EST

**Contains No Aspirin**

This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol<sup>®</sup> 8-hr Arthritis Pain. Manufactured for: Time-Cap Labs, Inc., 7 Michael Avenue, Farmingdale, NY 11735, USA. Manufactured by: Marksans Pharma Ltd., Plot No. L-82, L-83, Verna, Indl. Estate, Verna, Goa - 403722, India.

**M** Marksans


\*Capsule-Shaped Bi-Layer Tablets

400

Caplets\*

Lot No.: **Varnish Omit Area**

Exp. Date:



NDC 25000-071-45

NDC 25000-108-02

Acetaminophen Extended-Release Tablets USP, 650 mg - Muscle Aches and Pain  
24 count carton label





NDC 25000-108-02  
 Acetaminophen Extended-Release Tablets USP, 650 mg - Muscle Aches and Pain  
 24 count bottle label

NDC 25000-108-02

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

MUSCLE ACHES & PAIN

# Acetaminophen

Extended-Release Tablets USP, 650 mg

Pain Reliever / Fever Reducer

For Up to 8 Hours Relief of Minor Muscle Aches and Pain



\*Capsule-Shaped 8-Layer Tablets

24 Caplets\*

## IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USE.

Active ingredient (in each caplet)	Purpose
Acetaminophen 650 mg.....	Pain reliever/fever reducer

**Uses** ■ temporarily relieves minor aches and pains due to: ■ muscular

LOT :

EXP :

R010/23

aches ■ backache ■ minor pain of arthritis ■ toothache ■ premenstrual and menstrual cramps ■ headache ■ temporarily reduces fever **Warnings Liver warning:** This product contains acetaminophen. Severe liver

damage may occur if you take ■ more than 6 caplets in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product. **Allergy**

**alert:** acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash. If a skin reaction occurs, stop use and seek medical help right away. **Do not use** ■ with any other drug

containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ if you are allergic to acetaminophen or any of the inactive ingredients in this

product. **Ask a doctor before use if you have liver disease. Ask a doctor or pharmacist before use if you are** taking the blood thinning drug warfarin. **Stop use and ask a doctor if** ■ pain gets worse or lasts more than 10 days ■ fever

gets worse or lasts more than 3 days ■ new symptoms occur ■ redness or swelling is present. These could be signs of a serious condition. **If pregnant or breast-feeding,** ask a health professional before use. **Keep out of reach of**

**children. Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children

or symptoms. **Directions** ■ **Do not take more than directed.** See overdose warning. adults and children 12 years and over ■ take 2 caplets every 8 hours with water ■ swallow whole; do not crush

take more than 6 caplets in 24 hours ■ do not use for more than 10 days unless directed by a doctor children under 12 years ■ ask a doctor **Other information** ■ store between 20-25°C (68-

even if you do not notice any signs, **do not** swallow whole, do not crush, chew, split, or dissolve **do not** store between 20° to 25° C (68° to 77°F) **The FDA approved**

dissolution methods differ from USP **Do not use if foil inner seal is broken or missing**  
**Inactive ingredients** carnauba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline

cellulose, povidone, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

**Questions or comments?**

Call at 1-877-376-4271

Mon-Fri 9.00am - 6.00pm EST

**Contains No Aspirin**

Manufactured for:

**Time-Cap Labs, Inc.**

7 Michael Avenue, Farmingdale, NY 11735, USA

Manufactured by:

**Marksans Pharma Ltd.**

Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa - 403722, India.

Mfg. Lic. No. : GO/DRUGS/515

NDC 25000-108-08

Acetaminophen Extended-Release Tablets USP, 650 mg - Muscle Aches and Pain  
100 count carton label





NDC 25000-108-08

Acetaminophen Extended-Release Tablets USP, 650 mg - Muscle Aches and Pain

100 count bottle label



NDC 25000-108-08

**DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN**

**MUSCLE ACHES & PAIN**



# Acetaminophen

## Extended-Release Tablets USP, 650 mg

**Pain Reliever / Fever Reducer**

For Up to 8 Hours Relief of Minor Muscle Aches and Pain



\*Capsule-Shaped Bi-Layer Tablets

**100 Caplets\***

LOT:

EXP:

R010/23

**IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USE.**

**Drug Facts**

Active ingredient (in each caplet)	Purpose
Acetaminophen 650 mg.....	Pain reliever/fever reducer

**Uses**

- temporarily relieves minor aches and pains due to:
  - muscular aches
  - backache
  - minor pain of arthritis
  - toothache
  - premenstrual and menstrual cramps
  - headache
  - the common cold
- temporarily reduces fever

**Warnings**

- Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take
- more than 6 caplets in 24 hours, which is the maximum daily amount
  - with other drugs containing acetaminophen

**Drug Facts (Continued)**

- 3 or more alcoholic drinks every day while using this product.
- Allergy alert:** acetaminophen may cause severe skin reactions. Symptoms may include:
  - skin reddening
  - blisters
  - rash
 If a skin reaction occurs, stop use and seek medical help right away.

**Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product.

**Ask a doctor before use if you have** liver disease.

**Ask a doctor or pharmacist before use if you are** taking the blood thinning drug warfarin.

**Stop use and ask a doctor if**

- pain gets worse or lasts more than 10 days
  - fever gets worse or lasts more than 3 days
  - new symptoms occur
  - redness or swelling is present
- These could be signs of a serious condition.

**Drug Facts (Continued)**

**If pregnant or breast-feeding,** ask a health professional before use. **Keep out of reach of children.**

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

**Do not take more than directed.** See overdose warning

**Drug Facts (Continued)**

**Inactive ingredients** carnauba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

**Questions or comments?**

Call at 1-877-376-4271 Mon-Fri 9.00am - 6.00pm EST

**Contains No Aspirin**

Manufactured for:

adults and children 12 years and over	<ul style="list-style-type: none"> <li>■ take 2 caplets every 8 hours with water</li> <li>■ swallow whole; do not crush, chew, split, or dissolve</li> <li>■ do not take more than 6 caplets in 24 hours</li> <li>■ do not use for more than 10 days unless directed by a doctor</li> </ul>
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Children under 12 years	<ul style="list-style-type: none"> <li>■ do not use</li> </ul>
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**Other information**

- store between 20-25°C (68-77°F)
- The FDA approved dissolution methods differ from USP
- do not use if carton is opened. Do not use if foil inner seal is broken or missing

**Time-Cap Labs, Inc.**  
7 Michael Avenue, Farmingdale, NY 11735, USA

Manufactured by:  
**Marksans Pharma Ltd.**  
Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa - 403722, India.

Mfg. Lic. No. : GO/DRUGS/515

## ACETAMINOPHEN EXTENDED-RELEASE TABLETS, 650 MG

acetaminophen tablet, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:25000-071
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

### Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TRIACETIN (UNII: XHX3C3X673)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	

### Product Characteristics

<b>Color</b>	WHITE (White to off white)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	71
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25000-071-02	1 in 1 CARTON	09/02/2021	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:25000-071-08	1 in 1 CARTON	09/02/2021	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:25000-071-10	1 in 1 CARTON	09/02/2021	
3		225 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:25000-071-11	1 in 1 CARTON	09/02/2021	
4		290 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:25000-071-45	400 in 1 BOTTLE; Type 0: Not a Combination Product	09/07/2021	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215486	09/02/2021	

<b>ACETAMINOPHEN EXTENDED-RELEASE TABLETS, 650 MG</b>			
acetaminophen tablet, extended release			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:25000-108
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	650 mg
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>
STARCH, CORN (UNII: O8232NY3SJ)			
POVIDONE K30 (UNII: U725QWY32X)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
TRIACETIN (UNII: XHX3C3X673)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			

<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	
<b>HYDROXYETHYL CELLULOSE (140 MPa.S AT 5%)</b> (UNII: 8136Y38GY5)	

### Product Characteristics

<b>Color</b>	WHITE (white to off white)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	71
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25000-108-02	1 in 1 CARTON	10/14/2022	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:25000-108-08	1 in 1 CARTON	10/14/2022	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215486	10/14/2022	

**Labeler -** MARKSANS PHARMA LIMITED (925822975)

### Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	MANUFACTURE(25000-071, 25000-108)

Revised: 10/2023

MARKSANS PHARMA LIMITED