

**ACETAMINOPHEN 250 MG AND IBUPROFEN 125 MG - acetaminophen 250 mg and ibuprofen 125 mg tablets tablet, film coated**  
**MARKSANS PHARMA LIMITED**

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**Acetaminophen 250 mg and Ibuprofen 125 mg Tablets**

**Active ingredients (in each caplet)**

Acetaminophen 250 mg

Ibuprofen 125 mg (NSAID\*)

\*nonsteroidal anti-inflammatory drug

**Purposes**

Pain reliever

Pain reliever

**Uses**

- temporarily relieves minor aches and pains due to:
  - o headache
  - o toothache
  - o backache
  - o menstrual cramps
  - o muscular aches
  - o minor pain of arthritis

**Warnings**

**Acetaminophen liver damage warning:**

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

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

**Acetaminophen allergy alert:** may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

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

**NSAID allergy alert:** ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

**NSAID stomach bleeding warning:**

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

**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 have ever had an allergic reaction to acetaminophen or any other pain reliever
- right before or after heart surgery

**Ask a doctor before use if**

- you have liver disease
- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic

**Ask a doctor or pharmacist before use if you are**

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

## When using this product

- take with food or milk if stomach upset occurs

## Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
  - o feel faint
  - o vomit blood
  - o have bloody or black stools
  - o have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
  - o chest pain
  - o trouble breathing
  - o weakness in one part or side of body
  - o slurred speech
  - o leg swelling
- pain gets worse or lasts more than 10 days
- redness or swelling is present in the painful area
- any new symptoms appear

## If pregnant or breast-feeding

ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

## Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt 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**

adults and children 12 years and over	• <b>take 2 caplets every 8 hours</b> while symptoms persist
children under 12 years	• ask a doctor

- do not take more than 6 caplets in 24 hours, unless directed by a doctor

## **Other information**

- read all warnings and directions before use. Keep carton.
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

## **Inactive ingredients**

colloidal anhydrous silica, corn starch, croscarmellose sodium, glyceryl dibehenate, hypromellose, microcrystalline cellulose, polydextrose, povidone, red iron oxide, titanium dioxide, triacetin, yellow iron oxide

## **Questions or comments?**

Call **1-877-376-4271** (weekdays 9 AM to 5 PM)

Distributed by:

### **Time-Cap Labs, Inc.**

7 Michael Avenue,  
Farmingdale,  
NY 11735, USA

## **Made in India**

## **PRINCIPAL DISPLAY PANEL**

NDC 25000-080-72

Acetaminophen 250 mg and Ibuprofen 125 mg Tablets

18 count carton label

Do not use with other medicines containing ACETAMINOPHEN; can cause liver damage.

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION.

Drug Facts

Active ingredients (in each caplet)
Acetaminophen 250 mg
Ibuprofen 125 mg (NSAID\*)
Pain reliever
Pain reliever
\*nonsteroidal anti-inflammatory drug

Uses
temporarily relieves minor aches and pains due to:
headache, toothache, backache, menstrual cramps, muscular aches, minor pain of arthritis

Warnings
Acetaminophen liver damage warning:
This product contains acetaminophen. Severe liver damage may occur if you take:

Drug Facts (continued)

Do not use
with other drugs containing acetaminophen
more than 6 caplets in 24 hours, which is the maximum daily amount for this product
3 or more alcoholic drinks every day while using this product

Acetaminophen allergy alert: may cause severe skin reactions.
Symptoms may include:
skin reddening, blisters, rash
If skin reaction occurs, stop use and seek medical help right away.

NSAID allergy alert: ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, blisters

Drug Facts (continued)

If an allergic reaction occurs, stop use and seek medical help right away.

NSAID stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:
are age 60 or older
have had stomach ulcers or bleeding problems
take a blood thinning (anticoagulant) or steroid drug
take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
have 3 or more alcoholic drinks every day while using this product
take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

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 have ever had an allergic reaction to acetaminophen or any other pain reliever
right before or after heart surgery

Ask a doctor before use if:
you have liver disease
stomach bleeding warning applies to you
you have problems or serious side effects from taking pain relievers
you have a history of stomach problems, such as heartburn
you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
you are taking a diuretic

Ask a doctor or pharmacist before use if you are

Drug Facts (continued)

under a doctor's care for any serious condition
taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
taking any other drug

When using this product
take with food or milk if stomach upset occurs

Stop use and ask a doctor if:
you experience any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools
have stomach pain that does not get better
you have symptoms of heart problems or stroke: chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling
pain gets worse or lasts more than 10 days
redness or swelling is present in the painful area

Drug Facts (continued)

any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt 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
adults and children 12 years and over: take 2 caplets every 8 hours while symptoms persist
children under 12 years: ask a doctor
do not take more than 6 caplets in 24 hours, unless directed by a doctor

Drug Facts (continued)
Other information
read all warnings and directions before use. Keep carton.
store at 20-25°C (68-77°F).
avoid excessive heat above 40°C (104°F).
Inactive ingredients: colloidal anhydrous silica, corn starch, croscarmellose sodium, glyceryl behenate, hypromellose, microcrystalline cellulose, polydextrose, povidone, red iron oxide, titanium dioxide, triacetin, yellow iron oxide
Questions or comments?
Call 1-877-376-4271 (weekdays 9 AM to 5 PM)

Lot No.:
Exp Date:
Varnish Omit Area

Do Not Use: If seal under bottle cap imprinted with "SEALED FOR YOUR PROTECTION" is broken or missing.
NDC 25000-080-72
3
Distributed by: Tims-Caplet, Inc.
7 Michael Avenue, Farmingdale, NY 11735, USA
Mfg. Lot No.: S0D9HSS515 281122

NDC 25000-080-72

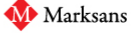
Acetaminophen and Ibuprofen (NSAID) Tablets, 250 mg/125 mg

Pain Reliever

CONTAINS 2 MEDICINES DUAL ACTION

18 Caplets\*

\*Capsule-Shaped Tablets



Compare to the active ingredients in Advil® Dual Action with Acetaminophen†



ACTUAL SIZE

NDC 25000-080-72

Acetaminophen 250 mg and Ibuprofen 125 mg Tablets

18 count bottle label

### Drug Facts (continued)

not notice any signs or symptoms.

#### Directions

- do not take more than directed
- adults and children 12 years and over: **take 2 caplets every 8 hours** over: while symptoms persist
- children under 12 years: ask a doctor
- do not take more than 6 caplets in 24 hours, unless directed by a doctor

#### Other information

- read all warnings and directions before use. Keep carton.
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

#### Inactive ingredients

colloidal anhydrous silica, corn starch, croscarmellose sodium, glyceryl dibehenate, hypromellose, microcrystalline cellulose, polydextrose, povidone, red iron oxide, titanium dioxide, triacetin, yellow iron oxide

#### Questions or comments?

Call 1-877-376-4271 (weekdays 9 AM, to 5 PM)

Distributed by:

Time-Cap Labs, Inc.

7 Michael Avenue,

Farmingdale, NY 11735, USA

Made in India

Mfg. Lic. No. : G0DRUSS515

R211/22

Adhesive Area

### Drug Facts (continued)

medical help right away.

**NSAID allergy alert:** ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin.

Symptoms may include:

- hives
- asthma (wheezing)
- skin reddening
- facial swelling
- shock
- rash
- blisters.

If an allergic reaction occurs, stop use and seek medical help right away.

#### NSAID stomach bleeding warning:

This product contains an NSAID, which may cause severe stomach

bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

#### Heart attack and stroke warning:

NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

**If pregnant or breast-feeding,** ask a health professional before use. It is especially important not to use

ibuprofen at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.** In case

of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do

### Varnish Omit Area

Lot No.:  
Exp. Date:  
**FREE REFILL**

NDC 25000-080-72

## Acetaminophen and Ibuprofen (NSAID) Tablets, 250 mg/125 mg

Pain Reliever

CONTAINS 2 MEDICINES  
DUAL ACTION

18 Caplets\*

\*Capsule-Shaped Tablets

Marksans



Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.

Do not use with other medicines containing ACETAMINOPHEN; can cause liver damage.

#### Purposes Active ingredients (in each caplet)

Acetaminophen 250 mg.....Pain reliever  
Ibuprofen 125 mg.....Pain reliever  
\*nonsteroidal anti-inflammatory drug

#### Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - backache
  - muscular aches
- minor pain of arthritis
- toothache
- menstrual cramps

#### Warnings

##### Acetaminophen liver damage warning:

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

- with other drugs containing acetaminophen
- more than 9 caplets in 24 hours, which is the maximum daily amount for this product
- 3 or more alcoholic drinks every day while using this product

##### Acetaminophen allergy alert:

may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash.

If skin reaction occurs, stop use and seek



Do not use with other medicines containing ACETAMINOPHEN; can cause liver damage.

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION.

Drug Facts

Active ingredients (in each caplet)
Acetaminophen 250 mg
Ibuprofen 125 mg (NSAID)\*
\*nonsteroidal anti-inflammatory drug

Purposes
Pain reliever
Pain reliever

Uses

- temporarily relieves minor aches and pains due to: headache, toothache, backache, menstrual cramps, muscular aches, minor pain of arthritis

Warnings

Acetaminophen liver damage warning: This product contains acetaminophen. Severe liver damage may occur if you take: with other drugs containing acetaminophen

Drug Facts (continued)

- more than 6 caplets in 24 hours, which is the maximum daily amount for this product
3 or more alcoholic drinks every day while using this product
Acetaminophen allergy alert: may cause severe skin reactions. Symptoms may include:

- skin reddening, blisters, rash
If skin reaction occurs, stop use and seek medical help right away.
NSAID allergy alert: ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, blisters

If an allergic reaction occurs, stop use and seek medical help right away.
NSAID stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

Drug Facts (continued)

- are age 60 or older
have had stomach ulcers or bleeding problems
take a blood thinning (anticoagulant) or steroid drug
take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
have 3 or more alcoholic drinks every day while using this product
take more or for a longer time than directed
Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

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 have ever had an allergic reaction to acetaminophen or any other pain reliever
right before or after heart surgery

Drug Facts (continued)

Ask a doctor before use if

- you have liver disease
stomach bleeding warning applies to you
you have problems or serious side effects from taking pain relievers
you have a history of stomach problems, such as heartburn
you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:

Drug Facts (continued)

- feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better
you have symptoms of heart problems or stroke: chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling
pain gets worse or lasts more than 10 days
redness or swelling is present in the painful area
any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt 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

Drug Facts (continued)

- adults and children 12 years and over: take 2 caplets every 8 hours while symptoms persist
children under 12 years: ask a doctor

- do not take more than 6 caplets in 24 hours, unless directed by a doctor

Other information

- read all warnings and directions before use. Keep carton.
store at 20-25°C (68-77°F)
avoid excessive heat above 40°C (104°F)

Inactive ingredients colloidal anhydrous silica, corn starch, croscarmellose sodium, glyceryl dibehenate, hypromellose, microcrystalline cellulose, polydextrose, povidone, red iron oxide, titanium dioxide, triacetin, yellow iron oxide

Questions or comments? Call 1-877-376-4271 (weekdays 9 AM to 5 PM)

Do Not Use if seal under bottle cap imprinted with "SEALED FOR YOUR PROTECTION" is broken or missing.



This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings US LLC, owner of the registered trademark Advil® Dual Action with Acetaminophen. Distributed by: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735, USA. Made in India. Mfg. Lic. No.: G00RUGS15 R21122

Lot No.: Varnish Omit Area
Exp Date:

NDC 25000-080-07

Acetaminophen and Ibuprofen (NSAID) Tablets, 250 mg/125 mg

Pain Reliever

CONTAINS 2 MEDICINES DUAL ACTION

90 Caplets\*

\* Capsule-Shaped Tablets



Compare to the active ingredients in Advil® Dual Action with Acetaminophen†



ACTUAL SIZE

NDC 25000-080-07

Acetaminophen 250 mg and Ibuprofen 125 mg Tablets

90 count bottle label

**Adhesive Area**

<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>■ have had stomach ulcers or bleeding problems</li> <li>■ take a blood thinning (anticoagulant) or steroid drug</li> <li>■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)</li> <li>■ have 3 or more alcoholic drinks every day while using this product</li> <li>■ take more or for a longer time than directed</li> </ul> <p><b>Heart attack and stroke warning:</b> NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.</p> <p><b>If pregnant or breast-feeding:</b> ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.</p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt 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> <ul style="list-style-type: none"> <li>■ <b>do not take more than directed</b></li> <li>■ adults and children 12 years and over: <b>take 2 caplets every 8 hours</b> while symptoms persist</li> <li>■ children under 12 years: ask a doctor</li> <li>■ do not take more than 6 caplets in 24 hours, unless directed by a doctor</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ read all warnings and directions before use. Keep carton.</li> <li>■ store at 20-25°C (68-77°F)</li> <li>■ avoid excessive heat above 40°C (104°F)</li> </ul> <p><b>Inactive ingredients</b> colloidal anhydrous silica, corn starch, croscarmellose sodium, glyceryl dibehenate, hypromellose, microcrystalline cellulose, polydextrose, povidone, red iron oxide, titanium dioxide, triacetin, yellow iron oxide</p> <p><b>Questions or comments?</b> Call 1-877-376-4271 (weekdays 9 AM to 5 PM)</p>
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NDC 25000-080-07

**Acetaminophen and Ibuprofen (NSAID) Tablets, 250 mg/125 mg**

*Pain Reliever*

**CONTAINS 2 MEDICINES  
DUAL ACTION**

**90 Caplets\***  
\*Capsule-Shaped Tablets

 ACTUAL SIZE

**Marksans**

**Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.**

**Do not use with other medicines containing ACETAMINOPHEN, can cause liver damage.**

<p><b>Drug Facts</b></p> <p><b>Active ingredients (in each caplet)</b></p> <p>Acetaminophen 250 mg ..... Pain reliever</p> <p>Ibuprofen 125 mg (NSAID)* ..... Pain reliever</p> <p>*nonsteroidal anti-inflammatory drug</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>■ temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> <li>■ headache</li> <li>■ toothache</li> <li>■ backache</li> <li>■ menstrual cramps</li> <li>■ muscular aches</li> <li>■ minor pain of arthritis</li> </ul> </li> </ul> <p><b>Warnings</b></p> <p><b>Acetaminophen liver damage warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take: <ul style="list-style-type: none"> <li>■ with other drugs containing acetaminophen</li> <li>■ more than 6 caplets in 24 hours, which is the maximum daily amount for this product</li> <li>■ 3 or more alcoholic drinks every day while using this product</li> </ul> <b>Acetaminophen allergy alert:</b> may cause severe skin reactions. Symptoms may include: <ul style="list-style-type: none"> <li>■ skin reddening</li> <li>■ blisters</li> <li>■ rash</li> <li>■ skin reddening</li> <li>■ skin reddening</li> <li>■ rash</li> <li>■ blisters</li> </ul> </p> <p><b>NSAID allergy alert:</b> ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: <ul style="list-style-type: none"> <li>■ hives</li> <li>■ facial swelling (wheezing)</li> <li>■ asthma</li> <li>■ rash</li> <li>■ blisters</li> </ul> </p> <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p><b>NSAID stomach bleeding warning:</b> This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: <ul style="list-style-type: none"> <li>■ are age 60 or older</li> </ul> </p>	<p><b>Lot No.:</b></p> <p><b>Exp. Date:</b></p> <p style="text-align: center;"><b>Varnish Omit Area</b></p> <p style="text-align: center;"><b>SEE HERE</b></p> <p style="text-align: right;">R211ZZ Mfg. Lic. No.: G09D05515</p> <p style="text-align: right;">Distributed by: Time-Cap Labs, Inc. 2 Michael Avenue, Farmingdale, NY 11735, USA Made in India</p>
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NDC 25000-080-74

Acetaminophen 250 mg and Ibuprofen 125 mg Tablets

288 count bottle label



<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>■ Have 3 or more alcoholic drinks every day while using this product</li> <li>■ Take more or for a longer time than directed</li> <li>■ <b>Heart attack and stroke warning:</b> NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.</li> </ul> <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 have ever had an allergic reaction to acetaminophen or any other pain reliever</li> <li>■ Right before or after heart surgery</li> </ul> <p><b>Ask a doctor before use if</b></p> <ul style="list-style-type: none"> <li>■ You have liver disease</li> <li>■ Stomach bleeding warning applies to you</li> <li>■ You have problems or serious side effects from taking pain relievers</li> <li>■ You have a history of stomach problems, such as heartburn</li> <li>■ You have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke</li> <li>■ You are taking a diuretic</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are</b></p> <ul style="list-style-type: none"> <li>■ Under a doctor's care for any serious condition</li> <li>■ Taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin</li> <li>■ Taking any other drug</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>■ Take with food or milk if stomach upset occurs</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ You experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> <li>■ Feel faint</li> <li>■ vomit blood</li> <li>■ have bloody or black stools</li> </ul> </li> <li>■ Have stomach pain that does not get better</li> <li>■ You have symptoms of heart problems or stroke: <ul style="list-style-type: none"> <li>■ chest pain</li> <li>■ trouble breathing</li> <li>■ weakness in one part or side of body</li> <li>■ slurred speech</li> <li>■ leg swelling</li> </ul> </li> <li>■ Pain gets worse or lasts more than 10 days</li> <li>■ Redness or swelling is present in the painful area</li> <li>■ Any new symptoms appear</li> </ul> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.</p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt 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> <ul style="list-style-type: none"> <li>■ Do not take more than directed</li> <li>■ Adults and children 12 years and over: <b>take 2 caplets every 8 hours</b> while symptoms persist</li> <li>■ Children under 12 years: ask a doctor</li> <li>■ Do not take more than 6 caplets in 24 hours, unless directed by a doctor</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ Read all warnings and directions before use.</li> <li>■ Store at 20-25°C (68-77°F)</li> <li>■ Avoid excessive heat above 40°C (104°F)</li> </ul> <p><b>Inactive ingredients:</b> colloidal anhydrous silica, corn starch, croscarmellose sodium, glyceryl dibehenate, hypromellose, microcrystalline cellulose, polydextrose, polydioxane, red iron oxide, titanium dioxide, triacetin, yellow iron oxide</p> <p><b>Questions or comments?</b> Call 1-877-376-4271 (weekdays 9 AM to 5 PM)</p>

NDC 25000-080-74

Compare to the active ingredients in Advil®  
Dual Action with Acetaminophen††

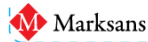
# Acetaminophen and Ibuprofen (NSAID) Tablets, 250 mg/125 mg

Pain Reliever

**CONTAINS 2 MEDICINES  
DUAL ACTION**

**288 Caplets\***

\*Capsule-Shaped Tablets



ACTUAL SIZE

**Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.**

**Do not use with other medicines containing ACETAMINOPHEN, can cause liver damage.**

## Drug Facts

### Active ingredients (in each caplet)

Acetaminophen 250 mg (NSAID)\*  
Ibuprofen 125 mg (NSAID)\*

Pain reliever  
Nonsteroidal anti-inflammatory drug

### Uses

■ Temporarily relieves minor aches and pains due to:  
 ■ headache ■ toothache ■ backache  
 ■ menstrual cramps ■ muscular aches ■ minor pain of arthritis

### Warnings

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

**Acetaminophen allergy alert:** may cause severe skin reactions. Symptoms may include:  
 ■ skin redness ■ blisters ■ rash  
 If skin reaction occurs, stop use and seek medical help right away.

**NSAID allergy alert:** ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:  
 ■ hives ■ facial swelling ■ asthma (wheezing)  
 ■ shock ■ skin redness ■ rash ■ blisters  
 If an allergic reaction occurs, stop use and seek medical help right away.

**NSAID stomach bleeding warning:**  
 This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:  
 ■ are age 60 or older  
 ■ have had stomach ulcers or bleeding problems  
 ■ take a blood thinning (anticoagulant) or steroid drug  
 ■ take other drugs containing prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

†† This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings US LLC, owner of the registered trademark Advil® Dual Action with Acetaminophen. Distributed by: **Time-Cap Labs, Inc.**  
 7 Michael Avenue, Farmingdale, NY 11735, USA  
**Made in India**



3 108000 000000 074117

Lot No.: 60DRUUS515  
Exp. Date: PZ11/22

Varnish Omit Area



# ACETAMINOPHEN 250 MG AND IBUPROFEN 125 MG

acetaminophen 250 mg and ibuprofen 125 mg tablets tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:25000-080
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)		Acetaminophen	250 mg	
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)		IBUPROFEN	125 mg	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
POVIDONE K30 (UNII: U725QWY32X)				
STARCH, CORN (UNII: O8232NY3SJ)				
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
TRIACETIN (UNII: XHX3C3X673)				
POLYDEXTROSE (UNII: VH2XOU12IE)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
<b>Product Characteristics</b>				
Color	YELLOW	Score	no score	
Shape	CAPSULE	Size	15mm	
Flavor		Imprint Code	80	
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25000-080-72	1 in 1 CARTON	07/11/2023	
1		18 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:25000-080-07	1 in 1 CARTON	07/11/2023	
2		90 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:25000-080-74	288 in 1 BOTTLE; Type 0: Not a Combination Product	07/11/2023	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA216994	07/11/2023		

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

## Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	MANUFACTURE(25000-080)

Revised: 7/2023

MARKSANS PHARMA LIMITED