

**DUAL ACTION- acetaminophen and ibuprofen (nsaid) tablets, 250 mg/ 125 mg tablet, film coated**

**Dr. Reddy's Laboratories Inc**

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

***Active ingredients (in each caplet)***

Acetaminophen USP, 250 mg

Ibuprofen USP, 125 mg (NSAID\*)

\*nonsteroidal anti-inflammatory drug

***Purposes***

Pain Reliever

Pain Reliever

**Uses**

***Uses***

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

**Warnings**

***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:
- 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**

***Directions***

- **do not take more than directed**

adults and children 12 years and over	<ul style="list-style-type: none"> <li>• <b>take 2 caplets every 8 hours</b> while symptoms persist</li> </ul>
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children under 12 years	<ul style="list-style-type: none"><li>• ask a doctor</li></ul>
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- do not take more than 6 caplets in 24 hours, unless directed by a doctor

## **Other information**

### ***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**

### ***Inactive ingredients***

black iron oxide, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, glyceryl dibehenate, hypromellose, polydextrose, polyethylene glycol, pregelatinized starch, propylene glycol, sodium lauryl sulfate, titanium dioxide

## **Questions or comments?**

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

call **1-888-375-3784** Weekdays (8 AM to 8 PM EST)

Distributed By:

**Dr. Reddy's Laboratories, Inc.**

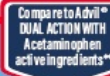
Princeton, NJ 08540

**Made in India**

Rev: 10/24

## **Principal Display Panel- Container**

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



**CONTAINS 2 MEDICINES**  
Acetaminophen+Ibuprofen

# Dual Action Acetaminophen and Ibuprofen (NSAID) Tablets, 250 mg /125 mg PAIN RELIEVER

**144 Caplets\***  
\*Capsule-Shaped Tablets



actual size

**TAMPER EVIDENT:** 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 USP, 250 mg.....Pain Reliever  
Ibuprofen USP, 125 mg (NSAID)\*.....Pain Reliever  
\*nonsteroidal anti-inflammatory drug

### Purposes

**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 reddening ■ blisters ■ rash If skin reaction occurs, stop use and seek medical help right away.

**DISTRIBUTED BY:**  
Dr. Reddy's Laboratories, Inc.  
Princeton, NJ 08540

Made in India



15 009 8998

DRUGS/AP/59/87

Rev: 10/24

Peel Here 

LOT:  
EXP:

## Drug Facts (continued)

**NSAID allergy alert:** ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:  
■ hives ■ facial swelling ■ asthma (w/ 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: ■ feel faint ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better

## Drug Facts (continued)

■ 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

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.  
■ store at 20-25°C (68-77°F)  
■ avoid excessive heat above 40°C (104°F)

### Inactive ingredients

black iron oxide, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, glyceryl dibehenate, hypromellose, polydextrose, polyethylene glycol, pregelatinized starch, propylene glycol, sodium lauryl sulfate, titanium dioxide

### Questions or comments?

call 1-888-375-3784 Weekdays (8 AM to 8 PM EST)

\*\*This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Advil® DUAL ACTION WITH Acetaminophen. Advil® is a registered trademark owned by Haleon US Holdings LLC.

# Acetaminophen 250 mg and Ibuprofen 125 mg Tablets

## Pain Reliever

**HealthCare Aisle**

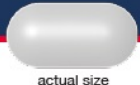
NDC 75907-158-25

Compare to Advil®  
DUAL ACTION WITH  
Acetaminophen  
active ingredients\*

**CONTAINS 2 MEDICINES**  
Acetaminophen+Ibuprofen

**Dual Action**  
**Acetaminophen and**  
**Ibuprofen (NSAID)**  
Tablets, 250 mg /125 mg  
PAIN RELIEVER

**250 Caplets\***  
\*Capsule-Shaped Tablets



actual size

**TAMPER EVIDENT: 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 USP, 250 mg.....Pain Reliever  
Ibuprofen USP, 125 mg (NSAID)\*.....Pain Reliever  
\*nonsteroidal anti-inflammatory drug

**Uses**  
temporarily relieves minor aches and pains due to:  
headache  
backache  
muscular aches  
menstrual cramps  
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  
hives  
blistering  
rash  
itching  
If a 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)  
skin redness  
rash  
blistering  
If an allergic reaction occurs, stop use and seek medical help right away.


Peel Here

LOT:  
EXP:

150099105

DRUGS/AP/59/97

Rev: 10/24



3 75907 15825 4

MADE IN INDIA

MADE IN INDIA

DISTRIBUTED BY:  
Dr. Reddy's Laboratories, Inc.  
Princeton, NJ 08540

**Drug Facts (continued)**  
**NSAID stomach bleeding warning:**  
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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  
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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  
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

**Drug Facts (continued)**  
It may cause problems in the unborn child or complications during delivery.  
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**Directions**  
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children under 12 years  
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ask a doctor.  
do not take more than 6 caplets in 24 hours, unless directed by a doctor

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read all warnings and directions before use.  
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<b>DUAL ACTION</b>			
acetaminophen and ibuprofen (nsaid) tablets, 250 mg/ 125 mg tablet, film coated			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75907-158

Route of Administration ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	125 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>GLYCERYL DIBEHENATE</b> (UNII: R8WTH25YS2)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	ACI
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75907-158-14	144 in 1 BOTTLE; Type 0: Not a Combination Product	02/06/2025	
2	NDC:75907-158-25	250 in 1 BOTTLE; Type 0: Not a Combination Product	02/06/2025	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA218247	02/06/2025	

**Labeler** - Dr. Reddy's Laboratories Inc (802315887)

# Establishment

Name	Address	ID/FEI	Business Operations
Dr. Reddy's Laboratories Limited		918608162	manufacture(75907-158) , pack(75907-158) , analysis(75907-158)

Revised: 2/2025

Dr. Reddy's Laboratories Inc