NAPROXEN SODIUM - naproxen sodium tablet, coated tablet MARKSANS PHARMA LIMITED

NAPROXEN SODIUM- naproxen sodium tablet, coated

Active ingredient(s)

For Tablets:

Active ingredient (in each tablet)

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)* *nonsteroidal anti-inflammatory drug

For Caplets:

Active ingredient (in each caplet)

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)* *nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/ fever reducer

Uses

temporarily relieves minor aches and pains due to:

- minor pain of arthritis
- muscular aches
- backache
- menstrual cramps
- headache
- toothache
- the common cold

temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium 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.

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

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- 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
- you have problems or serious side effects from taking pain relievers or fever reducers

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 naproxen 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 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 fever gets worse or lasts more than 3 days you have difficulty swallowing it feels like the pill is stuck in your throat 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 naproxen sodium 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)

Directions

For Tablets:

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

	• take 1 tablet every 8 to 12 hours while symptoms
	last
Adults and children 12 years and	 for the first dose you may take 2 tablets within the
older	first hour

	• do not exceed 2 tablets in any 8- to 12-hour period
	 do not exceed 3 tablets in a 24-hour period
Children under 12 years	ask a doctor

For Caplets:

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

	 take 1 caplet every 8 to 12 hours while symptoms
	last
Adults and children 12 years and	 for the first dose you may take 2 caplets within the
older	first hour
	 do not exceed 2 caplets in any 8- to 12-hour period
	 do not exceed 3 caplets in a 24-hour period
Children under 12 years	ask a doctor

Other information

For Tablets:

- each tablet contains: sodium 20 mg
- store at 20-25°C (68-77°F).
- avoid high humidity and excessive heat above 40°C (104°F).

For Caplets:

- each caplet contains: sodium 20 mg
- store at 20-25°C (68-77°F).
- avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, FD&C blue #2 Lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide

Questions or comments?

call toll free 1-877-376-4271

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

Principal Display Panel

NDC 25000-141-43 Naproxen Sodium Tablets, USP 220 mg 10's count bottle label NDC 25000-141-43

Naproxen Sodium Tablets, USP 220 mg (NSAID)

Pain reliever / fever reducer

STRENGTH TO LAST 12 HOURS

10 Tablets

M

Marksans

See Carton for Full information. Warnings Allergy alert: Naproxen sodium 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. Stomach bleeding warning: This

LOT: EXP: R504/22

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** if

you have ever had an allergic reaction to any other pain reliever/fever reducer. Ask a doctor or pharmacist before use if you are taking any other drug. 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), or if pain or fever gets worse. If pregnant or breast feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison

Control Center right away (1-800-222-1222).

Directions Adults and children 12 years and older: take 1 tablet every 8 to 12 hours while symptoms last. For the first dose you may take 2

exceed 2 tablets in any 8- to 12hour period. Do not exceed 3 tablets in a 24-hour period. Children under 12 years: ask a doctor **Questions or comments?** call toll free 1-877-376-4271

Do not use if seal under cap imprinted with "SEALED for your PROTECTION" is broken or missing tablets within the first hour. Do not

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 - 403 722, India.

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

NDC 25000-141-43 Naproxen Sodium Tablets, USP 220 mg 10's count carton label



NDC 25000-141-02 Naproxen Sodium Tablets, USP 220 mg 24's count bottle label



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

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you have ever had an allergic reaction to any other pain reliever/fever reducer. Ask a doctor or pharmacist before use if you are taking any other drug. 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

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Manufactured for: Time-Cap Labs, Inc.

7 Michael Avenue Farminadale

Manufactured by:

Marksans Pharma Ltd.

Plot No. 1-82 1-83

NY 11735, USA

Verna Indl. Estate, Verna, GOA - 403 722, India.

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

NDC 25000-141-02 Naproxen Sodium Tablets, USP 220 mg 24's count carton label



NDC 25000-141-14

Naproxen Sodium Tablets, USP 220 mg (NSAID)

Pain reliever / fever reducer

STRENGTH TO LAST 12 HOURS

1000 Tablets

M

Marksans

Drug Facts

Active ingredient (in each tablet) Put

Naproxen sodium 220 mg (naproxen 200 mg)

(NSAID)* Pain reliever/fever reducer *nonsteroidal anti-inflammatory drug

Uses

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

Warnings

Allergy alert: Naproxen sodium 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.



Drug Facts (Continued)

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

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

■ the stomach bleeding warning applies to you

- 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
- you have problems or serious side effects from taking pain relievers or fever reducers

Drug Facts (Continued)

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 naproxen may decrease this benefit of aspirin
- taking any other drug

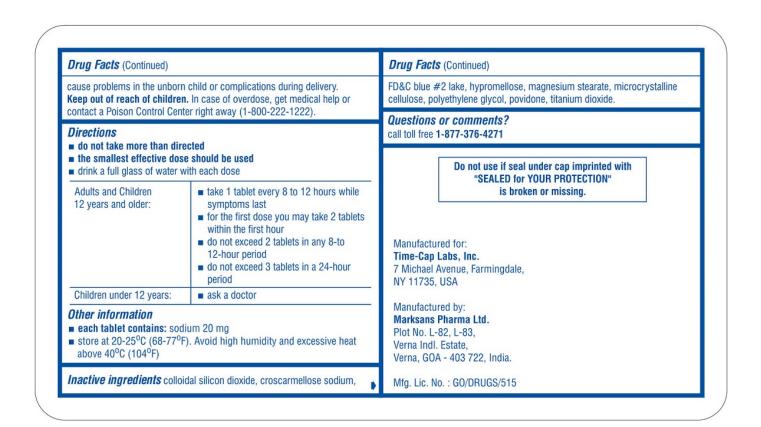
When using this product

■ 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
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- 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 naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may



NDC 25000-144-14 Naproxen Sodium Tablets, USP 220 mg (Capsule-shaped tablet) 1000's count bottle label NDC 25000-144-14

Naproxen Sodium Tablets, USP 220 mg (NSAID)

Pain reliever / fever reducer

STRENGTH TO LAST 12 HOURS

1000 Tablets (oval-shaped)



Marksans

Drug Facts

Active ingredient (in each caplet) Purposes

Naproxen sodium 220 mg (naproxen 200 mg)

(NSAID)* Pain reliever/fever reducer *nonsteroidal anti-inflammatory drug

Uses

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

Warnings

Allergy alert: Naproxen sodium 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.



Drug Facts (Continued)

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

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- 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
- you have problems or serious side effects from taking pain relievers or fever reducers

Drug Facts (Continued)

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 naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

■ take with food or milk if stomach upset occurs

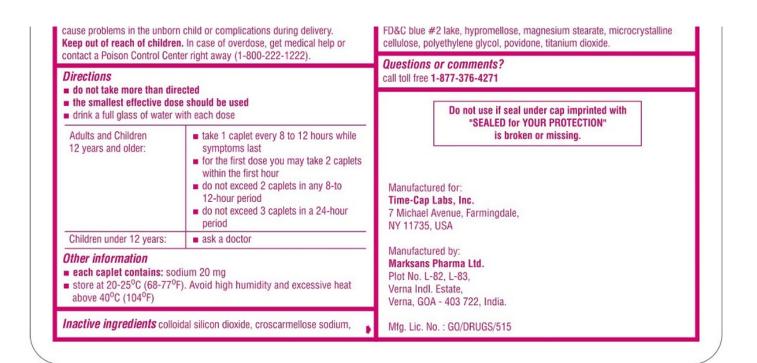
Stop use and ask a doctor if

- 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
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- 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 naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may

Drug Facts (Continued)

Drug Facts (Continued)



NDC 25000-144-43 Naproxen Sodium Tablets, USP 220 mg (Capsule-shaped tablet) 10's count bottle label



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

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side of body, slurred speech, leg swelling), or if pain or fever gets worse. If pregnant or breast feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison

Control Center right away (1-800-222-1222).

Directions Adults and children 12 years and older: take 1 caplet every 8 to 12 hours while symptoms last. For the first dose you may take 2 caplets within the

first hour. Do not exceed 2 caplets in any 8- to 12-hour period. Do not exceed 3 caplets in a 24-hour period. Children under 12 years: ask a doctor. Questions or comments? call toll free 1-877-376-4271

Do not use if seal under cap imprinted with "SEALED for your PROTECTION" is broken or missing

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 - 403 722, India.

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

NDC 25000-144-43 Naproxen Sodium Tablets, USP 220 mg (Capsule-shaped tablet) 10's count carton label



NDC 25000-144-02 Naproxen Sodium Tablets, USP 220 mg (Capsule-shaped tablet) 24's count bottle label



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

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Questions or comments? call toll free 1-877-376-4271

Do not use if seal under cap imprinted with "SEALED for your PROTECTION" is broken or missing 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 - 403 722, India.

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

NDC 25000-144-02 Naproxen Sodium Tablets, USP 220 mg (Capsule-shaped tablet) 24's count carton label



NAPROXEN SODIUM

naproxen sodium tablet, coated tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:25000-144	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg		

Inactive Ingredients				
Ingredient Name	Strength			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)				
POVIDONE (UNII: FZ989GH94E)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				

Product Characteristics				
Color	BLUE	Score	no score	
Shape	OVAL	Size	12mm	
Flavor		Imprint Code	144	
Contains				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25000- 144-14	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/04/2011	
2	NDC:25000- 144-20	4 in 1 BOX	05/04/2011	
2		6500 in 1 BAG; Type 0: Not a Combination Product		
3	NDC:25000- 144-30	6 in 1 BOX	05/04/2011	
3		6500 in 1 BAG; Type 0: Not a Combination Product		
	NDC:25000-	160 :- 1 DOV	05/04/2011	

4	144-02	100 III 1 DOV	03/04/2011
4		1 in 1 CARTON	
4		24 in 1 BOTTLE; Type 0: Not a Combination Product	
5	NDC:25000- 144-43	10 in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2011
6	NDC:25000- 144-98	1 in 1 BOX	05/04/2011
6		32165 in 1 BAG; Type 0: Not a Combination Product	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090545	05/04/2011	

NAPROXEN SODIUM

naproxen sodium, coated tablets tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:25000-141
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Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)		
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)		
POVIDONE (UNII: FZ989GH94E)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		

Product Characteristics			
Color	BLUE	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	141
Contains			

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:25000- 141-14	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/28/2011		
2	NDC:25000- 141-26	2 in 1 BOX	05/28/2011		
2		1600 in 1 BAG; Type 0: Not a Combination Product			
3	NDC:25000- 141-30	6 in 1 BOX	05/28/2011		
3		6500 in 1 BAG; Type 0: Not a Combination Product			
4	NDC:25000- 141-02	160 in 1 BOX	05/28/2011		
4		1 in 1 CARTON			
4		24 in 1 BOTTLE; Type 0: Not a Combination Product			
5	NDC:25000- 141-43	10 in 1 BOTTLE; Type 0: Not a Combination Product	05/28/2011		
6	NDC:25000- 141-98	1 in 1 BOX	05/28/2011		
6		32165 in 1 BAG; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation		
ANDA	ANDA090545	05/28/2011	

Labeler - MARKSANS PHARMA LIMITED (925822975)

Establishment				
Name	Address	ID/FEI	Business Operations	
MARKSANS PHARMA LIMITED		925822975	MANUFACTURE(25000-141, 25000-144)	

Revised: 6/2023 MARKSANS PHARMA LIMITED