

SAFETY NADOL- acetaminophen tablet, coated
Sinew Pharma Inc.

SafeTynadol

Drug Facts

Active Ingredient (In each tablet)

Acetaminophen 500mg

Purpose

Pain reliever/fever reducer

Uses

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

Warnings

This product contains acetaminophen. Severe liver damage may occur if you take more than
4,000 mg of acetaminophen in 24 hours with other drugs containing acetaminophen
3 or more alcohol drinks every day while using this product. 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. **Liver warning: Allergy
alert:**

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 this product or any of its ingredients

Ask a doctor before use

if you have liver disease

Ask a doctor or a pharmacist before use

if you are taking blood thinning drug warfarin

Stop use and ask a doctor if

□pain gets worse or last more than 10 days □new symptoms occur □fever gets worse or lasts more than 3 days □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 over dose, 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	□take 2 tablets every 6 hours while symptoms last □do not take more than 6 tablets in 24 hours, unless directed by a doctor □do not use for more than 10 days unless directed by a doctor
Children under 12 years	Ask a doctor

Other Information

Store at 20-25 °C (66-77 °F)

Inactive ingredients

Pregelatinized Starch, polyvinylpyrrolidone K-30, Corn starch, Stearic acid, Sodium Starch Glycolate, Mannitol, Sucralose, Low Substituted Hydroxypropyl Cellulose, light anhydrous silicic acid, Magnesium stearate, PEG 6000, Hydroxypropyl methylcellulose 6cps, Titanium dioxide, Sicopharm yellow 10, Sicopharm red 30

Questions or comments ?

X-XXX-XXX-XXXX

Package Labeling:



Extra Strength

SafeTynadol

Acetaminophen 500 mg
Pain Reliever/ Fever Reducer
For Adults

200 TABLETS



actual size

NDC XXXXX-XXX-XX

Compare to active ingredient
of Tylenol® Extra Strength

Drug Facts

Active Ingredient (In each tablet)	Purpose
Acetaminophen 500 mg	Pain reliever/fever reducer

Uses

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

Warnings

- Liver warning:** This products acetaminophen. Severe liver damage may occur if you take
- more than 4,000 mg of acetaminophen in 24 hours
 - with other drugs containing acetaminophen
 - 3 or more alcohol 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 capturing 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 this product or any of its ingredients

Ask a doctor before use if you have liver disease

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

Stop use and ask a doctor if

- pain gets worse or last more than 10 days
 - new symptoms occur
 - fever gets worse or lasts more than 3 days
 - 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 over dose, 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"> take 2 tablets every 6 hours while symptoms last do not take more than 6 tablets in 24 hours, unless directed by a doctor do not use for more than 10 days unless directed by a doctor
Children under 12 years	Ask a doctor

Other Information ■ store at 20-25 °C (66-77 °F)

Inactive ingredients Pregelatinized Starch, polyvinylpyrrolidone K-30, Corn starch, Stearic acid, Sodium Starch Glycolate, Mannitol, Sucralose, Low Substituted Hydroxypropyl Cellulose, light anhydrous silicic acid, Magnesium stearate, PEG 6000, Hydroxypropyl methylcellulose 6cps, Titanium dioxide, Sicopharm yellow 10, Sicopharm red 30

Questions or comments ? X-XXX-XXX-XXXX

This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Extra Strength Tylenol® Tablets.

DISTRIBUTED BY:
SINEW PHARMA INC.
ADDRESS XXX
© 2020 SINEW PHARMA INC.
OR IT S AFFILIATES.
ALL RIGHT RESERVED.

SAFETYADOL

acetaminophen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81389-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
MANNITOL (UNII: 3OWL53L36A)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 2165RE0K14)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	yellow	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81389-001-01	200 in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	01/21/2021	

Labeler - Sinew Pharma Inc. (656182232)

Revised: 10/2023

Sinew Pharma Inc.