

22 M/77

NOVARTIS

Drug Facts

Active ingredients (in each tablet):

Purpose:

Warnings:

Directions:

Other information:

Questions:

Drug Facts (continued)

Other information:

Inactive ingredients:

Questions:

TAVIST

ALLERGY/SINUS/HEADACHE

Antihistamine / Nasal Decongestant / Pain Reliever / Fever Reducer

TAVIST **New!**

Contains fexofenadine HCl 120 mg, pseudoephedrine HCl 30 mg, and acetaminophen 500 mg.



24 CAPLETS*
*caplet-shaped tablet

ALLERGY/SINUS/HEADACHE

- Sinus congestion / pressure
- Runny nose & sneezing
- Headache
- Fever

Drug Facts (continued)

Directions:

Warnings:

Other information:

Questions:

Drug Facts (continued)

Warnings:

Directions:

Other information:

Questions:



Drug Facts (continued)

Warnings: Do not use if you are allergic to any of the ingredients. Do not use if you are taking other medications that contain pseudoephedrine. Do not use if you are taking other medications that contain phenylephrine. Do not use if you are taking other medications that contain oxymetazoline. Do not use if you are taking other medications that contain xylometazoline. Do not use if you are taking other medications that contain ipratropium bromide. Do not use if you are taking other medications that contain guaifenesin. Do not use if you are taking other medications that contain dextromethorphan. Do not use if you are taking other medications that contain acetaminophen. Do not use if you are taking other medications that contain aspirin. Do not use if you are taking other medications that contain ibuprofen. Do not use if you are taking other medications that contain naproxen. Do not use if you are taking other medications that contain celecoxib. Do not use if you are taking other medications that contain rofecoxib. Do not use if you are taking other medications that contain valdecoxib. Do not use if you are taking other medications that contain etoricoxib. Do not use if you are taking other medications that contain meloxicam. Do not use if you are taking other medications that contain celecoxib. Do not use if you are taking other medications that contain rofecoxib. Do not use if you are taking other medications that contain valdecoxib. Do not use if you are taking other medications that contain etoricoxib. Do not use if you are taking other medications that contain meloxicam.

Directions: See important information about directions for use on each caplet.

Other information: See important information about other information on each caplet.

Contains: See important information about contents on each caplet.

Keep out of reach of children.

Use only as directed.

See the back of the caplet for more information.

Antihistamine / Nasal Decongestant / Pain Reliever / Fever Reducer

TAVIST

Contains: pseudoephedrine, diphenhydramine, acetaminophen, and aspirin.

ALLERGY/SINUS/HEADACHE

48 CAPLETS*

Contains Pseudoephedrine. This is a prescription drug. It may be habit forming. Do not use if you are taking other medications that contain pseudoephedrine. Do not use if you are taking other medications that contain phenylephrine. Do not use if you are taking other medications that contain oxymetazoline. Do not use if you are taking other medications that contain xylometazoline. Do not use if you are taking other medications that contain ipratropium bromide. Do not use if you are taking other medications that contain guaifenesin. Do not use if you are taking other medications that contain dextromethorphan. Do not use if you are taking other medications that contain acetaminophen. Do not use if you are taking other medications that contain aspirin. Do not use if you are taking other medications that contain ibuprofen. Do not use if you are taking other medications that contain naproxen. Do not use if you are taking other medications that contain celecoxib. Do not use if you are taking other medications that contain rofecoxib. Do not use if you are taking other medications that contain valdecoxib. Do not use if you are taking other medications that contain etoricoxib. Do not use if you are taking other medications that contain meloxicam.

Antihistamine / Nasal Decongestant / Pain Reliever / Fever Reducer

TAVIST

Contains: pseudoephedrine, diphenhydramine, acetaminophen, and aspirin.

ALLERGY/SINUS/HEADACHE



48 CAPLETS*
tablet-shaped pill

- Relieves nasal congestion
- Relieves sneezing
- Relieves itching
- Relieves watery eyes
- Relieves pain
- Reduces fever

Drug Facts (continued)

Warnings: Do not use if you are allergic to any of the ingredients. Do not use if you are taking other medications that contain pseudoephedrine. Do not use if you are taking other medications that contain phenylephrine. Do not use if you are taking other medications that contain oxymetazoline. Do not use if you are taking other medications that contain xylometazoline. Do not use if you are taking other medications that contain ipratropium bromide. Do not use if you are taking other medications that contain guaifenesin. Do not use if you are taking other medications that contain dextromethorphan. Do not use if you are taking other medications that contain acetaminophen. Do not use if you are taking other medications that contain aspirin. Do not use if you are taking other medications that contain ibuprofen. Do not use if you are taking other medications that contain naproxen. Do not use if you are taking other medications that contain celecoxib. Do not use if you are taking other medications that contain rofecoxib. Do not use if you are taking other medications that contain valdecoxib. Do not use if you are taking other medications that contain etoricoxib. Do not use if you are taking other medications that contain meloxicam.

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37.00

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37.00

Drug Facts (continued)

Other information: See important information about other information on each caplet.

Contains: See important information about contents on each caplet.

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NOVARTIS

NCH Response to FDA Approvable Letter Dated August 4, 2000
NDA 21-082 -- Clemastine Fumarate / Acetaminophen / Pseudoephedrine Hydrochloride
Tablets (cont'd)

BLISTER PACK

Tavist Allergy/Sinus/Headache
(clemastine fumarate 0.335 mg (equivalent to 0.25 mg clemastine), pseudoephedrine HCl 30 mg,
and acetaminophen 500 mg tablets)
antihistamine/nasal decongestant/pain reliever/fever reducer

Manufacturer: Novartis Consumer Health, Inc.
Summit, NJ 07901-1313

Lot Number XXXXX
Exp. Date XXXXX

NCH Response:

*We agree with FDA's recommended wording and have also added
'© 2000' under Novartis (logo).*