

FEDRIN- acetaminophen, phenylephrine tablet
Afasco Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredients (In Each Tablet)

Acetaminophen 500 mg, Phenylephrine HCl 5 mg

Pain reliever/fever reducer, Nasal decongestant

Uses:

For temporary relief of nasal congestion associated with sinusitis.

Temporarily relieves headache and sinus pain.

Warnings:

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 8 tablets in 24 hours, if you take with other drugs containing acetaminophen (prescription or nonprescription), or if you have 3 or more alcoholic drinks every day while using this product.

Ask a doctor before use if you have: heart disease, high blood pressure, thyroid disease, diabetes, trouble urinating due to an enlarged prostate gland, cough that occurs with too much phlegm (mucus), chronic cough that lasts such as occurs with smoking, asthma, or emphysema or chronic bronchitis.

Stop use and ask a doctor if: you get nervous, dizzy or sleepless, cough lasts more than 7 days, comes back or occurs with fever, rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health care professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. 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 use more than directed.

Adults and children: (12 years and older) Take 2 tablets with water every 6 hours as needed. Do not take more than 8 tablets in 24 hours, or as directed by doctor.

Children: (under 12 years)

Do use unless directed by a doctor.

SEE ORIGINAL BOX FOR COMPLETE PRODUCT INFORMATION



Made in USA

2 Tablets

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Acetaminophen 500 mgPain reliever/fever reducer
Phenylephrine HCl 5 mgNasal decongestant

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Ask a doctor before use if you have: heart disease, high blood pressure, thyroid

Questions? Contact Afassco Minden, NV 89423
Store at room temperature
Tamper evident: Do not use packet if torn or cut.
Manufactured for Afassco Inc. Minden, NV 89423

Warnings (continued)

disease, diabetes, trouble urinating due to an enlarged prostate gland, cough that occurs with too much phlegm (mucus), chronic cough that lasts such as occurs with smoking, asthma, or emphysema or chronic bronchitis. Stop use and ask a doctor if: you get nervous, dizzy or sleepless, cough lasts more than 7 days, comes back or occurs with fever, rash or headache that lasts. These could be signs of a serious condition. If pregnant or breast-feeding, ask a health care professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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Table with product details for FEDRIN, including Product Information, Active Ingredient/Active Moiety, and Inactive Ingredients.

SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

Product Characteristics

Color	blue	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	FR33
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51532-0140-2	2 in 1 PACKET; Type 0: Not a Combination Product	10/25/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/25/2016	

Labeler - Afassco Inc. (609982723)

Revised: 12/2019

Afassco Inc.