

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-470

LABELING

1.7361

3.4722

See new warnings information

DO NOT USE IF SEALED PACKET IS OPEN, TORN OR BROKEN. NDC 0000-0000-00

NEXCEDE™

Ketoprofen 12.5 mg (NSAID)
Pain Reliever • Fever Reducer

Thin Film



Peppermint FLAVORED

INDIVIDUALLY PACKED ORAL SOLUBLE FILM

SEE STOMACH BLEEDING WARNING ON OTHER SIDE

TO OPEN, FOLD ALONG DOTTED LINE AND TEAR AT SLIT. PEEL BACK FOIL TO EXPOSE PRODUCT.

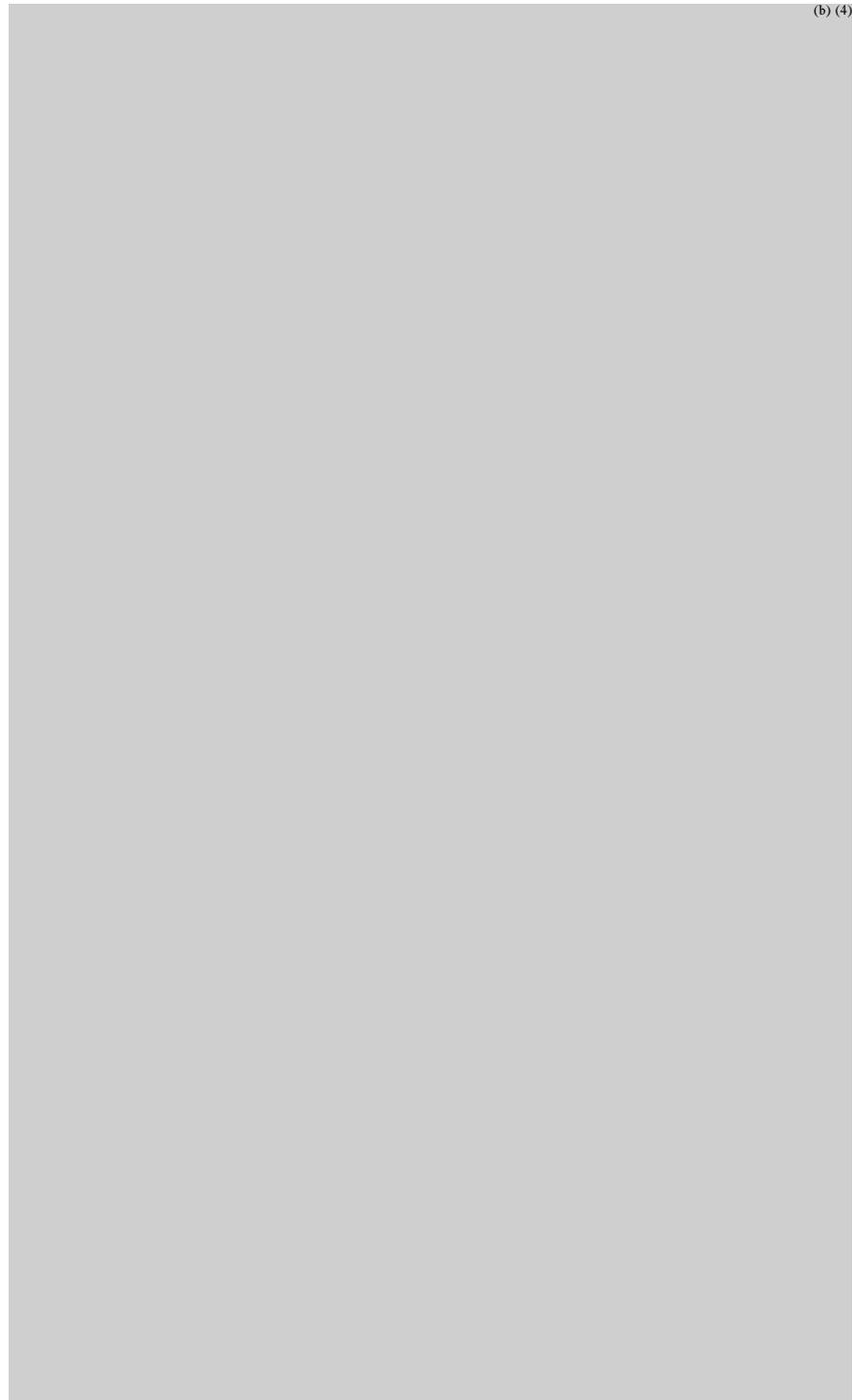
Stomach bleeding warning: This product contains an (NSAID), which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing a prescription or nonprescription NSAID (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

THIS PACKET DOES NOT CONTAIN FULL PRODUCT INFORMATION. SEE CARTON FOR COMPLETE LABELING INFORMATION. READ ALL WARNINGS AND DIRECTIONS ON CARTON BEFORE USE. DO NOT DISCARD CARTON.

LOT
EXP

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1.7361

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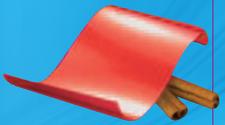
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Ketoprofen 12.5 mg (NSAID)
Pain Reliever • Fever Reducer

Thin Film



Cinnamon FLAVORED

INDIVIDUALLY PACKED ORAL SOLUBLE FILM

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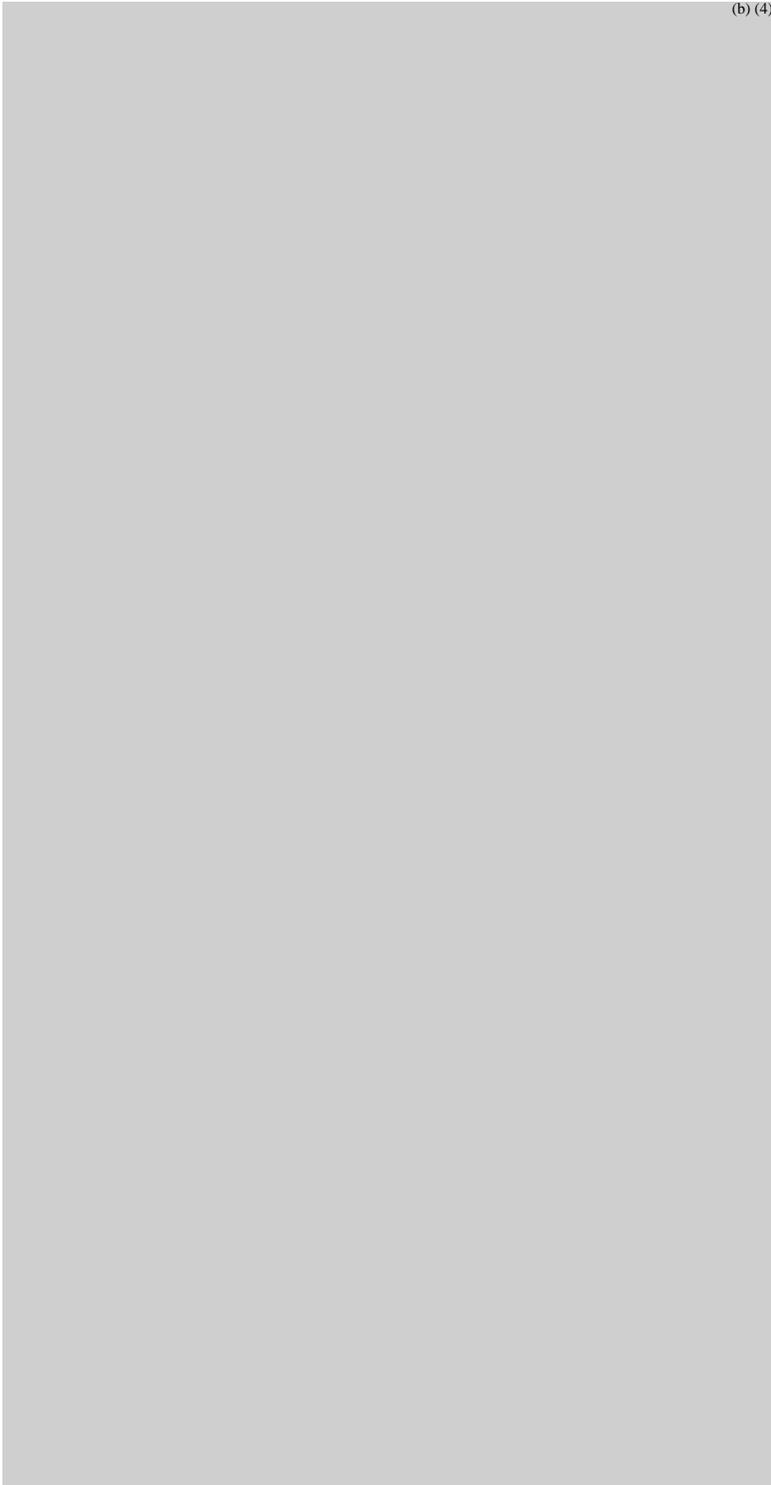
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NEXCEDE™

Ketoprofen 12.5 mg (NSAID)
Pain Reliever • Fever Reducer

Thin Film

**Peppermint
FLAVORED**

40 INDIVIDUALLY PACKED
ORAL SOLUBLE FILMS

F.P.O.

THIS CARTON CONTAINS TAMPER-EVIDENT PACKETS:
DO NOT USE IF SEALED PACKETS ARE OPEN, TORN OR BROKEN.

NEXCEDE™

Ketoprofen 12.5 mg (NSAID)
Pain Reliever • Fever Reducer

Thin Film

**Peppermint
FLAVORED**

40 INDIVIDUALLY PACKED
ORAL SOLUBLE FILMS

Drug Facts

Active ingredient (in each film)	Purpose
Ketoprofen 12.5 mg (NSAID)*	Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug	

Uses

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

Drug Facts (continued)

Warnings

Allergy alert: Ketoprofen 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 a prescription or nonprescription NSAID (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

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

- stomach bleeding warning applies to you

- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, or asthma
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug
- under a doctor's care for any serious condition
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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)

- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 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 ketoprofen during the last 3 months of 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.

Directions

- do not take more than directed
- the smallest effective dose should be used
- if taken with food, this product may take longer to work
- adults and children 16 years and over:
 - allow 1 film to dissolve on tongue every 4 to 6 hours while symptoms persist
 - if pain or fever does not get better in 1 hour, you may take 1 more film. With experience, some people may find they need 2 films for the first dose.
- do not take more than:
 - 2 films in any 4 to 6 hour period
 - 6 films in any 24 hour period
- children under 16 years: ask a doctor

Other information

- store at controlled room temperature 20 - 25° C (68 - 77° F)
- read all product information before using. Keep this box for important information.

Inactive ingredients acesulfame potassium, acetone, dibasic sodium phosphate, FD&C blue #1, flavors, hydroxypropyl methylcellulose, polyethylene glycol 400, purified water, sodium hydroxide, sucralose, titanium dioxide, xylitol

Questions or comments? 1-800-468-7746

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NEXCEDE™

Ketoprofen 12.5 mg (NSAID)
Pain Reliever • Fever Reducer

Thin Film



40 INDIVIDUALLY PACKED
ORAL SOLUBLE FILMS

F.P.O.

THIS CARTON CONTAINS TAMPER-EVIDENT PACKETS:
DO NOT USE IF SEALED PACKETS ARE OPEN, TORN OR BROKEN.

NEXCEDE™

Ketoprofen 12.5 mg (NSAID)
Pain Reliever • Fever Reducer

Thin Film



40 INDIVIDUALLY PACKED
ORAL SOLUBLE FILMS

**Cinnamon
FLAVORED**

Drug Facts

Active ingredient (in each film)	Purpose
Ketoprofen 12.5 mg (NSAID)*	Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug	

Uses

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

Drug Facts (continued)

Warnings

Allergy alert: Ketoprofen 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 a prescription or nonprescription NSAID (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

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

- stomach bleeding warning applies to you

- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, or asthma
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug
- under a doctor's care for any serious condition
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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

LOT
EXP



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NEXCEDE™

Drug Facts (continued)

- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 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 ketoprofen during the last 3 months of 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.

Directions

- do not take more than directed
- the smallest effective dose should be used
- if taken with food, this product may take longer to work
- adults and children 16 years and over:
 - allow 1 film to dissolve on tongue every 4 to 6 hours while symptoms persist
 - if pain or fever does not get better in 1 hour, you may take 1 more film. With experience, some people may find they need 2 films for the first dose.
- do not take more than:
 - 2 films in any 4 to 6 hour period
 - 6 films in any 24 hour period
- children under 16 years: ask a doctor

Other information

- store at controlled room temperature 20 - 25° C (68 - 77° F)
- read all product information before using. Keep this box for important information.

Inactive ingredients acesulfame potassium, acetone, dibasic sodium phosphate, FD&C red #40, flavors, hypromellose, maltodextrin, polyethylene glycol 400, purified water, sodium hydroxide, sucralose, titanium dioxide, xylitol

Questions or comments? 1-800-468-7746

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NEXCEDE™

Ketoprofen 12.5 mg (NSAID)

Pain Reliever • Fever Reducer



Peppermint
FLAVORED

20 INDIVIDUALLY PACKED
ORAL SOLUBLE FILMS

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THIS CARTON CONTAINS TAMPER-EVIDENT PACKETS.
DO NOT USE IF SEALED PACKETS ARE OPEN, TORN OR BROKEN.

Drug Facts (continued)

Warnings
Ketoprofen 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

Active ingredient (in each film)
Ketoprofen 12.5 mg (NSAID)
Purpose
Pain reliever/fever reducer
Uses
Temporarily relieves minor aches and pains due to:
• headache • the common cold • toothache • muscular aches
• backache • menstrual cramps • minor pain of arthritis
Temporarily reduces fever

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 a prescription or nonprescription NSAID (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

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 • stomach bleeding warning applies to you • you have problems or serious side effects from taking pain relievers or fever reducers • you have a history of stomach problems, such as heartburn • you have high blood pressure, heart disease, liver cirrhosis, kidney disease, or asthma • you are taking a diuretic

Ask a doctor or pharmacist before use if you are • taking any other drug containing an NSAID (prescription or nonprescription) • taking a blood thinning (anticoagulant) or steroid drug • under a doctor's care for any serious condition • taking any other drug

When using this product • take with food or milk if stomach upset occurs • the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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 • pain gets worse or lasts for more than 10 days • fever gets worse or lasts for more than 3 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 ketoprofen during the last 3 months of 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.

Directions • do not take more than directed • the smallest effective dose should be used • If taken with food, this product may take longer to work • adults and children 16 years and over:
• allow 1 film to dissolve on tongue every 4 to 6 hours while symptoms persist
• if pain or fever does not get better in 1 hour, you may take 1 more film. With experience, some people may find they need 2 films for the first dose.
• do not take more than:
• 2 films in any 4 to 6 hour period • 6 films in any 24 hour period
• children under 16 years: ask a doctor

Drug Facts (continued)

Other information • store at controlled room temperature 20° - 25° C (68° - 77° F) • read all product information before using. Keep this box for important information.

Inactive ingredients acetaminophen, acetone, dibasic sodium phosphate, FD&C blue #1, flavors, hydrocodone, hydrocodone, polyethylene glycol 400, purified water, sodium hydroxide, sucralose, titanium dioxide, xylitol

Questions or comments? 1-800-468-7746



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See new warnings information NDC 0000-0000-00

NEXCEDE™

Ketoprofen 12.5 mg (NSAID)

Pain Reliever • Fever Reducer



Peppermint
FLAVORED

10 INDIVIDUALLY PACKED
ORAL SOLUBLE FILMS

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Drug Facts (continued)

Warnings
Allergy alert: Ketoprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
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• shock • skin reddening • rash • blisters
If an allergic reaction occurs, stop use and seek medical help right away.

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

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 a prescription or nonprescription NSAID (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

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 • stomach bleeding warning applies to you • you have problems or serious side effects from taking pain relievers or fever reducers • you have a history of stomach problems, such as heartburn • you have high blood pressure, heart disease, liver cirrhosis, kidney disease, or asthma • you are taking a diuretic

Ask a doctor or pharmacist before use if you are • taking any other drug containing an NSAID (prescription or nonprescription) • taking a blood thinning (anticoagulant) or steroid drug • under a doctor's care for any serious condition • taking any other drug

When using this product • take with food or milk if stomach upset occurs • the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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 • pain gets worse or lasts for more than 10 days • fever gets worse or lasts for more than 3 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 ketoprofen during the last 3 months of 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.

Directions • do not take more than directed • the smallest effective dose should be used • If taken with food, this product may take longer to work • adults and children 16 years and over:
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Drug Facts (continued)

Other information • store at controlled room temperature 20° - 25° C (68° - 77° F) • read all product information before using. Keep this box for important information.

Inactive ingredients acetaminophen, acetone, dibasic sodium phosphate, FD&C blue #1, flavors, hydroxyethylcellulose, hydroxypropylmethylcellulose, polyethylene glycol 400, purified water, sodium hydroxide, sucralose, titanium dioxide, xylitol

Questions or comments? 1-800-468-7746



LOT
EXP

F.P.O.

See new warnings information NDC 0000-0000-00

NEXCEDE™

Ketoprofen 12.5 mg (NSAID)

Pain Reliever • Fever Reducer

Thin Film



Cinnamon
FLAVORED

10 INDIVIDUALLY PACKED
ORAL SOLUBLE FILMS

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Drug Facts (continued)

Warnings
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Drug Facts (continued)

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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 • stomach bleeding warning applies to you • you have problems or serious side effects from taking pain relievers or fever reducers • you have a history of stomach problems, such as heartburn • you have high blood pressure, heart disease, liver cirrhosis, kidney disease, or asthma • you are taking a diuretic

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When using this product • take with food or milk if stomach upset occurs • the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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 • pain gets worse or lasts for more than 10 days • fever gets worse or lasts for more than 3 days • redness or swelling is present in the painful area • any new symptoms appear

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Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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Drug Facts (continued)

Other information • store at controlled room temperature 20° - 25° C (68° - 77° F) • read all product information before using. Keep this box for important information.

Inactive ingredients acetaminophen, acetone, dibasic sodium phosphate, FD&C Red #40, folic acid, hydroxyethylcellulose, hydroxypropylmethylcellulose, polyethylene glycol 400, purified water, sodium hydroxide, sucrose, titanium dioxide, xylitol

Questions or comments? 1-800-468-7746



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