ADVIL SINUS CONGESTION AND PAIN- ibuprofen, phenylephrine hydrochloride tablet, coated
Select Corporation

Advil® Sinus Congestion & Pain

Drug Facts

Active ingredients (in each tablet)	Purposes
Ibuprofen 200 mg (NSAID)*	Pain reliever/fever reducer
Phenylephrine HCl 10 mg	Nasal decongestant

* nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves these symptoms associated with the common cold or flu:
  - headache
  - fever
  - sinus pressure
  - nasal congestion
  - minor body aches and pains
- reduces swelling of the nasal passages
- temporarily restores freer breathing through the nose

Warnings

Allergy alert

Ibuprofen 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
- in children under 12 years of age because this product contains too much medication for children under this age
- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

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, asthma, thyroid disease, diabetes, have trouble urinating due to an enlarged prostate gland, or had a stroke
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are
- under a doctor's care for any serious condition
- taking any other product that contains phenylephrine or any other nasal decongestant
- taking aspirin for heart attack or stroke, because ibuprofen 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 7 days
- fever gets worse or lasts more than 3 days
- nasal congestion lasts for more than 7 days
- symptoms continue or get worse
- redness or swelling is present in the painful area
- you get nervous, dizzy, or sleepless
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen 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
- adults and children 12 years of age and over:
    - take 1 tablet every 4 hours while symptoms persist.
    - do not use more than 6 tablets in any 24-hour period unless directed by a doctor
- children under 12 years of age: do not use because this product contains too much medication for children under this age

Other information

- store at 20-25°C (68-77°F). Avoid excessive heat above 40°C (104°F).
- read all warnings and directions before use. Keep card.

Inactive ingredients

acesulfame potassium, artificial flavor, carnauba wax, colloidal silicon dioxide, corn starch, croscarmellose sodium, glycerin, hypromellose, lactic acid, lecithin, maltodextrin, medium-chain triglycerides, microcrystalline cellulose, pharmaceutical ink, polydextrose, polyvinyl alcohol, pregelatinized starch, propyl gallate, sodium lauryl sulfate, stearic acid, sucralose, synthetic iron oxide, talc, titanium dioxide, triacetin, xanthan gum

Questions or comments?

Call weekdays from 9 AM to 5 PM EST toll free at 1-800-88-ADVIL

Product Repackaged and Distributed
with permission of Pfizer Consumer Healthcare by:
Select Corporation Carrollton, TX 75007

PRINCIPAL DISPLAY PANEL - 1 Tablet Pouch Blister Pack

NON-DROWSY

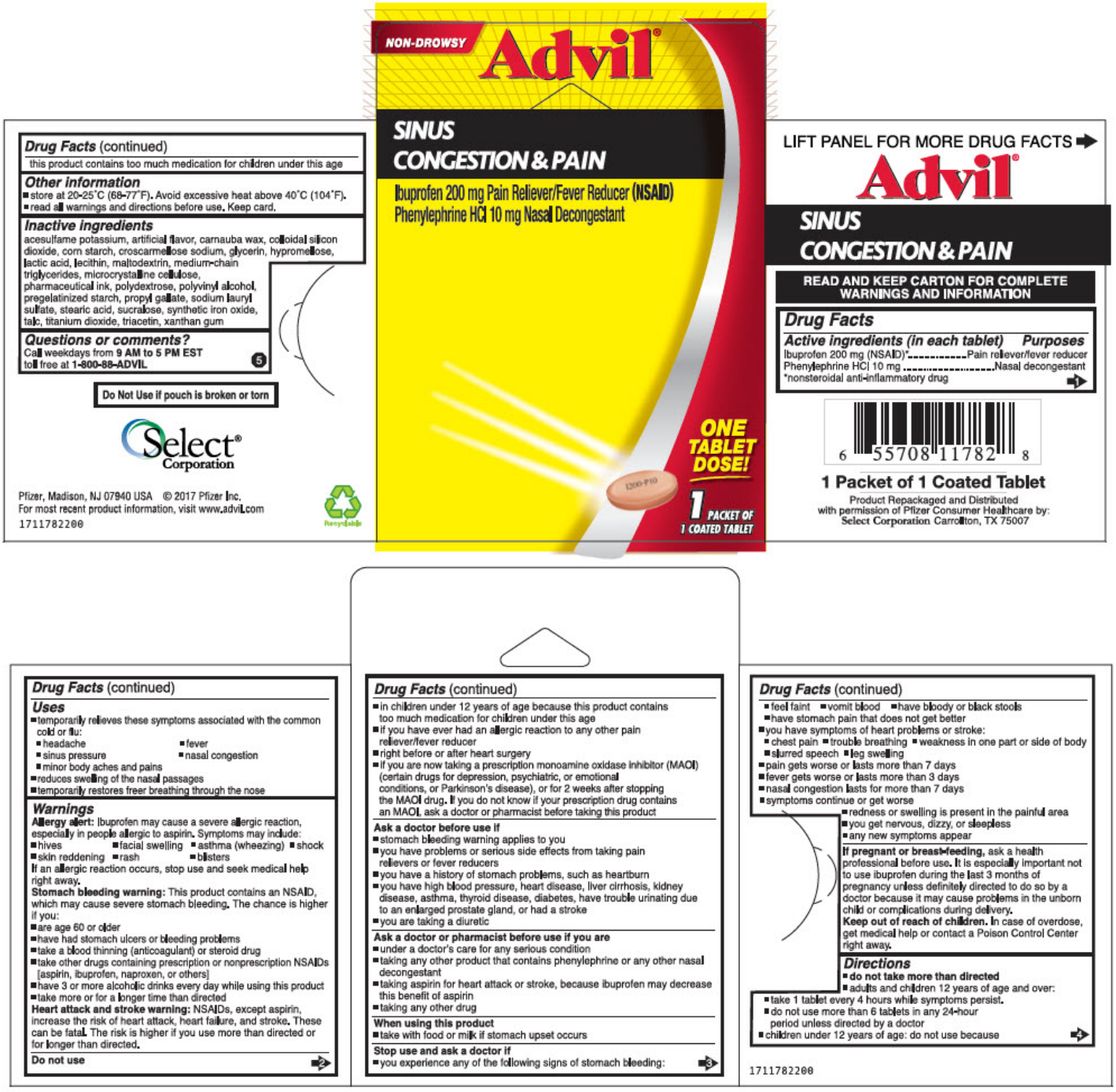
Advil®

SINUS
CONGESTION & PAIN

Ibuprofen 200 mg Pain Reliever/Fever Reducer (NSAID)
Phenlephrine HCl 10 mg Nasal Decongestant

ONE
TALBET
DOSE!

1 PACKET OF
1 COATED TABLET



ADVIL SINUS CONGESTION AND PAIN

ibuprofen, phenylephrine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52904-782(NDC:0573-0199)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Ibuprofen (UNII: WK2XYI10QM) (ibuprofen - UNII:WK2XYI10QM)	Ibuprofen	200 mg

PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
acesulfame potassium (UNII: 23OV73Q5G9)	
carnauba wax (UNII: R12CBM0EIZ)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
croscarmellose sodium (UNII: M28OL1HH48)	
glycerin (UNII: PDC6A3C0OX)	
hypromellose, unspecified (UNII: 3NXW29V3WO)	
lactic acid, unspecified form (UNII: 33X04XA5AT)	
egg phospholipids (UNII: 1Z74184RGV)	
maltodextrin (UNII: 7CVR7L4A2D)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
microcrystalline cellulose (UNII: OP1R32D61U)	
polydextrose (UNII: VH2XOU12IE)	
polyvinyl alcohol, unspecified (UNII: 532B59J990)	
propyl gallate (UNII: 8D4SNN7V92)	
sodium lauryl sulfate (UNII: 368GB5141J)	
stearic acid (UNII: 4ELV7Z65AP)	
sucralose (UNII: 96K6UQ3ZD4)	
ferric oxide red (UNII: 1K09F3G675)	
talc (UNII: 7SEV7J4R1U)	
titanium dioxide (UNII: 15FIX9V2JP)	
triacetin (UNII: XHX3C3X673)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	BROWN	**Score**	no score
Shape	OVAL	**Size**	15mm
Flavor		**Imprint Code**	1200;P10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52904-782-03	1 in 1 BLISTER PACK	07/01/2015	
1		1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:52904-782-04	2 in 1 BLISTER PACK	07/01/2015	
2		1 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:52904-782-25	25 in 1 CARTON	07/01/2015	

3		1 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:52904-782-50	50 in 1 CARTON	07/01/2015	
4		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022565	07/01/2015	

Labeler - Select Corporation (053805599)

Revised: 4/2022 Select Corporation