**SUDAFED PE SINUS CONGESTION- phenylephrine hydrochloride tablet, film coated**
**Johnson & Johnson Consumer 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.*

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**Sudafed PE Sinus Congestion**

***Drug Facts***

**Active ingredient (in each tablet)**

Phenylephrine HCl 10 mg

**Purpose**

Nasal decongestant

**Uses**

- temporarily relieves sinus congestion and pressure
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies

**Warnings**

**Do not use** 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 you have**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

**When using this product do not exceed recommended dose**

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with a fever

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

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

## Directions

| | |
|---|---|
| adults and children 12 years and over | ▪ take 1 tablet every 4 hours<br>▪ do not take more than 6 tablets in 24 hours |
| children under 12 years | ask a doctor |

## Other information

- store between 20-25°C (68-77°F)
- **do not use if blister unit is torn or broken**

## Inactive ingredients

carnauba wax, D&C yellow no. 10 aluminum lake, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, microcrystalline cellulose, modified starch, polyethylene glycol, polyvinyl alcohol, powdered cellulose, pregelatinized starch, sodium starch glycolate, talc, titanium dioxide

## Questions or comments?

call **1-888-217-2117** (toll-free) or **215-273-8755** (collect)

## PRINCIPAL DISPLAY PANEL

PREVIOUSLY SUDAFED PE ® CONGESTION
NDC 50580-437-02

SUDAFED PE®

SINUS
CONGESTION

Phenylephrine HCl, Nasal Decongestant

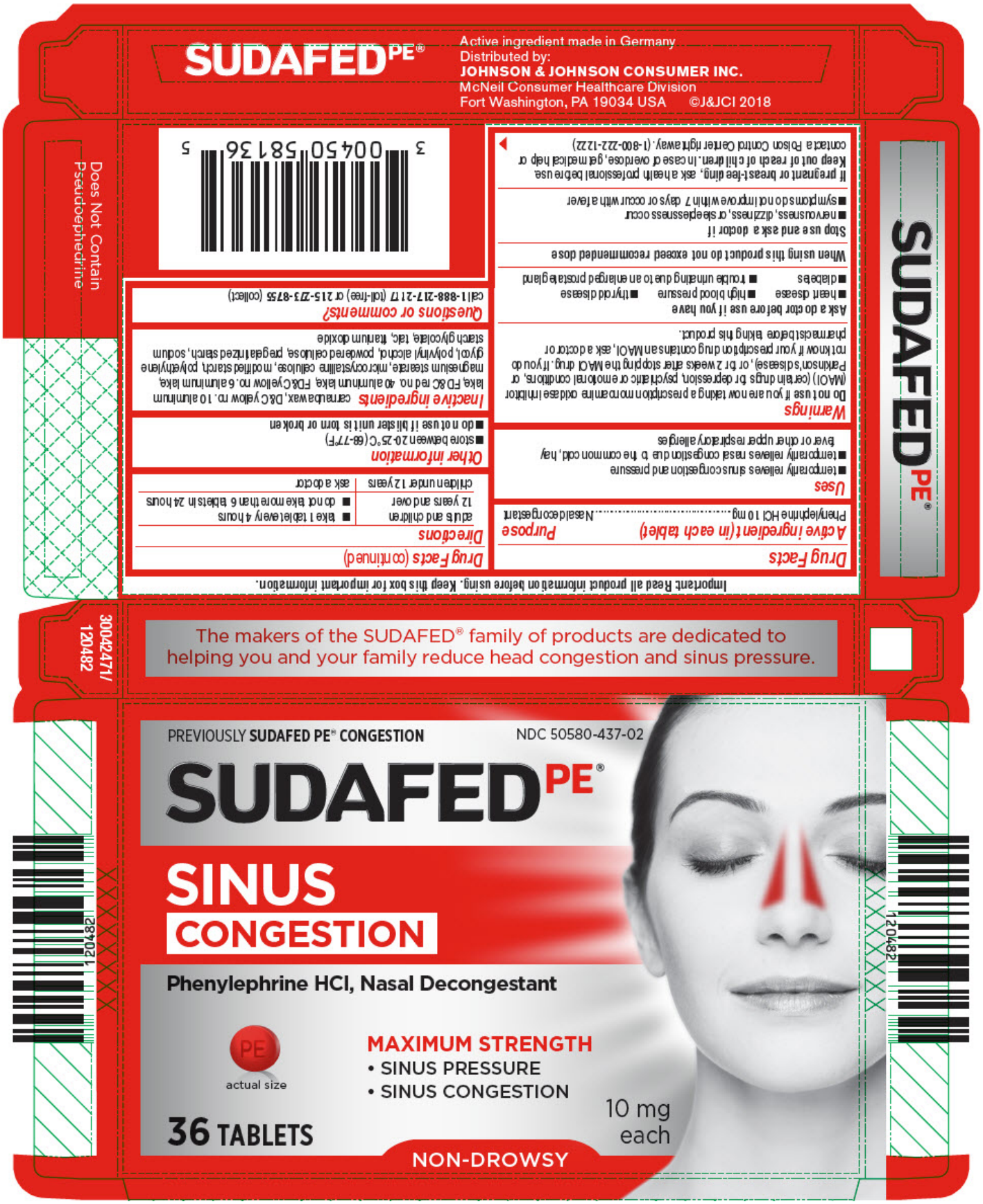
actual size

MAXIMUM STRENGTH
- SINUS PRESSURE
- SINUS CONGESTION

36 TABLETS

NON-DROWSY

10 mg
each


SUDAFED PE®
Active ingredient made in Germany
Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA ©J&JCI 2018
Does Not Contain Pseudoephedrine
3 0045058136 5
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Ask a doctor before use if you have
■ heart disease ■ high blood pressure ■ thyroid disease
■ diabetes ■ trouble urinating due to an enlarged prostate gland
When using this product do not exceed recommended dose
Stop use and ask a doctor if
■ nervousness, dizziness, or sleeplessness occur
■ symptoms do not improve within 7 days or occur with a fever
If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)
Drug Facts (continued)
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adults and children 12 years and over: ■ take 1 tablet every 4 hours ■ do not take more than 6 tablets in 24 hours
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Questions or comments?
call 1-888-217-2177 (toll-free) or 215-273-8755 (collect)
Important: Read all product information before using. Keep this box for important information.
The makers of the SUDAFED® family of products are dedicated to helping you and your family reduce head congestion and sinus pressure.
30042471/
120482
PREVIOUSLY SUDAFED PE® CONGESTION
NDC 50580-437-02
SUDAFED PE®
SINUS
CONGESTION
Phenylephrine HCl, Nasal Decongestant
PE
actual size
MAXIMUM STRENGTH
• SINUS PRESSURE
• SINUS CONGESTION
36 TABLETS
10 mg
each
NON-DROWSY
120482

# SUDAFED PE SINUS CONGESTION

phenylephrine hydrochloride tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:50580-437 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 10 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **D&C YELLOW NO. 10 ALUMINUM LAKE** (UNII: CQ3XH3DET6) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POLYVINYL ALCOHOL, UNSPECIFIED** (UNII: 532B59J990) | |
| **POWDERED CELLULOSE** (UNII: SMD1X3XO9M) | |
| **SODIUM STARCH GLYCOLATE TYPE A** (UNII: H8AV0SQX4D) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | red | **Score** | no score |
| **Shape** | ROUND | **Size** | 7mm |
| **Flavor** | | **Imprint Code** | WL;80;PE |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:50580-437-01 | 1 in 1 CARTON | 06/17/2019 | |
| **1** | | 18 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **2** | NDC:50580-437-02 | 2 in 1 CARTON | 06/17/2019 | |
| **2** | | 18 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| | NDC:50580 | | | |

| | | | | |
|---|---|---|---|---|
| **3** | NDC:50580-437-03 | 3 in 1 PACKAGE | 09/03/2019 | |
| **3** | | 2 in 1 CARTON | | |
| **3** | | 18 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part341 | 06/17/2019 | |

## Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 3/2023 Johnson & Johnson Consumer Inc.