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SUDAFED[®]

DECONGESTANT TABLETS

Pseudoephedrine hydrochloride

- This medicine is used to help clear cold, flu and allergy symptoms such as blocked sinuses, stuffy nose and catarrh.
- This medicine is for use by adults and children aged 12 years and over.
- **Do not take this medicine:**
 - There are some people who should not take this medicine. To find out if you are one of them see section 2 ▶
 - If you have ever had a **bad reaction** to any of the ingredients. For the list of ingredients see section 6 ▶
- **Speak to your doctor:**
 - If you suffer from any of the conditions mentioned in section 2. See section 2 ▶
 - If you are taking any **other medicines**. See section 2 ▶
- **Follow the dosage instructions carefully.** See section 3 ▶

Now read this whole leaflet carefully before you use this medicine. Keep the leaflet: you might need it again.

1 What the medicine is for

Sudafed Decongestant Tablets is a medicine used to provide relief from cold, flu and allergy symptoms such as blocked sinuses, stuffy nose and catarrh. The tablets contain pseudoephedrine hydrochloride, which is a decongestant that relieves nasal and sinus congestion. This medicine is for use by adults and children aged 12 years and over.

2 Before taking this medicine

This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

⊗ Do not use this medicine...

- If you have ever had a **bad reaction** (e.g. rash, swelling of the face and throat, difficulty breathing) to any of the ingredients.
- If you have **very high blood pressure** or **severe heart disease**.
- If you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs).

If any of these apply to you, **get advice from a doctor or pharmacist without using Sudafed Decongestant Tablets.**

⚠ Talk to your doctor or pharmacist...

- If you have **liver** or **kidney problems**.
- If you have **high blood pressure** or **heart disease**.
- If you have **diabetes** or have been diagnosed with an **intolerance to some sugars**.
- If you have an **overactive thyroid gland**.
- If you have **glaucoma** (increased pressure in the eye).
- If you have **prostate problems** (difficulty with passing water or needing to pass water often).
- If you are taking any **other medicines**, including:
 - **Antihypertensives** (drugs used to treat **high blood pressure**, such as guanethidine, methyldopa, alpha and beta blockers, debrisoquine, bretylium and betanidine).
 - **Sympathomimetic drugs** (stimulants or appetite suppressants and drugs used to treat **congestion** and **asthma**).
 - **Tricyclic antidepressants** (used to treat **mood disorders**).

If you are not sure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

If any of these bullet points apply to you now or in the past, **talk to a doctor or pharmacist.**

⚠ If you are pregnant or breast-feeding:

- Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breast-feeding.

turn over ▶

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spot = 12 x 2 centered in the margin of 14 mm
Distance between cutted line/middel of the spot = 83.6 mm

Barcodes placed at 14 mm
Height for bars : 10 mm

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reading way →

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⚠ Some of the ingredients can cause problems

- This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3 How to take this medicine

Check the table that follows to see how much medicine to take.

- For oral use only.
- Do not take more than the stated dose shown.
- Take with a glass of water.

i Children under 12 years old
Do not give to children under 12 years old.

i Adults and children aged 12 years and over

Age	Dose
Adults and children aged 12 years and over	Swallow 1 tablet every 4 - 6 hours up to 4 times a day

- Leave at least 4 hours between doses.
- Do not take more than 4 tablets in 24 hours.
- If symptoms persist talk to your doctor.

⚠ If anyone has too much
If anyone has too much contact a doctor or your nearest Accident & Emergency Department (Casualty) taking this leaflet and pack with you

⚠ If you forget to take the medicine
If you forget to take a dose, take the next dose when needed provided that the last dose was taken at least 4 hours ago. **Do not** take a double dose.

4 Possible side-effects

Sudafed Decongestant Tablets can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

If anyone experiences any of the following, stop using this medicine and talk to your doctor:

- A few people have had hallucinations, but this is rare..
- Occasionally people get skin rashes that are sometimes itchy.
- A few men, especially men with prostate problems, may have trouble passing water.

Other effects which may occur include:

- Restlessness, having trouble getting to sleep or bad dreams.

If you experience any side-effects not included in this leaflet or are not sure about anything, **talk to your doctor or pharmacist.**

5 Storing this medicine

Store below 30°C in the original package to protect from moisture. Keep the product out of the reach and sight of children.

Do not use after the end of the month shown as an expiry date on the packaging. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What's in this medicine?
The active ingredient in Sudafed Decongestant Tablets is: Pseudoephedrine hydrochloride 60 mg per tablet.

Other ingredients are: Lactose, microcrystalline cellulose, maize starch, silica, magnesium stearate, hypromellose, polyethylene glycol, talc and red iron oxide (E172).

What the medicine looks like
Sudafed Decongestant Tablets are reddish brown film-coated tablets, available in packs of 12 tablets.

Product Licence holder: McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.
Manufacturer: Janssen-Cilag, Domaine de Maigremont, 27100 Val de Reuil, France.
This leaflet was revised July 2012.
Sudafed is a registered trade mark.

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COLOURS:	
Job Bag No. 12-0087	<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="background-color: black; color: white; padding: 5px;">BLACK</div> <div style="background-color: #0000FF; color: white; padding: 5px;">PMS 300</div> <div style="background-color: #808080; color: white; padding: 5px;">PROFILE</div> </div>
Version 1	
Product Sudafed Decongestant	
Description Pil	
Country UK	
Date 10/07/12	
SIZE:	
145 x 210 mm	Main body text (PIL's only) 7.5 pts

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SUDAFED[®]

DECONGESTANT

Tablets

Pseudoephedrine hydrochloride

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 - This medicine is for use by adults and children aged 12 years and over.
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 - If you have ever had a **bad reaction** to any of the ingredients. *For the list of ingredients see section 6* ▶
 - **Speak to your doctor:**
 - If you suffer from any of the conditions mentioned in section 2. *See section 2* ▶
 - If you are taking any **other medicines**. *See section 2* ▶
 - **Follow the dosage instructions carefully.** *See section 3* ▶
- Now read this whole leaflet carefully before you use this medicine.** Keep the leaflet: you might need it again.

1 What the medicine is for

Sudafed Decongestant Tablets is a medicine used to provide relief from cold, flu and allergy symptoms such as blocked sinuses, stuffy nose and catarrh. The tablets contain pseudoephedrine hydrochloride, which is a decongestant that relieves nasal and sinus congestion. This medicine is for use by adults and children aged 12 years and over.

2 Before taking this medicine

This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

X Do not use this medicine...

- If you have ever had a **bad reaction** (e.g. rash, swelling of the face and throat, difficulty breathing) to any of the ingredients.
- If you have **very high blood pressure** or **severe heart disease**.
- If you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs).

If any of these apply to you, **get advice from a doctor or pharmacist without using Sudafed Decongestant Tablets.**

⚠ Talk to your doctor or pharmacist...

- If you have **liver or kidney problems**.
- If you have **high blood pressure** or **heart disease**.
- If you have **diabetes** or have been diagnosed with an **intolerance to some sugars**.
- If you have an **overactive thyroid gland**.
- If you have **glaucoma** (increased pressure in the eye).
- If you have **prostate problems** (difficulty with passing water or needing to pass water often).
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 - **Sympathomimetic drugs** (stimulants or appetite suppressants and drugs used to treat **congestion** and **asthma**).
 - **Tricyclic antidepressants** (used to treat **mood disorders**).

If you are not sure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

If any of these bullet points apply to you now or in the past, **talk to a doctor or pharmacist.**

⚠ If you are pregnant or breast-feeding:

- Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breast-feeding.

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Height for bars : 10 mm



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3 How to take this medicine

Check the table that follows to see how much medicine to take.

- For oral use only.
- Do not take more medicine than the label tells you to.
- Take with a glass of water.

i Children under 12 years old

Do not give to children under 12 years old.

i Adults and children aged 12 years and over

Age	Dose
Adults and children aged 12 years and over	Swallow 1 tablet every 4 - 6 hours up to 4 times a day

- Leave at least 4 hours between doses.
- Do not take more than 4 tablets in 24 hours.
- If you do not get better, talk to your doctor.

⚠ If anyone has too much

If anyone has too much contact a doctor or your nearest Accident & Emergency Department (Casualty) taking this leaflet and pack with you

⚠ If you forget to take the medicine

If you forget to take a dose, take the next dose when needed provided that the last dose was taken at least 4 hours ago. **Do not** take a double dose.

4 Possible side-effects

Sudafed Decongestant Tablets can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

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- Occasionally people get skin rashes that are sometimes itchy.
- A few men, especially men with prostate problems, may have trouble passing water.

Other effects which may occur include:

- Restlessness, having trouble getting to sleep or bad dreams.

Reporting of side-effects

If you get any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side-effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side-effects you can help provide more information on the safety of this medicine.

5 Storing this medicine

Store below 30°C in the original package to protect from moisture.

Keep the product out of the sight and reach of children.

Do not use after the end of the month shown as an expiry date on the packaging.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What's in this medicine?

The active ingredient in Sudafed Decongestant Tablets is: Pseudoephedrine hydrochloride 60 mg per tablet.

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This leaflet was revised September 2013.

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Job Bag No.	13-0065	BLACK	PMS 3005
Version	1	PROFILE	
Product	Sudafed Decongestant		
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Country	UK		
Date	27/09/2013		
Manufacturer			
Software	Illustrator CS4		
		SIZE:	Main body text (PIL's only)
		145 x 210 mm	7.5 pts

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