

SUDAFED[®]

SINUS PAIN

RELIEF

200mg/6.1mg Tablets

Ibuprofen & Phenylephrine Hydrochloride

Read this leaflet carefully because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor or pharmacist if your symptoms worsen or do not improve.

1 What this medicine is for

This medicine contains ibuprofen and phenylephrine hydrochloride. Ibuprofen belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) which work by changing how the body responds to pain, swelling and high temperature. Phenylephrine hydrochloride is a decongestant which shrinks the blood vessels in the nose and sinuses which opens the airways helping you to breathe more easily. This medicine is used to relieve the symptoms of cold and 'flu with associated congestion, including aches and pains, headache, fever, sore throat, blocked nose and sinuses.

2 Before you take the medicine

X Do not take this medicine if you:

- are allergic to ibuprofen, phenylephrine hydrochloride, to any of the ingredients (listed in section 6), or to aspirin or other painkillers (an allergic reaction may be recognised as shortness of breath, runny nose, skin rash or itching)
- have or have had a stomach ulcer, perforation or bleeding
- have kidney or heart failure or severe liver failure
- have heart problems or high blood pressure (particularly due to a tumour near the kidney)
- have diabetes
- have prostate problems
- have glaucoma (increased pressure in the eye)
- have an overactive thyroid gland
- are taking more than 75mg of aspirin a day
- are taking Monoamine Oxidase inhibitor medicines (used for depression) or have taken them within the last 14 days
- are pregnant or breast feeding.

! Warnings and precautions

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

Skin reactions

Serious skin reactions have been reported in association with Sudafed Sinus Pain Relief 200mg/6.1mg Tablets treatment. You should stop taking this medicine and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

! You should discuss your treatment with your doctor or pharmacist before taking Sudafed Sinus Pain Relief 200mg/6.1mg Tablets if you:

- are elderly because you may be at more risk of having serious side effects, particularly stomach problems
- have or have suffered from asthma or have allergies
- have liver or kidney problems

- have stomach or bowel disorders including Crohn's disease or a condition known as ulcerative colitis
- have Systemic Lupus Erythematosus (SLE) – an illness which affects your immune system. It causes joint pains, skin changes and problems with other parts of your body
- have problems with your blood circulation (including Raynaud's Phenomenon, which might appear as paleness or a blue tinge to the skin and/or pain of the fingers, toes, ears and nose in response to cold)
- have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA").
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Children and adolescents:

There is a risk of kidney problems in dehydrated children between 12 and 18 years.

! Other medicines and Sudafed Sinus Pain Relief 200mg/6.1mg Tablets

You must not take these tablets if you are taking certain other medicines - see section 2 'Do not take this medicine if'. Sudafed Sinus Pain Relief 200mg/6.1mg Tablets may affect or be affected by some other medicines. For example:

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- corticosteroids
- methotrexate (a medicine for cancer)
- cardiac glycosides (medicines used to treat heart failure)
- ciclosporin and tacrolimus (immunosuppressant medicines often used following organ transplants)
- mifepristone (a medicine used to terminate pregnancy – NSAIDs should not be used for 12 days after mifepristone)
- lithium, SSRI's or Monoamine Oxidase Inhibitors (for depression or mental problems)
- zidovudine (a medicine to treat viruses)
- quinolone antibiotics (medicines used to treat bacterial infections)
- tricyclic antidepressants (e.g. amitriptyline)
- other nasal decongestants (e.g. pseudoephedrine).

Some other medicines may also affect or be affected by the treatment of Sudafed Sinus Pain Relief 200mg/6.1mg Tablets. You should therefore always seek the advice of your doctor or pharmacist before you use Sudafed Sinus Pain Relief 200mg/6.1mg Tablets with other medicines.

! Pregnancy and Breast feeding

Do not take this medicine if you are pregnant or breast feeding. Ibuprofen belongs to a group of medicines which may affect fertility in women. Fertility goes back to normal when you stop taking the medicine. It is unlikely that if you only take this medicine occasionally it will affect your chances of becoming pregnant. If you have problems becoming pregnant talk to your doctor before taking this medicine.

Important information about some of the ingredients of this medicine.

This product contains 31.66mg sucrose per tablet.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This product contains tartrazine (E102) which may cause allergic reactions.

turn over ►

3 How to take the medicine

Age	Dose and how often to take
Adults, the elderly and children over 12 years	Take 2 tablets every 8 hours, as required. Swallow tablets with a glass of water preferably with or after food. Leave at least 4 hours between doses and do not exceed six tablets in any 24 hour period.

Do not give to children under 12 years.

- This medicine is for short-term use only.
 - Take the lowest dose for the shortest time necessary.
- In Adults:** Do not take Sudafed Sinus Pain Relief 200mg/6.1mg Tablets for longer than 10 days unless your doctor tells you to. Talk to a doctor or pharmacist if you do not get better or get worse, or if new symptoms occur.
- In Children between 12 and 18 years:** If in children between 12 and 18 years this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

If you take more Sudafed Sinus Pain Relief 200mg/6.1mg Tablets than you should:

If you have taken more tablets than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

4 Possible side effects

Most people take this medicine without any problems, but it can have side effects, like all medicines. To reduce the chance of side effects, especially if you are elderly, use the lowest effective dose for the shortest possible time.

If you get any of the following at any time during your treatment STOP TAKING, and get medical help straight away:

Allergic reactions:

The following reactions may mean you are having an allergic reaction to this medicine:

- asthma, worsening of asthma, unexplained wheezing or shortness of breath
- swelling of the face, lips, tongue and throat (causing difficulty in swallowing or breathing)
- rapid heart rate, low blood pressure, collapse
- also, there may be skin reaction (including hives, rash and itching) – very rarely these can be severe with blistering and peeling skin

Skin problems:

- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using this medicine if you develop these symptoms and seek medical attention immediately. See also section 2.

Stomach and bowel problems including:

- indigestion or heartburn
- pains in your stomach (abdomen) or other abnormal stomach problems
- pass blood in your stools or motions
- pass black tarry stools or motions
- vomit any blood or dark particles that look like coffee grounds

- worsening of bowel problems (ulcerative colitis or Crohn's disease)

Blood disorders which can cause:

- unexplained or unusual bruising or bleeding
- sore throat or mouth ulcers
- fever (high temperature)
- extreme paleness or weakness and exhaustion

Heart and circulation effects:

Ibuprofen may be associated with a small increased risk of heart attack (myocardial infarction), high blood pressure, heart failure, swelling due to fluid build-up (oedema) or stroke.

Other side effects that may occur include:

Other stomach and intestine effects including:

- diarrhoea, flatulence, constipation and vomiting.

Other heart and circulation effects including:

- fast heart rate, changes in heart rhythm, palpitations, high blood pressure.

Liver problems that might be indicated by yellowing of the skin and eyes (jaundice) and/or pale coloured stools and dark urine.

Kidney problems that might be indicated by passing less or more urine than normal, cloudy urine, blood in the urine, pain in the back and/or swelling (particularly of the legs) – very rarely kidney failure.

Nervous system problems including headache, dizziness, tinnitus and aseptic meningitis (which can have symptoms such as severe headache, stiff neck, disorientation, fever and eye sensitivity to light in those with existing auto-immune disorders such as lupus).

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 How to store this medicine

Do not use after the expiry date (EXP) shown on the pack.

Do not store above 25°C. Store in the original container.

Keep out of the sight and reach of children.

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 this medicine contains:

The active ingredients are: Ibuprofen 200mg and Phenylephrine Hydrochloride 6.1mg per coated tablet.

The other ingredients are: Calcium Hydrogen Phosphate Dihydrate, Croscarmellose Sodium, Cellulose Powdered, Talc, Simeticone, Silica Colloidal Anhydrous. The sugar coating contains: Talc, Sucrose, Povidone K90, Calcium Carbonate, Macrogol 6000, Macrogol 4000, Green Spruce Food Colourant 630004 (Containing Sodium Sulphate (E514), Tartrazine (E102) and Brilliant Blue (E133)), Titanium Dioxide, Shellac and Theobroma Oil.

What this medicine looks like and contents of the pack. The tablets are circular, green sugar coated tablets. This pack contains 16 tablets.

Marketing Authorisation Holder:

Galpharm Healthcare Ltd., Wrafton, Braunton, Devon, EX33 2DL, United Kingdom.

Manufacturer: Galpharm International Ltd., Elmhurst Park, Middle Field Road, Barnsley, South Yorkshire, S75 4LS, United Kingdom.

Distributor: McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG.

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