SCHEDULING STATUS:

S2

ADVIL® COLD and SINUS

Ibuprofen 200 mg and **Pseudoephedrine hydrochloride** 30 mg per tablet.

Contains Sugar (sucrose 174,6 mg per tablet)

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

ADVIL COLD and SINUS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ADVIL COLD and SINUS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ADVIL COLD and SINUS with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days for treatment of a cold and after 3 days for treatment of a fever.

What is in this leaflet

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2. What you need to know before you use ADVIL COLD and SINUS

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1. WHAT ADVIL COLD AND SINUS IS AND WHAT IT IS USED FOR

The active substance ibuprofen belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (known as NSAIDs), which reduce fever and relieve pain.

The other active substance pseudoephedrine hydrochloride is a decongestant, which relieves nasal congestion.

ADVIL COLD and SINUS tablets are used for the relief of symptoms associated with the common cold, sinusitis, or flu, such as blocked nose, headache, fever, body aches and pain.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ADVIL COLD AND SINUS

Do not take ADVIL COLD and SINUS if:

- you are allergic to ibuprofen, any other nonsteroidal anti-inflammatory medicine, aspirin or any other pain or fever relieving medicine
- you are allergic to pseudoephedrine hydrochloride
- you are allergic to any other ingredient contained within the tablets (see "**Section 6 What ADVIL COLD and SINUS is and what it is used for**")

- you have had or are suffering from asthma, recurrent ulcers or bleeding ulcers, any bleeding disorder, heart failure or any heart or blood pressure disorder, a liver disorder or a kidney disorder
- you have had or are suffering from prostatic hypertrophy (enlargement of the prostate gland), overactive thyroid, diabetes mellitus (sugar diabetes), glaucoma (an eye disease)
- you are pregnant or breast-feeding (see "**Pregnancy and breastfeeding and fertility**")
- you are taking a prescription monoamine oxidase inhibitor (medicine prescribed for depression, psychiatric or emotional conditions or Parkinson's disease) or if it has been less than 14 days since you have stopped treatment with a monoamine oxidase inhibitor (MAOI)
- ADVIL COLD and SINUS must not be given to children under 12 years.

Warnings and precautions

Take special care with ADVIL COLD and SINUS:

- If you have trouble sleeping, take the last dose for each day several hours before bedtime.
- Do not drink alcoholic beverages while taking ADVIL COLD and SINUS, as stomach problems may be more likely to occur if you drink alcoholic beverages.
- The risk of gastrointestinal bleeding or ulceration is higher with increasing doses, in patients with a history of ulcers and the elderly.
- Serious skin reactions have been reported in association with NSAID therapy. Discontinue treatment at the first appearance of rash or any other sign of hypersensitivity and contact your doctor.

- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), a severe skin reaction, has been reported in patients taking NSAIDs such as ADVIL COLD and SINUS. Some of these events have been fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy (swelling of lymph nodes), and/or facial swelling. Other clinical appearances may include hepatitis (disease of the liver), nephritis (inflamed tissues in the kidney), haematological abnormalities (blood abnormalities), myocarditis (inflammation of the heart muscle), or myositis (inflammation of the muscles). Sometimes symptoms of DRESS may resemble an acute viral infection. Eosinophilia (increased level of a certain type of blood cell) is often present. Because this disorder is variable in its presentation, other organ systems not noted here may be involved. It is important to note that early appearance of allergic reactions, such as fever or lymphadenopathy (swelling of lymph nodes), may be present even though rash is not evident. If such signs or symptoms are present, ADVIL COLD and SINUS should be discontinued, and the patient should be evaluated immediately.

Ask your doctor or pharmacist for advice before taking ADVIL COLD and SINUS tablets if:

- you are older than 65 years.
- you are allergic to any other pain or fever relieving medicines, such as aspirin or other NSAIDs (see "**Do not take ADVIL COLD and SINUS if**").

Ask your doctor or pharmacist for advice before taking ADVIL COLD and SINUS tablets if you have suffered or suffer from any other medical problem, or if you are under a doctor's care for any continuing medical condition, for example:

- asthma, high blood pressure, heart failure or heart disease, fluid retention, hepatitis or other liver disease, kidney disease, diabetes mellitus (sugar diabetes)

- stomach or colon irritation or bleeding, colitis, Crohn's disease, diverticulitis, stomach ulcer or other stomach or intestinal problems
- epilepsy, anaemia, systemic lupus erythematosus (SLE)
- bleeding problems.

Other medicines and ADVIL COLD and SINUS

Always tell your health care provider before taking ADVIL COLD and SINUS tablets if you are taking any other medicine on a regular basis, this includes complimentary, prescription, non-prescription or traditional medicines.

Examples of medicines that may interact with ADVIL COLD and SINUS tablets include:

- medicines to reduce the clotting of the blood
- medicines to treat diabetes.
- medicines to reduce your blood pressure or medicines to stimulate the heart.
- lithium, methotrexate, corticosteroids, diuretics, quinolones, selective serotonin reuptake inhibitors (a class of antidepressant), alcohol, phenytoin, beta blockers, insulin, oral antidiabetic agents, antiplatelets such as clopidogrel and ticlopidine
- aspirin, any other product that contains ibuprofen or any other pain or fever relieving medicine
- central nervous system stimulation-producing agents, levodopa, quinidine, tricyclic antidepressants, halogenated anaesthetics, digitalis, thyroid hormones, citrates, nitrates.
- monoamine oxidase inhibitors (see "**Do not take ADVIL COLD and SINUS tablets if**:")
- any other medicine that contains pseudoephedrine hydrochloride or any other decongestant.

ADVIL COLD and SINUS with food, drink and alcohol

No data available

Pregnancy and breastfeeding and fertility

The ADVIL COLD and SINUS tablets are not recommended for use in pregnant or breast-feeding women.

The use of ADVIL COLD and SINUS tablets during the last 3 months of pregnancy can harm your unborn child or cause problems at delivery.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

No data available

ADVIL COLD and SINUS contains sucrose

The ADVIL COLD and SINUS tablets are sugar-coated tablets.

The sugar-coating of these tablets contains sugar (sucrose 174,6 mg per tablet).

3. HOW TO TAKE ADVIL COLD AND SINUS

Do not share medicines prescribed for you with any other person.

Always take ADVIL COLD and SINUS exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose is:

Adults and children 12 years and older:

Take one tablet every 4 to 6 hours. If symptoms do not respond to one tablet, a second tablet may be taken.

Do not take more than 6 tablets in any 24-hour period.

ADVIL COLD and SINUS should be taken with a glass of water, with food or after meals.

Do not take for a cold for more than 7 days or for fever for more than 3 days, unless directed by a doctor.

If the cold or fever persists or gets worse, or if new symptoms occur, consult a doctor.

Use the lowest effective dose for the shortest possible duration of treatment.

For safe and effective use of ADVIL COLD and SINUS, do not take more of it, do not take it more often, and do not take it for a longer time than ordered by your health care professional or as directed on the package label.

If you take more ADVIL COLD and SINUS than you should

In case of accidental overdose, immediately consult your doctor or pharmacist. If neither is available, immediately contact the nearest hospital or poison control centre.

If you forget to take ADVIL COLD and SINUS

Do not take double dose to make up for forgotten individual doses.

Continue taking the tablets as directed on the label.

Contact your healthcare professional for further advice.

4. POSSIBLE SIDE EFFECTS

ADVIL Cold & Sinus can have side effects.

Stop taking ADVIL COLD and SINUS and get medical assistance right away if any of the following side-effects occur: fainting, facial swelling, fast or irregular breathing; shortness of breath, chest pain, wheezing or tightness in chest; fast or irregular heartbeat or pulse; unusual flushing or warmth of the skin; hive-like swellings on face, eyelids, mouth, lips or tongue; puffiness or swelling of eyelids.

Drug reaction with eosinophilia and systemic symptoms (DRESS):

- 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), see "**Take special care with ADVIL COLD and SINUS**".

Stop taking ADVIL COLD and SINUS and check with your doctor immediately if any of the following side-effects occur: abdominal or stomach pain, cramping or burning; bloody or black stools; chest pain, convulsions (seizures), fever with or without chills; severe or continuing nausea or heartburn or indigestion; sores or ulcers on lips or mouth; unexplained nosebleeds; unusual bleeding or bruising; spitting up blood; vomiting of blood or material that looks like coffee grounds; skin rash; hallucinations.

Also, check with your doctor as soon as possible if any of the following side-effects occur: bladder pain; bloody or cloudy urine; any problem with urination; blurred vision or any change in vision; ringing or buzzing in ears; bleeding from cuts and scratches that lasts longer than usual; severe headache; burning feeling in the throat, chest or stomach; mood or mental changes; unusual tiredness; yellow eyes or skin.

Other side-effects may occur. However, check with your doctor if any of the following side-effects continue or are bothersome: general feeling of discomfort or illness, dizziness,

lightheadedness, heartburn, indigestion, nausea, bloated feeling, sensitivity to light (eyes or skin); trouble sleeping, nervousness, restlessness.

Not all side effects reported for ADVIL COLD and SINUS are included in this leaflet. If your general state of health worsens or if you experience any untoward effects while taking ADVIL COLD and SINUS, please consult your doctor, pharmacist or other health care provider for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ADVIL COLD and SINUS.

5. HOW TO STORE ADVIL COLD AND SINUS

Store at or below 25 °C. Protect from light and exposure to air.

Store in the original package.

Do not use this medicine after the expiry date shown on the carton.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

WHAT ADVIL COLD and SINUS contains

The active substance in ADVIL COLD AND SINUS is

Ibuprofen 200 mg

Pseudoephedrine hydrochloride 30 mg

The other ingredients are:

Anhydrous colloidal silica, black printing ink, butterscotch colouring agent (iron oxide red, iron oxide yellow, titanium dioxide), carnauba wax, croscarmellose sodium, maize starch, methyl parahydroxybenzoate, microcrystalline cellulose, opaglos, povidone, pregelatinised starch, propyl parahydroxybenzoate, sodium lauryl sulphate, stearic acid and sucrose.

What ADVIL COLD and SINUS looks like and contents of the pack

ADVIL COLD AND SINUS:

butterscotch coloured, oval-shaped, sugar-coated tablet with a polished surface and “Advil Cold and Sinus” printed on one side

ADVIL COLD AND SINUS is marketed in cartons containing blister packs of 6, 10 or 20 tablets per carton.

Holder of Certificate of Registration

Haleon South Africa (Pty) Ltd

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