

SINUTAB® 3-WAY**PATIENT INFORMATION LEAFLET****SCHEDULING STATUS****S2****SINUTAB® 3-WAY TABLETS**

Pseudoephedrine hydrochloride and ibuprofen.

Sugar free.

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

SINUTAB® 3-WAY are available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use SINUTAB® 3-WAY carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SINUTAB® 3-WAY with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see your doctor if your symptoms worsen or do not improve after 3 days if you are using SINUTAB® 3-WAY for fever, or after 7 days if you are using SINUTAB® 3-WAY for a cold.

What is in this leaflet

1. What SINUTAB® 3-WAY is and what it is used for.
2. What you need to know before you take SINUTAB® 3-WAY.
3. How to take SINUTAB® 3-WAY.
4. Possible side effects.
5. How to store SINUTAB® 3-WAY.
6. Contents of the pack and other information.

1. What SINUTAB® 3-WAY is and what it is used for

SINUTAB® 3-WAY contains a nonsteroidal anti-inflammatory (ibuprofen) and a decongestant (pseudoephedrine).

It belongs to a class of medicines used to treat the common cold, nasal congestion and allergies.

SINUTAB® 3-WAY is used to relieve the symptoms of colds, sinusitis or the flu, including nasal congestion, headache, fever, body aches and pain.

Ibuprofen is an anti-inflammatory medicine which helps to relieve pain, headache, inflammation and fever (high temperature).

Pseudoephedrine is a decongestant which helps to unblock stuffy noses and clear nasal and sinus congestion.

2. What you need to know before you take SINUTAB® 3-WAY**Do not take SINUTAB® 3-WAY**

- If you are hypersensitive (allergic) to ibuprofen, pseudoephedrine or any of the other ingredients in SINUTAB® 3-WAY (see What SINUTAB® 3-WAY contains).
- If you are taking, or have taken in the last 14 days, medicines for depression, known as monoamine oxidase inhibitors (MAOIs) or linezolid, a medicine used to treat bacterial infections.
- If you have had an allergic reaction to aspirin or any other nonsteroidal anti-inflammatory medicines (such as asthma, swelling, shock or hives).
- If you have any form of heart disease.
- If you are going for, or just after you have had heart surgery.
- If you have high blood sugar (diabetes), a hyperactive thyroid, phaeochromocytoma (a rare tumour which affects your heart rate and blood pressure), closed-angle glaucoma (increased pressure in your eye), hyperexcitability, or you have difficulty in passing urine because of an enlarged prostate (if you are male).
- If you have liver disease.

- If you have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure.
- If you have very high blood pressure (severe hypertension) or hypertension not controlled by your medication.
- If you suffer from or have a history of stomach ulcers, perforation or any form of gastrointestinal bleeding.
- If you are pregnant (20 weeks or more), trying to become pregnant or are breastfeeding (see Take special care with SINUTAB® 3-WAY and Pregnancy, breastfeeding and fertility).
- Do not give SINUTAB® 3-WAY to children that are younger than 12 years of age.
- If you are taking digoxin (used to treat heart conditions).

Warnings and precautions

Take special care with SINUTAB® 3-WAY

- Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using SINUTAB® 3-WAY immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 "Possible side effects" for symptoms).
- If you are elderly, as adverse effects such as gastrointestinal bleeding, ulceration and perforation can lead to death.
- If you have other gastrointestinal diseases (such as ulcerative colitis, Crohn's disease, gastro-oesophageal reflux disease, hiatus hernia or angiodysplasia (a small vascular malformation in your intestines)) as these conditions may be aggravated.
- Stop taking SINUTAB® 3-WAY as soon as you notice any gastrointestinal bleeding and contact your doctor immediately.
- If you are taking any medicines that prevent blood clots.

- If you are taking corticosteroids (used to reduce inflammation and suppress your immune system).
- If you use alcohol.
- If you have a history of high blood pressure and/or heart failure.
- If you have or are at risk of developing any heart disease.
- If you have developed a rash or any signs of hypersensitivity. Contact your doctor immediately.
- If you are taking SINUTAB® 3-WAY together with other medicines that contain ibuprofen, other non-steroidal anti-inflammatory drugs (NSAIDs) or any other non-prescription medicines to relieve pain.
- If you are pregnant (20 weeks or more). Taking SINUTAB® 3-WAY may cause serious kidney problems in your unborn child (see Do not take SINUTAB® 3-WAY and Pregnancy, breastfeeding and fertility).
- If you have asthma, suffer from fluid retention or if you are taking any diuretic medicines (used to treat/prevent the excessive build-up of fluid in your body).

Ibuprofen, as in SINUTAB® 3-WAY, treats fever and pain and may hide the symptoms of another condition.

If pain or fever persists or gets worse, or if new symptoms occur, stop taking SINUTAB® 3-WAY and speak to your doctor.

Inform your doctor if you suddenly:

- Develop pain of your stomach area, experience a loss of appetite or itching while you take SINUTAB® 3-WAY. These may be sign of vanishing bile duct syndrome.
- Have blood in your stool or experience pain, cramping or tenderness of your stomach area while you take SINUTAB® 3-WAY. These may be signs of ischaemic colitis.
- Develop a fever, rash, lymphadenopathy, and/or facial swelling. This may be signs of DRESS (Drug reaction with eosinophilia and systemic symptoms) (See Possible side effects). If such signs or symptoms are present, discontinue SINUTAB® 3-WAY.

SINUTAB® 3-WAY might increase the likelihood of developing renal tubal acidosis (RTA) (a kidney disease where your kidneys do not remove acids from your blood into the urine as they should) and hypokalaemia (low potassium levels in your blood causing weakness, confusion, tiredness, muscle cramps or changes in the way your heart beats).

Children and adolescents

Do not give SINUTAB® 3-WAY to children under 12 years of age.

Other medicines and SINUTAB® 3-WAY

Always tell your health care provider if you are taking any other medicines. (This includes all complementary or traditional medicines.)

Talk to your doctor or pharmacist before taking SINUTAB® 3-WAY if you are taking or using:

- Aspirin or other nonsteroidal anti-inflammatory medicines used for the treatment of pain and inflammation.
- Anticoagulants (medicines that prevent blood clots, such as warfarin).
- Diuretics (medicines that help you pass urine).
- Some antibiotics like quinolone antibiotics.
- Medicines to treat heart problems (such as quinidine or oxpentifylline).
- Cardiac glycosides (medicines used to control heart rhythms or contractions).
- Antihypertensive medicines (medicines used to treat high blood pressure), such as reserpine, methyldopa.
- Antiplatelet medicines (such as clopidogrel).
- Corticosteroids (a type of anti-inflammatory medicine, such as hydrocortisone).
- Lithium (used to treat mood disorders).
- SSRI antidepressants (such as fluoxetine).
- Zidovudine (used to treat HIV).

- Methotrexate (used to treat autoimmune conditions such as rheumatoid arthritis).
- Bisphosphonates (used to treat osteoporosis).
- Ciclosporin (used to suppress the body's immune system).
- Tacrolimus (a transplant medicine).
- Antacid preparations (used to treat hyperacidity and heartburn, such as aluminium hydroxide).
- Sympathomimetic medicines, such as tricyclic antidepressants (medicines to treat mood disorders), stimulants or appetite suppressants, and medicines used to treat congestion and pain.
- Central nervous system (CNS) depressants, such as hypnotics (sleeping tablets including barbiturates), monoamine oxidase inhibitors (such as moclobemide) or within 14 days of stopping treatment, or antidepressants (to treat mood disorders) and inhalation anaesthetics (for general surgery).
- Phenytoin (used to treat epilepsy). Sulphonylureas (medicines used to control diabetes (high blood sugar)).
- Ergot alkaloids (medicines used to treat migraine, such as ergotamine).
- Oxytocin (medicines used to help contractions during child birth).
- Ritonavir (used to treat HIV/AIDS).
- Avoid using SINUTAB® 3-WAY for at least 8 to 12 days after you are given mifepristone (for the termination of pregnancy).

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

SINUTAB® 3-WAY with food, drink and alcohol

Do not take SINUTAB® 3-WAY with alcohol.

Pregnancy, breastfeeding and fertility

Safety in pregnancy and during breastfeeding has not been established (see Do not take SINUTAB® 3-WAY).

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 professional for advice before taking SINUTAB® 3-WAY.

Taking SINUTAB® 3-WAY if you are pregnant (20 weeks or more) may cause kidney or heart problems in your unborn child (see Do not take SINUTAB® 3-WAY and Take special care with SINUTAB® 3-WAY).

You should not take SINUTAB® 3-WAY during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used.

It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.

If SINUTAB® 3-WAY is taken for more than a few days from 20 weeks of pregnancy onward, SINUTAB® 3-WAY can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus than a few days, your doctor may recommend additional monitoring.

Driving and using machines

- SINUTAB® 3-WAY may make you feel tired or dizzy. You may feel less alert, feel faint or pass out.
- SINUTAB® 3-WAY may affect your ability to drive a car or operate any tools or machinery. Therefore, caution is advised if you need to perform these tasks while taking SINUTAB® 3-WAY.

3. How to take SINUTAB® 3-WAY

DO NOT TAKE MORE THAN THE RECOMMENDED DOSE.

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

- For oral use only.

The usual dose is:

Adults and children over 12 years:

Take one tablet every four to six hours.

DO NOT TAKE MORE THAN SIX TABLETS IN 24 HOURS.

You should take the tablet with milk or food or after your meal.

High fat meals will delay the absorption of pseudoephedrine, resulting in a delay in providing relief of symptoms.

Do not take SINUTAB® 3-WAY for fever for more than 3 days, or for colds for more than 7 days unless directed by your doctor.

If cold and/or fever symptoms persist or worsen, or if new symptoms develop, talk to your doctor or pharmacist.

Children under 12 years:

Do not give SINUTAB® 3-WAY to children under 12 years of age (see Do not take SINUTAB® 3-WAY).

Always take SINUTAB® 3-WAY exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of SINUTAB® 3-WAY is too strong or too weak, tell your doctor or pharmacist.

If you take more SINUTAB® 3-WAY than you should

Overdose symptoms with ibuprofen include abdominal pain, nausea, vomiting, lethargy and drowsiness. Overdose symptoms with pseudoephedrine are nausea, vomiting, lack of sleep,

tremors, widening of the pupils of the eyes, anxiety, hallucinations, seizures and changes in your heartbeat.

In the event of overdosage, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre. Take along the rest of the remaining SINUTAB® 3-WAY and the leaflet so that the doctor can easily tell what medicine you have taken.

If you forget to take SINUTAB® 3-WAY

If you forget to take a dose, take it as soon as you remember provided the last dose was at least 6 hours ago. If it is almost time for your next dose, skip the missed dose and take SINUTAB® 3-WAY at the next scheduled time.

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

4. Possible side effects

SINUTAB® 3-WAY can have side effects.

Not all side effects reported for SINUTAB® 3-WAY are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking SINUTAB® 3-WAY, please consult your health care provider for advice.

If any of the following happens, stop taking SINUTAB® 3-WAY and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Skin rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SINUTAB® 3-WAY. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)
- Stop using SINUTAB® 3-WAY immediately and seek urgent medical attention if you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These include:
 - severe headache with a sudden onset
 - feeling sick
 - vomiting
 - confusion
 - seizures
 - changes in vision
- Presence of blood either in your stools or vomit.
- Peptic ulcers (breach in the membrane lining the digestive tract) or gastrointestinal bleeding which can be fatal.
- Becoming unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than usual.
- Abnormal blood test results for liver function tests, yellowing of your eyes or skin, vanishing bile duct syndrome (pain of your stomach area, experience a loss of appetite or itching).
- An increased heart rate (tachycardia) or a rapid, strong or irregular heartbeat (palpitations), or high blood pressure and heart failure.
- Stroke (sudden numbness or weakness in your face, arm or leg on one side of your body, slurred speech or blurred vision).
- Heart attack (chest pain, difficulty breathing, pain in your arm, back or neck, sweating or light-headedness).
- Asthmatic conditions and bronchospasm (difficulty breathing, wheezing or shortness of breath).

- Severe skin rash, including blistering and peeling of the skin (such as Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme), exanthematous pustulosis (small fluid (pus) filled bumps on your skin, redness and fever) or drug reaction with eosinophilia and systemic symptoms (DRESS) (skin rash, fever, swollen lymph nodes and inflammation) [see Warnings and precautions].
- Painful or difficult urination or the inability to completely empty your bladder.
- Inflammation of your kidneys or kidney failure (pain in your pelvic area, burning or painful urination, cloudy urine, drowsiness, fluid retention).
- Hypothermia (sudden drop in body temperature).
- Pancreatitis (pain of your stomach area which radiates to your back, nausea, vomiting, fever and increased heart rate).
- Aseptic meningitis (fever, headache, body aches, sensitivity to light, vomiting).
- Sudden onset of severe headache, nausea, vomiting, confusion, fits, visual disturbances.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

More frequent side effects:

- Gastrointestinal side effects which may include dry mouth, nausea and pain in the upper abdomen.
- Constipation, diarrhoea, indigestion (dyspepsia), vomiting and flatulence (excessive wind).
- Nervousness, lack of sleep, dizziness, tremor, drowsiness (somnolence), ringing in the ears (tinnitus), thirst and feeling of weakness (asthenia).
- Eye problems.

Less frequent side effects:

- Anxiety.

The following side effects have been reported but the frequencies are not known:

- Headache.

- Changes in vision.
- Euphoric mood (exaggerated feeling of optimism and well-being) or hallucinations (seeing or hearing things that are not real).
- Feeling of extreme restlessness.
- Paraesthesia (numb, burning or tingling sensation of your skin).
- Swelling of your arms, legs, hands or feet due to water retention.
- Jittery feeling.

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 or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug**

Reactions Reporting Form”, found online under SAHPRA’s publications:

<http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of SINUTAB® 3-WAY. For further information, please contact the Johnson & Johnson via www.kenvuecontact.eu or call centre on 0860 410032 (landline).

5. How to store SINUTAB® 3-WAY

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in a cool, dry place.
- Do not remove the tablets from the outer carton until required for use.
- Do not use your medicine after the expiry date stated on the label.
- 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 SINUTAB® 3-WAY contains

The active substances are 30 mg pseudoephedrine hydrochloride and 200 mg ibuprofen per tablet.

The other ingredients are Avicel pH 101 (pH adjuster), calcium stearate, candelilla wax, croscarmellose sodium, methylparaben, microcrystalline cellulose, Opadry clear (containing hypromellose, propylene glycol), Opadry white (containing hypromellose, propylene glycol and titanium dioxide), povidone, pregelatinised starch, propylparaben, sodium lauryl sulphate and stearic acid.

Preservatives: Methylparaben and propylparaben.

What SINUTAB® 3-WAY looks like and contents of the pack

SINUTAB® 3-WAY is a white, film-coated capsule-shaped tablet.

SINUTAB® 3-WAY is available in packs of 10 or 20 tablets which are packed into white opaque, or clear, plastic blister strips having an aluminium foil backing.

The blister strips are packed in a cardboard carton.

Holder of certificate of registration

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Access to the corresponding Professional Information

The latest electronic Professional Information may be found at the SAHPRA website:

<https://www.sahpra.org.za/pi-pil-repository/>.

Alternatively, you may directly contact Johnson & Johnson (Pty) Ltd.:

Consumer Contact Centre:

www.kenvuecontact.euEmail: consumer-za@kenvue.com

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