PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 2

PROPRIETARY NAME, STRENGTH AND PHARMACETICAL FORM

SINUMAX® tablets

Each tablet contains 500 mg paracetamol and 30 mg pseudoephedrine hydrochloride.

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

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

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

1. WHAT SINUMAX CONTAINS

- The active ingredients are paracetamol and pseudoephedrine hydrochloride.
- The other ingredients are: Magnesium stearate; microcrystalline cellulose; pregelatinised starch, sodium starch glycolate, FD&C Blue No. 2, D&C Yellow No. 10.
- Sugar free.

2. WHAT SINUMAX IS USED FOR

The active ingredients in SINUMAX relieve pain, reduce fever and have a decongestant effect. SINUMAX is used for the symptomatic relief of nasal, sinus and Eustachian tube mucal congestion and associated pain and fever due to colds and influenza.

3. BEFORE YOU TAKE SINUMAX

Do not take SINUMAX:

- if you are allergic to paracetamol, pseudoephedrine hydrochloride or any of the other ingredients of SINUMAX. (Refer to WHAT SINUMAX CONTAINS, above.);
- If you are pregnant or breastfeeding;
- if you are taking MAO inhibitors (certain medicines used for depression) or have taken them in the last 14 days before treatment with SINUMAX as it may cause an increase in blood pressure or hypertensive crisis;
- If you have a liver problem, are suffering from heart disease, high blood pressure, have an overactive thyroid gland or tumor of the adrenal gland or increased pressure in the eye (closed-angle glaucoma).

Take special care with SINUMAX:

This product contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

- *Overdose warning:* Taking more than the recommended dose (overdose) may result in liver damage. In case of overdose, get medical help immediately. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

- Serious skin reactions such as acute generalized exanthematous pustulosis (AGEP), Stevens - Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), have been reported in patients receiving paracetamol. If you experience signs of serious skin reactions such as swelling, itching, red severe rash, stop using SINUMAX immediately and contact your doctor.

- *Alcohol Warning:* If you take alcohol on a regular basis, you should ask their doctors whether you should take paracetamol or other pain relievers or fever reducers.

- Do not use with any other product containing paracetamol.

- If you have heart disease and or high blood pressure you must only use SINUMAX under a doctor's care.

- If you have thyroid disease or diabetes you should only take SINUMAX when advised to do so by your doctor.

- If you have decreased kidney function or have difficulty urinating due to prostate enlargement you should only take SINUMAX when advised to do so by your doctor.

- If you have a disease of the liver, consult with your doctor before taking SINUMAX.

- If you have sudden abdominal pain, rectal bleeding or other symptoms of ischæmic colitis (inflammation and injury of the large intestine as a result from inadequate blood supply), then pseudoephedrine should be discontinued and medical advice sought.

- If small blisters or pimples containing pus form on the skin, with or without fever or redness, then treatment with pseudoephedrine should be discontinued and a doctor should be consulted.

- If symptoms persist or get worse, or if new symptoms occur, you should stop using SINUMAX and consult a doctor.

- If you have a glucose-6-phosphate dehydrogenase deficiency (a blood condition), haemolysis (the rupture or destruction of red blood cells) may occur.

- If you use SINUMAX for longer than advised, you may not respond to the medicine in the same way as initially and you may become dependent on the medicine.

Taking SINUMAX with food and drink:

Do not drink alcohol during treatment with SINUMAX as the effects of SINUMAX and alcohol may intensify each other.

Pregnancy and breastfeeding:

Do not take SINUMAX if you are pregnant or breastfeeding.

Driving and using machinery:

SINUMAX may affect your reactions. If you feel that your reactions are affected, do not drive a car or other vehicle and do not use electric tools or operate machinery.

Taking other medicines with SINUMAX:

Do not take SINUMAX with other paracetamol containing medicines.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Talk to your doctor or pharmacist if you are taking:

- Medicines to treat high blood pressure (such as guanethidine, reserpine, methyldopa).
- Medicines to treat mood disorder (such a tricyclic antidepressants and Monoamine Oxidase Inhibitors (MAOI's)).
- Medicines to thin the blood (such as warfarin).
- If you will receive medicines that are used during an operation or medical procedure.
- Alcohol.

4. HOW TO TAKE SINUMAX

Do not exceed the recommended dose.

Adults (and children over 12 years): Two tablets every four to six hours.

Do not exceed eight tablets in 24 hours.

Children 6 to 12 years: A half to one tablet every six hours**.**

Do not exceed four tablets in 24 hours.

Do not give to children under 6 years.

Do not use continuously for longer than 10 days without consulting your doctor.

If you take more SINUMAX than you should:

If you have taken more than the recommended dose of SINUMAX, contact a doctor, pharmacist, hospital or poison control center immediately, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

Prompt treatment is essential.

5. POSSIBLE SIDE EFFECTS

SINUMAX can have side effects.

If any of the following happens, stop taking SINUMAX and tell your doctor immediately or go to the casualty department at your nearest hopistal:

- Allergic reactions such as swelling of the eyelids, face or lips, rash or itching sometimes with breathing problems.
- Sudden severe headache.
- Chest pains.
- Severe skin rash or peeling or mouth ulcers.
- Sudden abdominal pain.

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

The following side effects have been reported, tell your doctor if you notice any of the following:

- Other allergic reactions including skin rash.
- Abdominal pain, diarrhoea, vomiting.
- Anxiety, feeling excited, hallucinations, restlessness.
- Headache, sensation of ‘pins and needles’, tremor.
- Fast, slow or irregular heart beat, palpitations.
- High blood pressure.
- Difficulty in passing urine.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF SINUMAX

Keep SINUMAX in a cool, dry place, at or below 25 °C. Keep blister in carton until required for use. Protect from light, moisture and exposure to air.

This medicine can be kept for only a limited period. Do not use SINUMAX after the date (month and year) mentioned after "EXP", even if it has been stored properly. You are advised to return old medicine to your pharmacist.

Keep all medicines out of the reach and sight of children.

7. PRESENTATION OF SINUMAX

Cartons containing 2 blister strips each with 10 tablets or Securitainers with 20 tablets each.

8. IDENTIFICATION OF SINUMAX

Light green tablets with 'SINUMAX' on one side.

9. REGISTRATION NUMBER

U/5.8/88

Nam.Reg.No.: 90/5.8/00651
NS 1
Botswana Reg. No.:B9315305
S3

10. NAME AND ADDRESS OF REGISTRATION HOLDER

janssen

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11. DATE OF PUBLICATION

- the date on the registration certificate: 02 August 1988
- the date of the most recently revised Patient Information Leaflet as approved by advisory clinical committee: 23 July 2019