PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 2

PROPRIETARY NAME, STRENGTH AND PHARMACETICAL FORM

SINUMAX® WITH CODEINE tablets

500 mg Paracetamol, 30 mg pseudoephedrine hydrochloride and 8 mg codeine phosphate per tablet

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

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

- Keep this leaflet. You may need to read it again.
- Do not share SINUMAX WITH CODEINE with any other person
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days.

1. WHAT SINUMAX WITH CODEINE CONTAINS

- The active ingredients are paracetamol, pseudoephedrine hydrochloride and codeine phosphate.
- The other ingredients are: magnesium stearate, microcrystalline cellulose (Avicel), pregelatinised starch, sodium starch glycolate.
- Sugar free.

2. WHAT SINUMAX WITH CODEINE IS USED FOR

The active ingredients in SINUMAX WITH CODEINE relieve pain, reduce fever and have a decongestant effect. SINUMAX WITH CODEINE is used for the symptomatic relief of nasal and sinus congestion and fever associated with colds and influenza.

3. BEFORE YOU TAKE SINUMAX WITH CODEINE

Do not take SINUMAX WITH CODEINE:

- if you are hypersensitive (allergic) to paracetamol, pseudoephedrine hydrochloride, codeine phosphate or any of the other ingredients of SINUMAX WITH CODEINE. (Refer to WHAT SINUMAX WITH CODEINE 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 WITH CODEINE, 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 tumour of the adrenal gland or increased pressure in the eye (closed-angle glaucoma);
- If you are experiencing difficulty in breathing;
- After operations on the biliary tract;
- In acute alcoholism;
- if you suffer from increased pressure in the brain (possibly after a head injury or brain disease);
- In the management of pain in children under 18 years of age who have undergone an operation to remove the tonsils or adenoids;
- If you metabolise codeine rapidly;
- In children younger than 12 years.

Take special care with SINUMAX WITH CODEINE:

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.

- If you suffer from a liver or kidney disease;

- If pain or fever persists or gets worse, or if new symptoms occur, a doctor should be consulted;

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

- Alcohol warning: Chronic alcohol users should ask their doctors whether they should take paracetamol or other pain relievers or fever reducers;

- Do not use with any other product containing paracetamol;

- If you metabolise codeine rapidly as it may cause life-threatening or fatal respiratory depression or you may experience overdose symptoms, such as extreme sleepiness, confusion, or shallow breathing;

- Respiratory depression (slow or difficult breathing) and death have occurred in children who received codeine after having their tonsils or adenoids removed and are ultra-rapid metabolisers of codeine. Deaths have also occurred in nursing infants

who were exposed to high levels of morphine in breast milk because their mothers were ultra-rapid metabolisers of codeine;

- At the first sign of any toxicity (slow or difficult breathing, nausea, vomiting, faintness, abdominal pain or increased heart rate and sweating) medical help should be sought as soon as possible;

- If you have heart disease and or hypertension you must only use SINUMAX WITH CODEINE under a doctor's care;

- If you have thyroid disease or diabetes you should only take SINUMAX WITH CODEINE when advised to do so by a doctor;

- If you have myasthenia gravis (a disease which causing a weakening of the muscles) or impaired kidney or liver function, enlargement of prostate gland (prostatic hypertrophy) or shock;

- If you have inflamed or obstructive bowel disease or are at risk of paralytic ileus (a paralysis of the intestine);

- High doses and continued use of SINUMAX WITH CODEINE can cause an addiction similar to the addiction to morphine and may lead to the medicine not working anymore;

- Elderly patients require a reduced dose of SINUMAX WITH CODEINE;

- If you have convulsive disorder, a head injury or increased pressure in your head;

- If you are using benzodiazepines, sedatives (medicines used to help you sleep or that reduce anxiety) or alcohol. Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedations, respiratory depression, coma, and death;

- If you have respiratory problems and are obese;

- If you are using serotonergic medicines (for depression and mood disorders);

- Disorder of the adrenal gland: You may develop a disorder of the adrenal gland called adrenal insufficiency. This means that your adrenal gland is not making enough of certain hormones. You may experience symptoms such as:
    - nausea, vomiting,
    - feeling tired, weak or dizzy,
    - decreased appetite;

- Serotonin Syndrome: SINUMAX WITH CODEINE can cause Serotonin Syndrome, a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles and digestive system work. You may develop Serotonin Syndrome if you take SINUMAX WITH CODEINE with certain anti-depressants or migraine medications.

  Serotonin Syndrome symptoms include:
    - fever, sweating, shivering, diarrhea, nausea, vomiting;
    - muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination;
    - fast heartbeat, changes in blood pressure;

- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma;

- Sexual Function/Reproduction: Long term use of opioids may lead to a decrease in sex hormone levels. It may also lead to low libido (desire to have sex), erectile dysfunction or being infertile.

Taking SINUMAX WITH CODEINE with food and drink:

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

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or any other healthcare professional for advice before taking this medicine.

SINUMAX WITH CODEINE is not recommended for use in pregnant women.

The combination of codeine and paracetamol is contraindicated in breastfeeding women.

Codeine and the product to which it is broken down to in the body (morphine), can pass into breast milk of nursing mothers. Some women break codeine down to morphine more rapidly than others. These women will have higher levels of morphine in their blood and breast milk, which can lead to an overdose in both mother and nursing infant, therefore maternal use of codeine can lead to potentially serious adverse reactions, including death, in nursing infants. Signs and symptoms of overdose include extreme sleepiness, breathing difficulties and confusion.

Codeine crosses the placenta. Neonates who have been exposed to codeine in utero can develop withdrawal syndrome (neonatal abstinence syndrome) after delivery.

Driving and using machinery:

SINUMAX WITH CODEINE 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 WITH CODEINE:

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

Avoid alcohol when you are using SINUMAX WITH CODEINE.

The following medicines may interact with SINUMAX WITH CODEINE:

- other sedative medicines, which may enhance the drowsiness caused by SINUMAX WITH CODEINE;
- other opioid analgesics (medicines used to treat pain);
- general anesthetics (medicines used during surgery);
- benzodiazepines (medicines used to help you sleep or that help reduce anxiety);
- antidepressants (for depression and mood disorders). Do not take SINUMAX WITH CODEINE with MAO inhibitors (MAOI) or if you have taken MAOI's in the last 14 days;
- medicines used to treat serious mental or emotional disorders (such as schizophrenia);
- medicines used to treat migraines (e.g., triptans);
- medicines used to treat muscle spasms and back pain;

- warfarin and other anticoagulants (used for prevention or treatment of blood clots);
- antibiotic medicines (used to treat bacterial infections);
- some heart medication (such as quinidine).

4. HOW TO TAKE SINUMAX WITH CODEINE

Do not exceed the recommended dose.

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

Always take SINUMAX WITH CODEINE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose must be used for **5 days** only:

SINUMAX WITH CODEINE should be taken at the lowest effective dose for the shortest period of time.

Adults and children over 12 years:

Take 1 or 2 tablets every 4 to 6 hours. Do not to exceed 8 tablets in 24 hours.

Children and Adolescents aged 12 to 18 years:

Use only under the supervision of a healthcare professional.

Not suitable in children under 12 years of age.

If you take more SINUMAX WITH CODEINE than you should:

Paracetamol symptoms: First 24 hours – pallor, nausea, vomiting, lack of appetite and stomach pain.

12 to 48 hours- liver damage may become apparent.

Pseudoephedrine symptoms: within 4-8 hours - mild anxiety, increased rate of heart beat and/or mild high blood pressure.

Codeine symptoms: include restlessness, excitement, abnormally slow and/or shallow breathing and low blood pressure with failure of the circulatory system and coma. In children fits may occur.

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

5. POSSIBLE SIDE EFFECTS

SINUMAX WITH CODEINE can have side effects.

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

- Difficulties or slowness in breathing,
- swelling of the eyelids, face or lips, rash or itching especially those covering your whole body.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you breathe more slowly or weakly than expected (respiratory depression). This is a very serious side effect. You may need urgent medical attention or hospitalisation.

The following side effects have been reported

- allergic reaction, itching and skin rash (appearing as allergic wheals), or rash reappearing in the same site and fever.
- dizziness, headache, nausea, vomiting, sweating, thirst, rapid or irregular heartbeat, pain in front of the heart, palpitations, raised blood pressure, difficulty in urination, muscular weakness, tremor, anxiety, restlessness and inability to sleep.
- sleepiness, confusion, dry mouth, sweating, facial flushing, abnormally slow pulse, drop in blood pressure when standing up, abnormally low body temperature, restlessness, hyperactivity and changes in mood.
- Tolerance with dependence may occur after continued use.
- Abdominal pain, dyspepsia, diarrhoea.
- Agitation, dependence, drug withdrawal syndrome, euphoric mood, hallucination, somnolence/sleepiness.
- Sore throat.

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.

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

6. STORING AND DISPOSING OF SINUMAX WITH CODEINE

Store SINUMAX WITH CODEINE in a cool, dry place, at or below 25 °C. Protect from light, moisture and exposure to air. Keep the container tightly closed.

This medicine can be kept for only a limited period. Do not use SINUMAX WITH CODEINE after the date (month and year) mentioned after “EXP”, even if it has been

stored properly. Return all unused medicine to your pharmacist. Do not dispose of unused medicines in drains or sewerage systems (e.g.toilets).

Store all medicines out of the reach of children.

7. PRESENTATION OF SINUMAX WITH CODEINE

Plastic bottles containing 20 tablets.

8. IDENTIFICATION OF SINUMAX WITH CODEINE

A flat round, white tablet with bevelled edges and "SINUMAX CO" embossed on the one side and a breakline on the other side.

9. REGISTRATION NUMBER

29/5.8/0004

Namibia Reg. Nr.: Sinumax with Codeine: 04/5.8/0295 NS 2

10. THE NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFCATE OF REGISTRATION



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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

- Date of registration**:** 13 December 1994
- Date of most recently revised patient information leaflet as approved by Advisory Clinical Committee: 2 May 2019