1.3.2.1 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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MEDI SOOTHE WITH VITAMIN C - LEMON 800 mg/50 mg/45 mg powder

Aspirin (acetylsalicylic acid), Caffeine, Vitamin C (ascorbic acid)

Contains sugar: Sucrose 4 789,50 mg per sachet

Contains sweetener: Sucralose 8 mg per sachet

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

MEDI SOOTHE WITH VITAMIN C - LEMON is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use MEDI SOOTHE WITH VITAMIN C - LEMON carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share MEDI SOOTHE WITH VITAMIN C - LEMON with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What MEDI SOOTHE WITH VITAMIN C - LEMON is and what it is used for
2. What you need to know before you take MEDI SOOTHE WITH VITAMIN C - LEMON
3. How to take MEDI SOOTHE WITH VITAMIN C- LEMON
4. Possible side effects
5. How to store MEDI SOOTHE WITH VITAMIN C - LEMON
6. Contents of the pack and other information

1. What MEDI SOOTHE WITH VITAMIN C - LEMON is and what it is used for

MEDI SOOTHE WITH VITAMIN C - LEMON is used for the treatment of aches, pains, fever and headache associated with the common cold and influenza.

2. What you need to know before you take MEDI SOOTHE WITH VITAMIN C - LEMON

Do not take MEDI SOOTHE WITH VITAMIN C- LEMON:

- If you are hypersensitive (allergic) to aspirin (acetylsalicylic acid), other salicylates, caffeine, vitamin C (ascorbic acid) or any of the other ingredients of MEDI SOOTHE WITH VITAMIN C - LEMON (listed in section 6).
- If you have a history of allergic reactions to aspirin or other medicines used to treat inflammation (non-steroidal anti-inflammatory drugs (NSAIDs)).
- If you are taking medicines that prevent blood clotting (anticoagulants).
- If you have stomach ulcers, tearing (perforation) or bleeding within the stomach or have a history of these problems.
- If you have a blood clotting disorder (e.g. haemophilia).
- If you have heart conditions such as heart failure.
- If you have a history of gout.
- If you have a condition called hyperoxaluria, which causes blood in the urine, pain when urinating, feeling an urge to urinate often, severe back pain or chills.
- If you have severe liver or kidney failure.
- If you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with MEDI SOOTHE WITH VITAMIN C - LEMON:

- Serious skin reactions may occur with MEDI SOOTHE WITH VITAMIN C - LEMON. Tell your doctor immediately if you notice any skin rash, sores in the mouth, blistering, fever, facial/gland swelling or any other signs of an allergic reaction (hypersensitivity) (see section 4).
- Do not exceed the prescribed dose of MEDI SOOTHE WITH VITAMIN C - LEMON.
- If you have a history of high blood pressure and/or heart failure as MEDI SOOTHE WITH VITAMIN C - LEMON may cause you to retain water, making these conditions worse.
- If you suffer from asthma.
- If you suffer from kidney or liver disease.
- If you are dehydrated.
- MEDI SOOTHE WITH VITAMIN C - LEMON can cause bleeding. Tell your doctor if you notice any unusual bleeding.
- MEDI SOOTHE WITH VITAMIN C - LEMON may increase bleeding during or after surgery. Tell your doctor that you are taking MEDI SOOTHE WITH VITAMIN C - LEMON if you have any surgical procedures planned.
- If you have a genetic disorder known as glucose-6-phosphate dehydrogenase deficiency.
- Increasing doses of MEDI SOOTHE WITH VITAMIN C - LEMON increases the risk of ulcers, perforation and bleeding in the stomach. These side effects are more likely if you have a history of stomach ulcers or if you are over 65 years old.
- If you are taking MEDI SOOTHE WITH VITAMIN C - LEMON and you experience any gastrointestinal pain, tell your doctor immediately and your treatment with MEDI SOOTHE WITH VITAMIN C - LEMON may be stopped.

- If you have a history of stomach conditions such as ulcerative colitis, Crohn's disease, hernia or reflux.
- Avoid drinking too many drinks that contain caffeine such as coffee, tea and some canned drinks while taking MEDI SOOTHE WITH VITAMIN C - LEMON.
- MEDI SOOTHE WITH VITAMIN C - LEMON should not be taken for a long period of time, as you may be at risk of losing vitamin C from your body after you then stop taking MEDI SOOTHE WITH VITAMIN C - LEMON.
- MEDI SOOTHE WITH VITAMIN C - LEMON may interfere with your blood tests, urine tests or skin tests. Tell your doctor you are taking MEDI SOOTHE WITH VITAMIN C - LEMON.

Children and adolescents

Aspirin as contained in MEDI SOOTHE WITH VITAMIN C - LEMON has been implicated in Reye's syndrome, a rare but serious illness in children and teenagers below the age of 16 years with chicken pox and influenza (flu). Consult your doctor before using MEDI SOOTHE WITH VITAMIN C - LEMON in these patients.

Other medicines and MEDI SOOTHE WITH VITAMIN C - LEMON

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

Tell your doctor if you are taking any of the following:

- Other non-steroidal anti-inflammatories (e.g. ibuprofen): medicines used for inflammation and pain.
- Corticosteroids (e.g. prednisone): medicines used to reduce inflammation.
- Anticoagulants (e.g. heparin): medicines used to prevent blood clots.

- Selective serotonin reuptake inhibitors (e.g. citalopram): medicines used to treat depression.
- Angiotensin-converting enzyme inhibitors (ACE inhibitors) (e.g. perindopril): medicines used to treat high blood pressure.
- Antacids: medicines used to relieve heartburn, indigestion or an upset stomach by lowering the acidity in the stomach.
- Anticonvulsants (e.g. phenytoin): medicines used to treat epilepsy.
- Beta-blockers (e.g. atenolol): medicines used to treat high blood pressure.
- Carbonic anhydrase inhibitors (e.g. acetazolamide): medicines used to treat glaucoma.
- Diuretics (e.g. furosemide): medicines used to treat high blood pressure.
- Antidiabetic medicines (e.g. glibenclamide): medicines used to treat diabetes.
- Methotrexate: medicines used to treat inflammatory conditions and certain cancers.
- Uricosuric medicines (e.g. probenecid and sulfinpyrazole): medicines used to treat gout.
- Amphetamine: medicine used to increase brain activity, and is commonly used to treat attention deficit hyperactivity disorder.
- Smoking.
- Oral contraceptives: medicines used in family planning.
- Iron supplements: medicines used to treat a shortage of iron in your body.
- Certain complementary medicines such as amygdalin.
- Desferrioxamine: medicines used to remove excess levels of iron from the body.

MEDI SOOTHE WITH VITAMIN C - LEMON with alcohol

Drinking alcohol while taking MEDI SOOTHE WITH VITAMIN C - LEMON may lead to drowsiness and impaired concentration being worsened.

It may also increase the chances of bleeding in the stomach. You should not drink alcohol together with MEDI SOOTHE WITH VITAMIN C - LEMON.

Pregnancy, breastfeeding and fertility

You should not take MEDI SOOTHE WITH VITAMIN C - LEMON if you are pregnant or breastfeeding your baby.

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 healthcare provider for advice before taking this medicine.

Driving and using machines

Adverse reactions such as dizziness have been reported in patients taking MEDI SOOTHE WITH VITAMIN C - LEMON which may affect your ability to drive, use machinery or perform any tasks that require concentration.

It is not always possible to predict to what extent MEDI SOOTHE WITH VITAMIN C - LEMON may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MEDI SOOTHE WITH VITAMIN C - LEMON affects them (see section 4).

MEDI SOOTHE WITH VITAMIN C - LEMON contains sucrose:

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

MEDI SOOTHE WITH VITAMIN C - LEMON contains 4 789,50 mg sucrose per sachet. This should be taken into account if you are a diabetic.

3. How to take MEDI SOOTHE WITH VITAMIN C - LEMON

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

Always take MEDI SOOTHE WITH VITAMIN C - LEMON 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 of MEDI SOOTHE WITH VITAMIN C - LEMON is:

Adults:

One sachet morning and night. A dose at midday may be taken if desired.

Empty contents of sachet into a tumbler. Half fill the tumbler with very hot water. Stir. Add cold water if necessary, but drink as hot as possible.

Do not take more than 3 doses every 24 hours.

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

Do not use MEDI SOOTHE WITH VITAMIN C - LEMON continuously for more than 10 days without consulting a doctor.

MEDI SOOTHE WITH VITAMIN C - LEMON is not to be given to children under the age of 16 except on medical advice.

If you have the impression that the effect of MEDI SOOTHE WITH VITAMIN C - LEMON is too strong or too weak, talk to your doctor or pharmacist.

If you take more MEDI SOOTHE WITH VITAMIN C - LEMON than you should

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

If you forget to take MEDI SOOTHE WITH VITAMIN C - LEMON

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

If you have missed a dose of MEDI SOOTHE WITH VITAMIN C - LEMON, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.

4. Possible side effects

MEDI SOOTHE WITH VITAMIN C - LEMON can have side effects.

Not all side effects reported for MEDI SOOTHE WITH VITAMIN C - LEMON are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MEDI SOOTHE WITH VITAMIN C - LEMON, please consult your healthcare provider for advice.

If any of the following happens, stop taking MEDI SOOTHE WITH VITAMIN C - LEMON and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS).

- fever, rash, facial swelling, enlarged glands, which may indicate a severe reaction to MEDI SOOTHE WITH VITAMIN C - LEMON.

These are all very serious side effects. If you have them, you may have had a serious reaction to MEDI SOOTHE WITH VITAMIN C - LEMON. 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:

- Temporary hearing loss,
- Wheezing and breathing difficulties may be triggered in patients suffering from or with a previous history of asthma (bronchospasm),
- Heart failure: symptoms include shortness of breath, excessive tiredness and leg swelling,
- Stomach ulceration or perforation: symptoms could include severe abdominal pain, vomiting blood (haematemesis) or liquid with what looks like coffee grounds, blood in the faeces (melaena) or passing black stools.
- Ulcers inside the mouth (ulcerative stomatitis),
- Rapid irregular action of the heart; irregular heartbeat (palpitations).
- Back pain or a pain in the side of the body between the upper belly (abdomen) and back and bloody, cloudy, dark urine as these may be symptoms of renal papillary necrosis (a disorder of the kidneys in which all or part of the renal papillae die).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea,
- vomiting,
- frequent/loose watery stools (diarrhoea),
- excess amount of air/gas in the stomach (flatulence),
- difficulty passing stools (constipation),
- heartburn or indigestion (dyspepsia),
- abdominal pain,
- inflammation of the colon (intestine) which results in abdominal pain or diarrhoea (exacerbation of colitis, Crohn's disease),
- inflammation of the stomach (gastritis).

Side effects with an unknown frequency

- Prolonged bleeding time,
- reduction in blood platelets, which increases risk of bleeding or bruising; too few platelets (thrombocytopenia, ecchymosis),
- salt and water retention.
- ringing in the ears (tinnitus).
- high blood pressure (hypertension),
- blood tests which show changes in the way the liver is working (increase in aminotransferase levels).
- kidney malfunction (renal dysfunction), symptoms could include reduced amount of urine swelling of your legs, ankles and feet from fluid retention drowsiness or fatigue,

- increased blood uric acid levels, symptoms could include severe pain in your joints, joint stiffness,
- dizziness,
- inability to sleep (insomnia),
- headache,
- nervousness,
- increased urine secretion (diuresis),
- increased gastric secretions,
- redness of skin, flushing.
- lack of red blood cells that leads to reduced oxygen flow with symptoms such as shortness of breath, light-headedness, dizziness (anaemia),
- laboured breathing (dyspnoea).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of MEDI SOOTHE WITH VITAMIN C - LEMON.

5. How to store MEDI SOOTHE WITH VITAMIN C - LEMON

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

The product must be consumed within 60 minutes after dissolving the powder in water.

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

The active substances are 800 mg aspirin (acetylsalicylic acid), 50 mg caffeine and 45 mg Vitamin C (ascorbic acid).

The other ingredients are *l*-menthol, Quinoline Yellow W.S. (E104), sucralose, sucrose, Trusil Lemon Special.

Contains sugar: Sucrose 4 789,50 mg

Contains sweetener: Sucralose 8 mg

What MEDI SOOTHE WITH VITAMIN C - LEMON looks like and contents of the pack

MEDI SOOTHE WITH VITAMIN C - LEMON is a fine, pale yellow, granular powder, free from caking or lumps.

Appearance of the powder dissolved in water: An opalescent, yellow solution.

Paper/low density polyethylene/aluminium/low density polyethylene individual sachets containing 6,1 g powder. Pack sizes of 8 or 24 sachets in a carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

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

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088