PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

PROPRIETARY NAME AND DOSAGE FORM

MED-LEMON HOT MEDICATION CHERRY MENTHOL WITH VITAMIN C (Powder)

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

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

- Keep this leaflet. You may need to read it again.
- Do not share MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C 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 10 days.

COMPOSITION

The active substances are 800 mg aspirin, 50 mg caffeine, 10 mg vitamin C and 2, 6 mg menthol, in each sachet.

The other ingredients are carmoisine, cherry flavour, gum Arabic, maltodextrin, potassium acid tartrate, starch, saccharin sodium, silicone dioxide.

Contains sugar (sucrose 4254,63 mg)

APPROVED INDICATIONS AND USE

MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C is recommended for the symptomatic treatment of aches, pains and fever (high temperature) associated with the common cold and influenza.

INSTRUCTIONS BEFORE TAKING MED-LEMON HOT MEDICATION CHERRY MENTHOL WITH VITAMIN C

Do not take MED-LEMON HOT MEDICATION CHERRY MENTHOL WITH VITAMIN C:

- if you are hypersensitive (allergic) to aspirin, other salicylates (the class of medicines to which aspirin belongs), caffeine, vitamin C, menthol or any of the other ingredients of MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C (see “COMPOSITION”).
- if you have a history of hypersensitivity reactions (e.g. asthma, bronchospasm – sudden constrictions of the muscles of the passage ways by which air passes through the nose to the air sacs of the lungs, rhinitis – irritation and inflammation of the mucous membranes inside the nose, urticaria (hives), nasal polyps – sac like growths of inflamed tissue lining the nose or sinuses) when you take aspirin or non-steroidal anti-inflammatory drugs (NSAIDs).
- If you have or ever had a problem of your blood not clotting properly.
- If you ever had a stomach ulcer, perforation or bleeding of the stomach.
- If you have renal, liver or heart failure
- If you have or have ever had gout
- If you are pregnant or breastfeeding

Take special care with MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C:

- if your symptoms do not improve within 10 days of continuous use. Please consult your doctor.
- when giving to children because aspirin may cause Reye’s syndrome. Reye’s syndrome is a rare disease, which may be fatal. For this reason MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C should not be given to children under 16 years of age unless prescribed by a doctor.
- if you have a history of high blood pressure or heart disease.
- if you are elderly.
- if stomach ulcer, perforation or bleeding occurs while taking MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C, treatment should be stopped and a doctor or medical practitioner should be consulted.

- if you experience serious skin reactions while taking MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C. Treatment should be discontinued at the first appearance of skin rash, lesions or any other sign of hypersensitivity.
- if you have asthma.
- if you have impaired (reduced) renal or liver function.
- if you think you are dehydrated (you may feel thirsty with a dry mouth)
- if you have any unusual bleeding. This should be reported to your doctor.

Do not exceed the recommended dose.

Taking MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C with food or drink:

Excessive intake of caffeine (e.g. coffee, tea and some canned drinks) should be avoided while taking MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C.

Co-administration of aspirin with alcohol increases the risk of gastrointestinal bleeding.

Human Repoduction:

MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C should not be taken during pregnancy and breastfeeding.

If you are pregnant or breastfeeding your baby while taking MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C, please consult your doctor, pharmacist or other healthcare professional for advice.

Effects on ability to drive and use machines:

The use of MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C may have minor/moderate influence on the ability to drive and use machines.

Using other medicines with MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C:

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

The following medicines may cause an interaction when used in combination with MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C:

- Non-steroidal anti-inflammatory drugs (a class of medicines that provides analgesic, fever reducing and anti-inflammatory effects, like ibuprofen).
- Corticosteroids (medicines used to reduce inflammation).
- Anticoagulants (medicines used to thin blood like warfarin).
- Anti-platelet agents (medicines that decrease formation of blood clots).
- Selective serotonin re-uptake inhibitors (used to treat depression, anxiety disorders and some personality disorders).
- Angiotensin-converting enzyme inhibitors (used to treat high blood pressure and weak heart muscles).
- Antacids
- Anticonvulsants (used to treat epileptic seizures).
- Diuretics (medicines that increase the volume of urine Hypoglycaemic agents (used to lower glucose levels in the blood).
- Methotrexate (used in the treatment of cancer and autoimmune diseases).
- Uricosuric agents (used in the treatment of gout).

INSTRUCTIONS ON HOW TO TAKE MED-LEMON HOT MEDICATION CHERRY MENTHOL WITH VITAMIN C

Always take MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Use the lowest effective dose for the shortest possible duration of treatment.

The usual dose 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 with very hot water. Stir. Add cold water if necessary, but drink as hot as possible.

Not to be given to children under the age of 16 except on medical advice.

Do not exceed 3 doses every 24 hours.

If you take more MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C than you should:

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

ASPIRIN

Common symptoms of aspirin overdose include vomiting, dehydration, tinnitus (ringing in the ears), vertigo (a feeling that you or your environment is moving), deafness, sweating, warm limbs with bounding pulses, increased respiratory rate and hyperventilation (breathing faster or deeper than normal).

Uncommon features include haematemesis (vomiting of blood), hyperpyrexia (a fever with an extreme elevation of body temperature), hypoglycaemia (low blood sugar) and renal failure. Features like confusion, disorientation, coma and convulsions are less common in adults than children.

CAFFEINE

Large doses may cause restlessness, excitement, anxiety,muscle tremor, tinnitus (ringing in the ears), scintillating scotoma (visual spot disturbances), tachycardia (increased rate of heartbeat), and extrasystoles (abnormal heartbeats).

Overdose of caffeine may result in pain in the upper abdomen just below the ribs, vomiting, diuresis (excessive urine production), tachycardia (high heart rate), CNS stimulation (insomnia, restlessness, excitement, agitation, jitteriness, tremors and convulsions).

VITAMIN C (Ascorbic Acid)

Large doses may cause diarrhoea and other gastrointestinal disturbances such as nausea and abdominal discomfort.

If you forget to take a dose of MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C:

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

SIDE EFFECTS

MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C can have side effects.

Not all side effects reported for MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C are included in this leaflet. Should your general health worsen while receiving MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happen, stop taking MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C and tell your doctor immediately or go to the casualty department at your nearest hospital:

- If you experience allergic reactions such as skin rash or itching, wheezing or coughing or difficulty breathing, or swelling of the lips, tongue, throat or face.
- If you have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories, and experience a similar reaction with MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C.
- Any swelling or water retention.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C. 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:

- You experience unexplained bruising or bleeding.
- Prolonged bleeding time.
- You have any bleeding from your stomach (symptoms can include blood in your stools or vomit).

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

<u>The following side effects may occur more frequently:</u>

ASPIRIN:

- Stomach ulcers.
- Nausea
- Vomiting.
- Diarrhoea.
- Flatulence (winds).
- Constipation.
- Excess acid in the stomach (dyspepsia).

- Stomach pain.
- Inflammation of the stomach.
- Worsening of inflammation of the colon.
- Worsening of the symptoms of the disease called Crohn's disease.

The following side effects may occur less frequently:

ASPIRIN:

- Dizziness.

The following side effects may occur, but the frequency is unknown:

ASPIRIN:

- Certain blood diseases
- Nose bleeds.
- Sodium and water retention.
- Ringing of the ears, temporary hearing loss.
- Swelling.
- High blood pressure.
- Heart failure.
- Skin reactions, including serious reactions such as Stevens-Johnson syndrome and a life-threatening skin condition called toxic epidermal necrolysis.
- Kidney dysfunction.
- Increased blood uric acid levels.

CAFFEINE:

- Nervousness
- Dizziness.

MENTHOL:

- Hypersensitivity (allergic) reactions.

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

STORING AND DISPOSAL INFORMATRION OF MED-LEMON HOT MEDICATION CHERRY MENTHOL WITH VITAMIN C

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

Store in a cool (at or below 25 °C) dry place.

Do not store in a bathroom.

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

Return all unused medicine to your pharmacist.

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

PRESENTATION OF MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C

8 sachets per carton and 72 sachets per dispenser.

IDENTIFICATION OF MED-LEMON HOT MEDICATION - CHERRY MENTHOL WITH VITAMIN C

An off-white to slightly pink free flowing powder with a strong menthol and cherry odour.

REGISTRATION NUMBER

B/5.8/192

Botswana S4 Reg. Nr: BOT1703114;

Zimbabwe OTC Reg. Nr: 74/22.2.5/238

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Haleon South Africa (Pty) Ltd,

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DATE OF PUBLICATION

Date of registration of the medicine: 15 May 1970

Date of the most recent amendment to the patient information leaflet as approved by the authority:

28 June 2018