

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S2**

LOTEM SUSPENSION, each 10 ml contains:

Ibuprofen 200 mg

Paracetamol 250 mg

Sugar free

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

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

- Keep this leaflet. You may need to read it again.
- Do not share LOTEM SUSPENSION with any other person.
- Ask your health care 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 LOTEM SUSPENSION is and what it is used for
2. What you need to know before you take LOTEM SUSPENSION
3. How to take LOTEM SUSPENSION
4. Possible side effects
5. How to store LOTEM SUSPENSION
6. Contents of the pack and other information

1. What LOTEM SUSPENSION is and what it is used for

LOTEM SUSPENSION contains Ibuprofen and paracetamol belongs to a group of medicines referred to as non-steroidal anti-inflammatory medicines (NSAIDs).

LOTEM SUSPENSION is used for fever and the relief of mild to moderate pain.

2. What you need to know before you take LOTEM SUSPENSION

Do not take LOTEM SUSPENSION

- If you are hypersensitive (allergic) to ibuprofen and paracetamol or any of the other ingredients of LOTEM SUSPENSION (listed in section 6).

- If you have reduced liver and kidney function
- If you have or have had a stomach ulcer or have a history of inflammation and bleeding in the bowels.
- If you have heart failure (a chronic condition where the heart does not pump blood as well as it should).
- If you have hypersensitivity to aspirin or a class of medicines used to treat inflammation; mild to moderate pain; and fever.
- If you are pregnant, do not use NSAIDs at 20 weeks or later in your pregnancy unless specifically advised to do so by your health care professional because these medicines may cause problems in your unborn baby.
- If you are younger than 2 years old.
- If you suffer from asthma or bronchospasm or have ever had an allergic reaction or suffered from wheezing after taking ibuprofen, aspirin or any other anti-inflammatory pain killers.
- If you suffer from swelling and irritation inside the nose.
- If you have a condition which increases your tendency to bleed.
- If you are taking blood thinning medication.
- If you have severe liver or kidney function impairment.

Warnings and precautions

Special care should be taken with LOTEM SUSPENSION:

- Tell your doctor or health care provider if you are pregnant or plan to become pregnant. Taking NSAIDs at around 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of your pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. You should not take NSAIDs around 30 weeks of pregnancy or later.
- Dosages in excess of those recommended may cause severe liver damage.
- Use with caution in cases of alcoholism or impaired liver function due to risk of severe liver damage.
- If you have kidney or liver problems, including those due to drinking too much alcohol as you may be more at risk of the side effects of paracetamol.
- Use with caution if you have heart problems, water retention causing swelling or high blood pressure.
- Use in children, adolescents and the elderly.

- If you develop a fever, skin rash, swelling of the lymph nodes and/or swelling of the face. This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
- If you are diabetic and taking LOTEM SUSPENSION, this may influence your glucose test results.
- If you suffer from asthma or anaemia, your condition may worsen whilst taking LOTEM SUSPENSION.
- Avoid taking LOTEM SUSPENSION before surgery to avoid enhanced bleeding.
- Stop taking LOTEM SUSPENSION at the first sign of skin rashes, itching, redness or any sign of hypersensitivity.
- If you have or have had any allergies or allergic reactions (including hives, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing) which required hospital treatment.
- If you bleed easily.
- If you have gastrointestinal problems (nausea, vomiting, stomach pain, heartburn, indigestion) and or stomach ulcer(s).
- If you are an elderly person. The elderly and patients with a history of stomach ulcers are more susceptible to develop side-effects affecting the bowels when using NSAIDs. Therefore, they should be carefully monitored for stomach ulcers and bleeding as it may be fatal.

Other medicines and LOTEM SUSPENSION

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

LOTEM SUSPENSION should not be taken if you are taking:

- Anti-inflammatories: use of two or more together could result in an increase in side effects.
- Corticosteroids(used to treat inflammation): increased risk of ulceration or bleeding in the bowels.
- Blood thinners (e.g. warfarin) and alcohol: LOTEM SUSPENSION may enhance the effects of blood thinning when taken with these.
- Anti-platelet and anti-depressant medicines: increased risk of bleeding if you suffer from stomach ulcers.
- Hepatotoxic medicines (medicines that can cause damage to your liver).
- Enzyme inducing medicines.

- Metoclopramide (used to relieve feelings of sickness (nausea) or being sick (vomiting)).
- Cholestyramine (used to treat high cholesterol).
- Antidiabetic medicines (used to treat high sugar levels).
- Digoxin (used to treat heart failure and a fast heartbeat).
- Lithium, selective serotonin reuptake inhibitors (SSRIs) (used to treat depression).
- Methotrexate (used to treat rheumatoid arthritis, certain types of cancer and severe psoriasis).
- Antihypertensives (used to treat high blood pressure) or diuretics (water pills).
- Bone marrow depressants.

LOTEM SUSPENSION with food and drink

No known interactions with food and drinks. LOTEM SUSPENSION should be taken after meals with sufficient water. The use of alcohol with LOTEM SUSPENSION should be avoided as it increases the risk of stomach ulcers or gastrointestinal bleeding.

Pregnancy and breast-feeding

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 provider for advice before taking LOTEM SUSPENSION.

LOTEM SUSPENSION is not recommended for use by pregnant or breastfeeding women.

Children and adolescents

Do not give LOTEM SUSPENSION to children under the age of 2 years.

Driving and using machines

The effect on the ability to drive and use machines has not been established.

3. How to take LOTEM SUSPENSION

Always take LOTEM SUSPENSION 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.

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

Do not exceed the recommended dosage.

Shake the bottle before use.

Adults and children 12 years of age and older:

Take one to two medicine measures (5 to 10 ml) four hourly if necessary and not more than six medicine measures in twenty-four hours, orally after meals.

Children:

2 to 5 years: 2,5 ml to 5 ml three to four times daily, orally after meals.

6 to 12 years: 5 ml to 10 ml three to four times daily, orally after meals.

Safety in children under two years of age has not been proven.

Consult your doctor if no relief is obtained with the recommended dosage.

If you take more LOTEM SUSPENSION than you should

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

The most likely symptoms of overdosage include pallor, nausea, vomiting, anorexia, abdominal pain, acute renal failure, epigastric pain and nausea.

If you forget to take LOTEM SUSPENSION

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

4. Possible side effects

LOTEM SUSPENSION can have side effects.

Not all side effects reported for LOTEM SUSPENSION are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LOTEM SUSPENSION, please consult your healthcare provider for advice.

If any of the following happens, stop taking LOTEM SUSPENSION 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.

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

Frequent side effects:

- Dizziness.
- Nausea, stomach pain, vomiting, diarrhoea, flatulence, constipation, indigestion, stomach ulceration, perforation, or bleeding, bloody stool, haematemesis (if you vomit blood), and gastritis (inflammation of the lining of the stomach).

Less frequent side effects:

- Changes in your blood cell counts (agranulocytosis, thrombocytopaenia, anaemia, neutropenia, eosinophilia).
- Nervousness, headache, ringing/buzzing noise in ear(s), depression, drowsiness, sleeplessness.
- Blurred vision, changes in visual colour perception and other toxic amblyopia (damage to optic nerve).
- Changes in the way your heart beats (beating faster), flushing, high blood pressure, and heart failure.
- Yellowing of your skin and eyes, also called jaundice or hepatitis.
- Kidney problems, which may lead to kidney failure (you may pass more or less urine, have blood in the urine or cloudy urine, feel breathless, very tired or weak, have no appetite, or have swollen ankles).
- Aseptic meningitis (infection around the brain or spinal cord with fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light).

Side effects with an unknown frequency:

- Crohn's disease (an inflammatory disease that can affect any part of the gastrointestinal track causing symptoms such as pain, fever, diarrhoea and loss of body mass).
- Painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome, toxic epidermal necrolysis or erythema multiforme.
- Interstitial nephritis (passing more or less urine than is normal for you, dark urine, nausea, vomiting).

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 Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> . By reporting side effects, you can help provide more information on the safety of LOTEM SUSPENSION.

May also report to Adcock Ingram Limited using the following email:

Adcock.AEReports@adcock.com .

5. How to store LOTEM SUSPENSION

Keep all medicines out of reach of children.

Store at or below 30 °C in well-closed containers.

Protect from light.

Do not store in bathrooms.

Do not use after expiry date stated on the label.

Do not use LOTEM SUSPENSION if you notice any visible signs of deterioration.

Return all unused medicine to your pharmacists.

6. Contents of the pack and other information

What LOTEM SUSPENSION contains

Each 10 ml contains:

The active substances are: Ibuprofen 250 mg and Paracetamol 200 mg.

The other ingredients are:

Banana flavour, citric acid anhydrous, colour spectracol quinoline yellow, disodium edetate, glycerol, light kaolin (low bioburden), polyethylene glycol, polyvinylpyrrolidone k25, saccharin sodium, sodium citrate, sodium cyclamate, sodium dihydrogen phosphate dihydrate, sodium metabisulphite, xanthan gum.

What LOTEM SUSPENSION looks like and contents of the pack:

LOTEM SUSPENSION is a yellow, homogenous suspension with a banana taste and odour.

It is packed in an amber glass bottle of 100 ml and 200 ml.

Holder of Certificate of Registration

Adcock Ingram Limited

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Customer care: 0860ADCOCK (232625)

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Access to the corresponding professional information

For the Professional Information for LOTEM SUSPENSION scan the QR code.

The same information is available at www.adcock.com/products/productinformation.

Botswana: BOT1502743 S3

Namibia: NS1 04/2.8/1574
