PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

LOTEM SUSPENSION, 200 mg/250 mg

Ibuprofen

Paracetamol

Contains sweeteners:

Saccharine sodium 12,40 mg

Sodium cyclamate 90,00 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/give LOTEM SUSPENSION
3. How to take/give 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 which belongs to a group of medicines referred to as non-steroidal anti-inflammatory medicines (NSAIDs) and paracetamol which belongs to a group of medicines referred to as analgesics.

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 have active or history of recurrent haemorrhage/perforations.
- 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 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 LOTEM SUSPENSION from 30 weeks of pregnancy onwards because it may cause kidney and heart problems in your unborn baby.
- If you suffer from uncontrolled 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.

Warnings and precautions

Special care should be taken with LOTEM SUSPENSION:

- If you are pregnant or planning to become pregnant consult your healthcare provider before taking LOTEM SUSPENSION. Taking NSAIDs between 20 to 30 weeks of pregnancy may harm your unborn baby. If you are prescribed NSAIDs by your healthcare provider when you are between 20 and 30 weeks of your pregnancy, your health care provider may need to monitor the amount of fluid in your womb around your baby.
- If you are prescribed NSAIDs by your health care provider when you are between 20 and 30 weeks of your pregnancy, limit LOTEM SUSPENSION use to the lowest effective dose and shortest duration possible.
- 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.
- Ibuprofen should be discontinued if you experience blurred or diminished vision or changes in colour vision. If you have collagen disease you may be at risk of developing aseptic meningitis (inflammation of the brain linings).
- 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.

Children and adolescents

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

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/given if you are taking:

- Anti-inflammatories (NSAIDs): use of two or more together could result in an increase in side effects.
- Corticosteroids (used to treat inflammation): increased risk of gastrointestinal perforation, ulceration or bleeding in the bowels.
- Blood thinners (e.g. warfarin) LOTEM SUSPENSION may enhance the effects of blood thinning when taken with these.
- Anti-platelet medicines (medicines used to prevent blood clots), and selective serotonin reuptake inhibitors (SSRIs) (anti-depressant medicines): increased risk of bleeding if you suffer from stomach ulcers.
- Hepatotoxic medicines (medicines that can cause damage to your liver): increased risk of liver damage.
- Enzyme inducing medicines (medicines that increases metabolic rate): increased risk of liver damage and possible decrease in therapeutic effects of paracetamol.
- Nephrotic medicines (e.g. ciclosporin that can damage your kidneys and impair the function of your kidneys): increased risk of nephrotoxicity.
- Metoclopramide (used to relieve feelings of sickness (nausea) or being sick (vomiting): absorption of paracetamol may be increased.
- Cholestyramine (used to treat high cholesterol): absorption of paracetamol is reduced if given within one hour of cholestyramine.
- Alcohol, antiplatelet medicines (clopidogrel, ticlopidine), medicine that slow down or prevent bone loss (bisphosphonates) and medicine that help with blood flow (pentoxifylline): increased risk of gastrointestinal bleeding and ulceration.
- Antidiabetic medicines (used to treat high sugar levels): low blood sugar effects of these medicines may be increased.
- Digoxin (used to treat heart failure and a fast heartbeat): increase in serum digoxin concentrations.

- Lithium: increase in the time during which the concentration of the medicine in the body remains stable or consistent.
- Methotrexate (used to treat rheumatoid arthritis, certain types of cancer and severe psoriasis): increased and prolonged methotrexate plasma concentration and increased risk of methotrexate toxicity.
- Antihypertensives (used to treat high blood pressure) or diuretics (water pills): reduction or reversal of the antihypertensive effect may occur.
- Bone marrow depressants: the low white blood cell count and/or low blood platelet count effects of these medicines may be increased.

LOTEM SUSPENSION with food and drink and alcohol

No known interactions with food and drinks.

LOTEM SUSPENSION should be taken/given 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 breastfeeding and fertility

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.

Driving and using machines

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

It is not always possible to predict to what extent LOTEM SUSPENSION 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 LOTEM SUSPENSION affects them.

3. How to take LOTEM SUSPENSION

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

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 over twelve years:

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/give 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 health care 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, leucopenia and pancytopenia). Fluid retention may occur.

- Nervousness, headache, ringing/buzzing noise in the ear(s), depression, drowsiness, sleeplessness.
- Blurred vision, changes in visual colour perception and other toxic amblyopia (damage to optic nerve).
- Crohn's disease (an inflammatory disease that can affect any part of the gastrointestinal tract causing symptoms such as pain, fever, diarrhoea and loss of body mass).
- Changes in the way your heart beats (beating faster), flushing, high blood pressure, and heart failure.
- Pancreatitis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease.
- 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).
- Hypersensitivity reactions fever, asthma and rashes. Other allergic reactions may be accompanied by fever and mucosal lesions.
- Hepatotoxicity.
- 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:

- 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).
- Nephrotic syndrome (excreting too much protein in the urine).
- Renal failure (kidney failure).

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 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. By reporting side effects, you can help provide more information on the safety of LOTEM SUSPENSION.

Side effects may also be reported 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: Paracetamol 250 mg and Ibuprofen 200 mg.

Preservative:

sodium benzoate 0,1 % m/v

The other ingredients are:

Banana flavour, citric acid anhydrous, colour spectracol quinoline yellow, disodium edetate, glycerol, light kaolin (low bioburden), polyethylene glycol, polyvinylpyrolidone 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 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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Namibia: NS1 04/2.8/1574

PASIËNT INLIGTINGSBILJET

SKEDULERINGSTATUS: **S2**

LOTEM SUSPENSION, 200 mg/250 mg

Ibuprofeen

Parasetamol

Bevat versoeters:

Natriumsakkarien	**12,40 mg**
Natriumsiklamaat	**90,00 mg**

Suikervry

Lees hierdie hele biljet noukeurig deur, want dit bevat belangrike inligting vir u

LOTEM SUSPENSION is beskikbaar sonder 'n doktersvoorskrif om 'n minder ernstige siekte te behandel. Nietemin moet u steeds LOTEM SUSPENSION versigtig gebruik om die beste resultate daaruit te verkry.

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Moenie LOTEM SUSPENSION met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.
- U moet 'n dokter spreek indien u simptome vererger of nie na 10 dae verbeter nie.

Wat is in hierdie biljet

1. Wat LOTEM SUSPENSION is en waarvoor dit gebruik word
2. Wat u moet weet voordat u LOTEM SUSPENSION neem/gee
3. Hoe om LOTEM SUSPENSION te neem/gee
4. Moontlike newe-effekte
5. Hoe om LOTEM SUSPENSION te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat LOTEM SUSPENSION is en waarvoor dit gebruik word

LOTEM SUSPENSION bevat Ibuprofeen wat behoort aan 'n groep medisyne wat na verwys word as nie-steroïed anti-inflammatoriese medisyne (NSAIMs), en parasetamol wat behoort aan 'n groep medisyne wat na verwys word as analgetika.

LOTEM SUSPENSION word gebruik vir koors en die verligting van ligte tot matige pyn.

2. Wat u moet weet voordat u LOTEM SUSPENSION neem

Moenie LOTEM SUSPENSION neem nie

- Indien u aktiewe herhalende bloeding / perforasies het, of geskiedenis daarvan het.
- Indien u hipersensitief (allergies) is vir ibuprofeen en parasetamol of enige van die ander bestanddele van LOTEM SUSPENSION (gelys in afdeling 6).
- Indien u verminderde lewer- en nierfunksie het.
- Indien u 'n maagseer of bloeding in die ingewande het, of gehad het.
- Indien u hartversaking het ('n chroniese toestand waar die hart nie bloed so goed pomp as wat dit moet nie).
- Indien u hipersensitief is vir aspirien of 'n klas medisyne wat gebruik word om inflammasie te behandel; ligte tot matige pyn; en koors.
- Indien u swanger is, moenie LOTEM SUSPENSION vanaf 30 weke van swangerskap gebruik nie, want dit kan nier- en hartprobleme by u ongebore baba veroorsaak.
- Indien u aan onbeheerde asma of bronchospasma ly, of al ooit 'n allergiese reaksie gehad het of aan hygende asemhaling gely het nadat u ibuprofeen, aspirien of enige ander anti-inflammatoriese pynstillers geneem het.
- Indien u aan swelling en irritasie in die neus ly.
- Indien u 'n toestand het wat u neiging om te bloei verhoog.

- Indien u bloedverdunnende medikasie neem.

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met LOTEM SUSPENSION:

- Indien u swanger is of van plan is om swanger te raak, raadpleeg u gesondheidsorgverskaffer voordat u LOTEM SUSPENSION neem. Die neem van NSAIMs tussen 20 en 30 weke van swangerskap kan u ongebore baba benadeel. Indien u NSAIMs deur u gesondheidsorgverskaffer voorgeskryf word wanneer u tussen 20 en 30 weke swanger is, moet u gesondheidsorgverskaffer dalk die hoeveelheid vloeistof in u baarmoeder rondom u baba monitor.
- Indien u NSAIMs deur u gesondheidsorgverskaffer voorgeskryf word wanneer u tussen 20 en 30 weke swanger is, beperk die gebruik van LOTEM SUSPENSION tot die laagste effektiewe dosis en kortste moontlike duur.
- Dosisse bo dié wat aanbeveel word, kan ernstige lewerskade veroorsaak.
- Gebruik versigtig in gevalle van alkoholisme of verswakte lewerfunksie as gevolg van die risiko van ernstige lewerskade.
- Indien u nier- of lewerprobleme het, insluitend dié as gevolg van die drink van te veel alkohol, aangesien u 'n groter risiko vir die newe-effekte van parasetamol kan hê.
- Gebruik versigtig indien u hartprobleme, waterretensie wat swelling of hoë bloeddruk veroorsaak.
- Gebruik by kinders, adolessente en bejaardes.
- Ibuprofeen moet gestaak word indien u versteurde of verminderde visie of veranderinge in kleurvisie ervaar. Indien u kollageensiekte het, kan u die risiko loop om aseptiese breinvliesontsteking (inflammasie van die breinvoerings) te ontwikkel.
- Indien u koors, veluitslag, swelling van die limfknope en/of swelling van die gesig ontwikkel. Dit staan bekend as Geneesmiddelreaksie met Eosinofilie en Sistemiese Simptome (GRESS).

- Indien u diabeet is en LOTEM SUSPENSION neem, kan dit u glukosetoetsuitslae beïnvloed.
- Indien u aan asma of bloedarmoede ly, kan u toestand vererger terwyl u LOTEM SUSPENSION neem.
- Vermy die neem van LOTEM SUSPENSION voor sjirurgie om verhoogde bloeding te voorkom.
- Staak die gebruik van LOTEM SUSPENSION met eerste teken van veluitslag, jeukerigheid, rooiheid of enige teken van hipersensitiwiteit.
- Indien u enige allergieë of allergiese reaksies het, of gehad het (insluitend galbulte, swelling van die gesig, lippe, tong en/of keel wat probleme met asemhaling of sluk kan veroorsaak) wat hospitaalbehandeling vereis.
- Indien u maklik bloei.
- Indien u gastro-intestinale probleme het (naarheid, braking, maagpyn, sooibrand, slegte spysvertering) en of maagsere(s).

Indien u 'n bejaarde persoon is. Bejaardes en pasiënte met 'n geskiedenis van maagsere is meer vatbaar vir newe-effekte wat die ingewande beïnvloed wanneer NSAIMs gebruik word. Daarom moet hulle noukeurig gemonitor word vir maagsere en bloeding, aangesien dit dodelik kan wees.

Kinders en adolessente

Veiligheid by kinders jonger as twee jaar is nie bewys nie.

Ander medisyne en LOTEM SUSPENSION

Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in).

LOTEM SUSPENSION moet nie geneem/gegee word nie, indien u die volgende neem:

- Anti-inflammatoriese middels (NSAIMs): die gebruik van twee of meer saam kan lei tot 'n toename in newe-effekte.
- Kortikosteroïede (gebruik om inflammasie te behandel): verhoogde risiko vir gastro-intestinale perforasie, ulserasie of bloeding in die ingewande.
- Bloedverdunner (bv. warfarien): LOTEM SUSPENSION kan die gevolge van bloedverdunning versterk wanneer dit saam met hierdie middels geneem word.
- Anti-bloedplaatjiemedisyne (medisyne wat gebruik word om bloedklonte te voorkom), en selektiewe serotonienheropname inhibeerders (SSHI's) (anti-depressant medisyne): verhoogde risiko van bloeding indien u aan maagsere ly.
- Hepatotoksiese medisyne (medisyne wat skade aan u lewer kan veroorsaak): verhoogde risiko van lewerskade.
- Ensiem-induserende medisyne (medisyne wat metaboliese tempo verhoog): verhoogde risiko van lewerskade en moontlike afname in terapeutiese effekte van parasetamol.
- Nefrotiese medisyne (bv. siklosporien wat u niere kan beskadig en die funksie van u niere kan benadeel): verhoogde risiko van nefrotoksisiteit.
- Metoklopramied (word gebruik om gevoelens van naarheid of vomering (braking) te verlig): absorpsie van parasetamol kan verhoog word.
- Cholestiramien (word gebruik om hoë cholesterol te behandel): absorpsie van parasetamol word verlaag indien dit binne een uur na cholestiramien gegee word.
- Alkohol, bloedplaatjie-medisyne (klopidogrel, tiklopidien), medisyne wat beenverlies vertraag of voorkom (bisfosfonate) en medisyne wat help met bloedvloei (pentoksifillien): verhoogde risiko vir gastro-intestinale bloeding en ulserasie.
- Antidiabetiese medisyne (wat gebruik word om hoë suikervlakke te behandel): lae bloedsuiker-effekte van hierdie medisyne kan verhoog word.

- Digoksien (gebruik om hartversaking en 'n vinnige hartklop te behandel): toename in serum-digoksienkonsentrasies.
- Litium: toename in die tyd waartydens die konsentrasie van die medisyne in die liggaam stabiel of konstant bly.
- Metotreksaat (word gebruik om rumatoïede artritis, sekere soorte kanker en ernstige psoriase te behandel): verhoogde en langdurige metotreksaat plasmakonsentrasie en verhoogde risiko van metotreksaat toksisiteit.
- Antihipertensiewe middels (wat gebruik word om hoë bloeddruk te behandel) of diuretika (waterpille): vermindering of omkering van die antihipertensiewe effek kan voorkom.
- Beenmurgdepressante: die lae witbloedseltelling en/of lae bloedplaatjietelling effekte van hierdie medisyne kan verhoog word.

LOTEM SUSPENSION saam met kos en drank en alkohol

Geen bekende interaksies met kos en drank nie.

LOTEM SUSPENSION moet na etes met voldoende water geneem/gegee word. Die gebruik van alkohol met LOTEM SUSPENSION moet vermy word aangesien dit die risiko van maagsere of gastro-intestinale bloeding verhoog.

Swangerskap en borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, dink u is dalk swanger of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u LOTEM SUSPENSION neem.

LOTEM SUSPENSION word nie aanbeveel vir gebruik deur swanger of borsvoedende vroue nie.

Bestuur en gebruik van masjinerie

Die effek op die vermoë om te bestuur en masjinerie te gebruik is nie vasgestel nie.

Dit is nie altyd moontlik om te voorspel in watter mate LOTEM SUSPENSION die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie. Pasiënte moet verseker dat hulle nie aan bogenoemde aktiwiteite deelneem voordat hulle bewus is van die mate waartoe LOTEM SUSPENSION hulle raak nie.

3. Hoe om LOTEM SUSPENSION te neem

Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.

Neem LOTEM SUSPENSION altyd presies soos beskryf in hierdie biljet of soos u dokter of apteker u ingelig het. Raadpleeg u dokter of apteker indien u nie seker is nie.

Gebruik die laagste effektiewe dosis vir die kortste moontlike duur van behandeling.

Moenie die aanbevole dosis oorskry nie.

Skud die bottel voor gebruik.

Volwassenes en kinders ouer as twaalf jaar:

Neem een tot twee medisynemate (5 tot 10 ml) vier-uurliks indien nodig en nie meer as ses medisynemate in vier-en-twintig uur nie, mondelings na etes.

Kinders:

2 tot 5 jaar: 2,5 ml tot 5 ml drie tot vier keer per dag, mondelings na etes.

6 tot 12 jaar: 5 ml tot 10 ml drie tot vier keer per dag, mondelings na etes.

Veiligheid by kinders jonger as twee jaar is nie bewys nie.

Raadpleeg u dokter indien geen verligting verkry word met die aanbevole dosis nie.

Indien u meer LOTEM SUSPENSION neem as wat u moes

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

Die mees waarskynlike simptome van oordosering sluit in bleekheid, naarheid, braking, anoreksie, buikpyn, akute nierversaking, epigastriese pyn en naarheid.

Indien u vergeet om LOTEM SUSPENSION te neem

Moenie 'n dubbele dosis neem/gee om vergete dosisse op te maak nie.

4. Moontlike newe-effekte

LOTEM SUSPENSION kan newe-effekte hê.

Nie alle newe-effekte wat vir LOTEM SUSPENSION aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u LOTEM SUSPENSIE neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van LOTEM SUSPENSION en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- Swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal.
- Veluitslag of jeukerigheid.
- Floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op LOTEM SUSPENSION gehad. U sal dalk dringende mediese hulp of hospitalisasie benodig.

Gereelde newe-effekte:

- Duiseligheid.

- Naarheid, maagpyn, braking, diarree, winderigheid, hardlywigheid, slegte spysvertering, maagulserasie, perforasie of bloeding, bloederige ontlasting, hematemese (waar u bloed braak) en gastritis (inflammasie van die voering van die maag).

Minder gereelde newe-effekte:

- Veranderinge in u bloedseltellings (agranulositose, trombositopenie, anemie, neutropenie, eosinofilie, leukopenie en pansitopenie). Vloeistofretensie kan voorkom.
- Senuweeagtigheid, hoofpyn, lui-/gonsgeluid in die oor(e), depressie, slaperigheid, slapeloosheid.
- Versteurde visie, veranderinge in visuele kleurpersepsie en ander toksiese ambliopie (skade aan optiese senuwee).
- Crohn se siekte ('n inflammatoriese siekte wat enige deel van die spysverteringskanaal kan beïnvloed, wat simptome soos pyn, koors, diarree en verlies aan liggaamsmassa veroorsaak).
- Veranderinge in die manier waarop u hart klop (vinniger klop), blosing, hoë bloeddruk en hartversaking.
- Pankreatitis, ulseratiewe stomatitis, verergering van kolitis en Crohn se siekte.
- Vergeling van u vel en oë, ook genoem geelsug of hepatitis.
- Nierprobleme, wat tot nierversaking kan lei (u kan minder of meer urien uitlaat, bloed in die urien of troebel urien hê, voel uitasem, baie moeg of swak, geen eetlus hê nie, of geswelde enkels hê).
- Hipersensitiwiteitsreaksies, koors, asma en veluitslae. Ander allergiese reaksies kan gepaard gaan met koors en slymvliesletsels.
- Hepatotoksisiteit.
- Aseptiese meningitis (infeksie rondom die brein of rugmurg met koors, naarheid, braking, hoofpyn, stywe nek en uiterste sensitiwiteit vir helder lig).

Newe-effekte met 'n onbekende frekwensie:

- Pynlike, blaasvormende of afskilferende veluitslag, soos Stevens-Johnson se sindroom, toksiese epidermale nekrolise of veelvormige eriteem.
- Interstisiële nefritis (meer of minder urien uitlaat as wat normaal vir u is, donker urien, naarheid, braking).
- Nefrotiese sindroom (uitskeiding van te veel proteïene in die urien).
- Nierversaking (nierversaking).

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte

Indien u newe-effekte ervaar, raadpleeg u dokter of apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en eAanmeldingsplatform (who-umc.org) wat op SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van LOTEM SUSPENSION te verskaf.

Newe-effekte kan ook aangemeld word by Adcock Ingram Limited deur die volgende e-pos te gebruik: Adcock.AEReports@adcock.com .

5. Hoe om LOTEM SUSPENSION te bêre

Hou alle medisyne buite bereik van kinders.

Bêre teen of benede 30 °C in diggeslote houers.

Beskerm teen lig.

Moenie in badkamers bêre nie.

Moenie gebruik ná die vervaldatum wat op die etiket vermeld word nie.

Moenie LOTEM SUSPENSION gebruik indien u enige sigbare tekens van agteruitgang opmerk nie.

Neem alle ongebruikte medisyne terug aan u aptekers.

6. Inhoud van die verpakking en ander inligting

Wat LOTEM SUSPENSION bevat

Elke 10 ml bevat:

Die aktiewe stowwe is: Parasetamol 250 mg en Ibuprofeen 200 mg.

Preserveermiddel:

Natriumbensoaat 0,1 % m/v

Die ander bestanddele is:

Piesanggeursel, watervrye sitroensuur, spektrakol kinolien geel kleursel, dinatriumedetaat, gliserol, ligte kaolien (lae biolas), poliëtileenglikol, polivinielpirolidoon K25, natriumsakkarien, natriumsitraat, natriumsiklamaat, natriumdiwaterstoffosfaatdihidraat, natriummetabisulfiet, xantangom.

Hoe LOTEM SUSPENSION lyk en inhoud van die verpakking:

LOTEM SUSPENSION is 'n geel, homogene suspensie met 'n piesanggeur.

Dit is verpak in 'n amberkleurige glasbottel van 100 ml en 200 ml.

Houer van Sertifikaat van Registrasie

Adcock Ingram Limited

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