PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S6

LOMETASAN 1 mg/mL oral solution

Methadone hydrochloride

Sugar free

Contains sweetener (0,4 mL maltitol liquid per 1 mL).

Read all of this leaflet carefully before you start using LOMETASAN.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LOMETASAN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LOMETASAN is and what it is used for

LOMETASAN contains methadone which belongs to a class of medicines called opioids and is used to prevent withdrawal symptoms following addiction to opioids.

LOMETASAN has been prescribed to you and should not be given to anyone else. Opioids can cause addiction, and you may get withdrawal symptoms if you stop taking it suddenly. Your doctor should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely. The treatment should be given at the same time as medical and psychological treatment and social rehabilitation.

2. What you need to know before you take LOMETASAN

Do not take LOMETASAN:

- If you are allergic to methadone hydrochloride or any of the other ingredients of LOMETASAN (listed in section 6).
- If you have any breathing difficulties (obstructive airways disease) or a history of asthma. You must not use LOMETASAN during an asthma attack. Wait until the asthma attack has passed and you are fully recovered before taking LOMETASAN.
- If you are dependent on alcohol.
- If you have or have recently had a head injury.
- If you are at risk of paralytic ileus (a condition in which the muscles of the intestines do not allow food to pass through, resulting in a blocked intestine).
- If you use or have used monoamine oxidase (MAO) inhibitors (medicines used in the treatment of depression, Parkinson's disease) within the last two weeks.
- If you are in labour (giving birth to a child).
- LOMETASAN should not be given to children.
- If you are dependent on non-opioid medicines (e.g. aspirin or paracetamol).
- If you have a phaeochromocytoma (a rare tumour that usually grows in your adrenal glands, above your kidneys).

Warnings and precautions

Taking LOMETASAN regularly, particularly for a long time, can lead to addiction.

Opioids should only be used by those they are prescribed for. Do not give LOMETASAN to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Before taking LOMETASAN, tell your doctor:

- if your liver or kidneys are not functioning properly.
- if you have low thyroid function (hypothyroidism).
- if you have enlargement of the prostate gland.
- if you have a head injury.
- if you are an elderly or ill person. You may be sensitive to LOMETASAN and may cause low blood pressure and fainting.
- if you have or have had a heart disease or irregular heartbeat.
- if you have a family history of sudden death.
- if you have weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. This may be a symptom of your adrenal glands producing too little of the hormone called cortisol, and you may need to take hormone supplement.
- if you have diabetes (low blood sugar). Regular monitoring of your blood sugar levels is recommended if your dose of LOMETASAN changes.
- if you have a history of seizures (fits) or convulsions.
- if you have low blood pressure.
- if you have bowel problems.
- if you have low sodium or potassium levels in your blood.
- if you are taking medicines that affects your heart rhythm.
- if you have any breathing difficulties, such as asthma, obstructive airways disease, respiratory depression (when you breathe too slowly or too shallowly, leading to carbon oxide building up in your blood [hypercapnia]) (see **Do not take LOMETASAN** above).

Long-term use may cause decreased sex hormone levels and increased levels of the hormone prolactin. Contact your doctor if you experience symptoms such as decreased libido, impotence or absence of menstruation (amenorrhea).

Children and adolescents

LOMETASAN is not intended to be used in children and adolescents under the age of 18 years.

Other medicines and LOMETASAN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).
Please consult with your doctor, pharmacist or health care provider for advice if you need to take any other medicines.

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

- Monoamine oxidase (MAO) inhibitors (used to treat mood disorders, such as depression). You should wait at least 2 weeks after stopping treatment before you start taking LOMETASAN.
- Medicines used to treat mental disorders.
- Medicines used to treat depression.
- Alcohol, as it may enhance the sedative effects of LOMETASAN.
- Cimetidine (used to reduce stomach acid production).
- Rifampicin (used to treat tuberculosis [TB]).
- Antibiotics such as ciprofloxacin or macrolide antibiotics, such as clarithromycin or erythromycin (used to treat certain bacterial infections).
- Azole antifungal medicines, such as ketoconazole, voriconazole or fluconazole (used to treat fungal infections).
- Phenytoin, carbamazepine, phenobarbital and primidone (used to treat epilepsy).

- Medicines that make your urine acidic, such as ascorbic acid (vitamin C).
- Strong painkillers such as morphine, codeine and pentazocine.
- Naloxone (used to reverse the effects of opioid medicines).
- Naltrexone and buprenorphine (used to block the effect of opioid medicines).
- Antiretroviral medicines, such as nevirapine, efavirenz, abacavir, ritonavir, amprenavir, zidovudine, nelfinavir, didanosine and stavudine (used to treat human immunodeficiency virus [HIV] infection). The doctor may have to change the dose of LOMETASAN if you are taking these medicines.
- Cyclizine, domperidone and metoclopramide (used to treat nausea and vomiting).
- Loperamide or diphenoxylate (used to treat diarrhoea).
- Mexiletine (used to treat unusual heart rhythms).
- Medicines for heart problems, such as verapamil and quinidine.
- Medicines which affect the electrolyte balance, such as diuretics (water tablets e.g. spironolactone).
- St John’s wort (a herbal preparation used for mild depression).
- Grapefruit juice.
- Medicines to help you sleep (including anaesthetics) and medicines to calm you down called tranquillisers. The use of LOMETASAN and sedative medicines such as benzodiazepines or related medicines increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. If your doctor does prescribe LOMETASAN together with sedative medicines, the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking and follow your doctor’s dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

LOMETASAN with drink and alcohol

Do not drink alcohol while taking LOMETASAN. LOMETASAN can make you drowsy and drinking alcohol will make you even more drowsy.

Grapefruit juice may affect how LOMETASAN works. Do not drink grapefruit juice with LOMETASAN.

Pregnancy and breastfeeding

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 you take LOMETASAN.

Do not take LOMETASAN if you are pregnant or breastfeeding.

Driving and using machines

LOMETASAN can severely affect your ability to drive or use machines as it may make you sleepy or dizzy. You should only start doing these activities again with the permission of your doctor.

Do not drive while taking LOMETASAN until you know how it affects you.

LOMETASAN contains maltitol liquid, sodium benzoate and Sunset Yellow FCF

- Maltitol liquid. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this LOMETASAN.
- Sodium benzoate (E211). This medicine contains 1 mg sodium benzoate in each mL.
- Sunset Yellow FCF (E110). May cause allergic reactions.

3. How to take LOMETASAN

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

exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults

The usual dose for addiction is 20 mg once daily.
Your doctor will increase the dose over three weeks until you feel well and do not have withdrawal symptoms. The final dose is usually between 60 mg and 120 mg in 24 hours.

If you are elderly or very ill, you should be careful when taking repeated doses. If you suffer from impaired liver function, hypothyroidism or prostatic hypertrophy, your doctor may prescribe a lower initial dose.

Your doctor will tell you how long your treatment with LOMETASAN will last. Do not stop treatment early.
If you have the impression that the effect of LOMETASAN is too strong or too weak, talk to your doctor or pharmacist.

If you take more LOMETASAN than you should

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

The signs you may notice are difficulty in breathing; feeling very drowsy which may lead to a stupor or coma; very small pupils; cold and clammy skin; a very slow pulse rate; low blood pressure and muscle weakness. In extreme cases, you may stop breathing, your blood flow may stop, you may have a heart attack which could lead to death.

If you forget to take LOMETASAN

If you forget a dose do not take it. Wait until the next dose is due and take only that amount. Do not take a double dose to make up for a forgotten individual doses.

If you stop taking LOMETASAN

Do not suddenly stop taking LOMETASAN. If you want to stop taking LOMETASAN, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking LOMETASAN.

4. Possible side effects

LOMETASAN can have side effects.

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

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

- swelling of your hands, feet, ankles, face, lips, 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 LOMETASAN. 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:

- Heart problems. The signs of this may include changes in the way your heart beats, such as it is beating faster or slower, missed heart beats, breathing difficulties and dizziness,
- Your breathing becomes slow and shallow.
- You have asthma and it gets worse.

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:

- feeling sick (nausea) or being sick (vomiting),
- feeling weak, tired,
- weight gain,
- water retention,
- constipation,
- rash, that may appear and disappear,
- sweating a lot more than usual,
- blurred vision, small pupils, dry eyes,
- feeling of dizziness, spinning sensation,
- confusion, feeling “high” or over excited, feeling drowsy, sleep disturbances,
- seeing or hearing things that are not there (hallucinations),
- lower sexual urge or desire,
- headache.

Less frequent side effects:

- feeling dizzy, particularly when standing up. This may be a sign that you have low blood pressure,

- feeling down (dysphoria), agitation, difficulty sleeping,
- itching, rashes,
- dry mouth or nose, inflammation of the tongue,
- facial flushing,
- difficulty in passing urine,
- low body heat (hypothermia),
- addiction to this medicine,
- build-up of fluid in the lungs,
- menstrual cramps (dysmenorrhoea) or absence of menstruation (amenorrhoea), breast discharge (galactorrhoea),
- low potassium and magnesium which will be found by blood tests,
- reduced thyroid function (hypothyroidism),
- swollen arms and legs. This may be a sign of your body retaining more water than usual,
- disorder of the biliary part of the digestive system (bile duct dyskinesis).

Frequency unknown:

- reduction in blood platelets, which increase the risk of bleeding or bruising,
- high prolactin levels in the blood (which may cause the breasts to grow and produce breast milk),
- rapid, uncontrollable movements of the eyes,
- dependence and addiction,
- sleep apnoea (breathing pauses during sleep).

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 via the

Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of LOMETASAN.

5. How to store LOMETASAN

- Store at or below 30 °C.
- Protect from light.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the bottle/carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LOMETASAN contains

The active substance is methadone hydrochloride.

The other ingredients are D&C Yellow (E104), Green S (E142), hydrochloric acid (pH adjuster), maltitol liquid, purified water, sodium benzoate (preservative) and Sunset Yellow FCF (E110).

What LOMETASAN looks like and contents of the pack

LOMETASAN is a green coloured solution.

100 mL white rectangular HDPE bottle with a transparent window and a white PP screw cap with an induction wad.

500 mL white rectangular HDPE bottle with a transparent window and a white PP screw cap with an induction wad.

Holder of the certificate of registration

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