PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PENILENTE LA 1,2 MU, Powder for suspension for injection

PENILENTE LA 2,4 MU, Powder for suspension for injection

Benzathine benzylpenicillin

Sugar free

Read all of this leaflet carefully before you are given PENILENTE LA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What PENILENTE LA is and what it is used for
2. What you need to know before you use PENILENTE LA
3. How to use PENILENTE LA
4. Possible side effects
5. How to store PENILENTE LA
6. Contents of the pack and other information

1. What PENILENTE LA is and what it is used for

PENILENTE LA is used for the treatment of infections caused by organisms sensitive to the active ingredient of PENILENTE LA;

- Streptococcal pharyngitis (sore throat);
- Syphilis of less than 1 year duration;

- Uncomplicated cases of erysipeloid (an infection of the upper or outer skin and underlying layers);
- Prophylactic (preventative) use: recurrence of rheumatic fever.

2. What you need to know before you use PENILENTE LA

PENILENTE LA should not be administered to you if:

- You are hypersensitive (allergic) to **penicillin or cephalosporins** or any of the other ingredients of PENILENTE LA (listed in section 6);
- PENILENTE LA must not be given to babies born to mothers who are allergic to penicillin during the neonatal period;
- you have an inflammation of the inner layer of the heart (endocarditis);
- you have inflammation of the peritoneum (peritonitis), the thin tissue that lines the inner wall of the abdomen and covers most of the abdominal organs;
- you have acute inflammation of the protective membranes covering the brain and spinal cord (meningitis).

PENILENTE LA should not be injected into any of your veins.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

- If you have a history of allergic reaction to medicines containing penicillin, cephalosporin or other beta-lactam medicines;
- you have kidney disease (renal impairment), because of the risk of neurotoxicity (nerve toxicity);
- you have liver problems;
- you have congestive heart failure (heart failure).

PENILENTE LA should not be used in tissues with poor blood flow.

Serious and sometimes fatal allergic reactions are more likely to occur in patients with a history of penicillin allergy or other allergies. If you have a penicillin allergy, you may develop anaphylactic shock (e.g., skin rash, itching, swelling, difficulty to breath) and need to be treated immediately. Hypersensitivity reactions can also progress to Kounis syndrome, a serious allergic reaction that can cause a heart attack.
Before treatment, a hypersensitivity test should be performed if possible. If an allergic reaction occurs, your doctor will stop your treatment and, if necessary, start appropriate therapy.

If you have already been diagnosed with an allergy and/or allergic asthma or hay fever, you should tell your doctor. Severe immediate allergic reactions are possible even when the medicine is administered for the first time.
Based on general principles, in some cases you will remain under observation for at least half an hour after the medicine has been administered in case an acute allergic reaction should occur. If an allergy occurs, the doctor will take appropriate measures. Treatment with PENILENTE LA must be stopped immediately.

When treating syphilis, a reaction to the bacterial toxins may occur, which lasts up to several days (Jarisch-Herxheimer reaction, see section 4).
This reaction can be dangerous in cardiovascular syphilis (syphilis affecting your heart and blood vessels) or where there is a serious risk of increased damage to your organs such as involvement of the nerve of the eye (optic atrophy). Typical symptoms are sudden fever (sometimes with chills), pale skin; followed by skin redness, headache, painful muscles and joints or tiredness.
To suppress or alleviate a Jarisch-Herxheimer reaction, your doctor will start appropriate therapy.

In long-term treatment (more than a single dose), your doctor may arrange for checks on your blood count and liver and kidney function tests. Please make sure that you attend the check-ups prescribed by the doctor.

Injection of PENILENTE LA may result in a non-allergic clinical syndrome (Hoigné syndrome), inform your doctor or healthcare provider if you experience any of the following symptoms:

- Symptoms of shock;
- a feeling of worry (anxiety);
- the state of feeling irritated or restless (agitation);
- loss of contact with reality that may cause you to you think you are seeing or hearing things (hallucinations);
- fits (seizures);
- increased heart rate (tachycardia) and increased blood pressure (hypertension);
- cyanosis (blue discolouration of skin and mucous membranes);
- a sensation of impending death or symptoms of mortal fear;
- motor disorders (although no circulatory collapse).

This reaction may be due to accidental injection of PENILENTE LA into one of your veins.

Disturbances of blood electrolytes may follow the administration of large doses of PENILENTE LA.

As with other antibiotics, therapy with PENILENTE LA may also lead to the overgrowth of other organisms. Contact your doctor if you get other bacterial or fungal infections.

During treatment with antibiotics, including PENILENTE LA, diarrhoea may occur, even several weeks after you stopped your therapy. In case of severe or persistent diarrhoea, or if you notice that your stools contain blood or mucus, contact your doctor immediately. The therapy with PENILENTE LA must be stopped immediately, as it can be life-threatening. Do not take any medications which stop or slow down the bowel movements.

Pain may be experienced at the site of injection. Ice packs help in such cases.

The following complications can occur if PENILENTE LA is accidentally injected into an artery, especially in children: blockage of the blood vessel, blood clots or gangrene (death of blood tissue due to lack of blood flow). Initial symptoms are pale patches in the skin area of injection site.

If you are to receive repeated injections, each injection should be administered a large distance from the preceding injection.

An effect on laboratory test results should also be considered (see also section 4).

Other medicines and PENILENTE LA

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

PENILENTE LA should not be administered with other bacteriostatic antibiotics (acts by supressing the growth of bacteria e.g., clindamycin and chloramphenicol).

Caution should be exercised when administering PENILENTE LA at the same time as the following medicines:

- Probenecid, a medicine used to treat gout or hyperuricaemia (high uric acid);
- methotrexate, a medicine used in chemotherapy. The combination with methotrexate is not recommended;
- anticoagulants, medicines used to thin your blood or prevent your blood from clotting, such as aspirin or warfarin.

Pregnancy, 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 healthcare provider for advice before receiving PENILENTE LA.

Safety and/or efficacy during pregnancy and lactation have not been established.

You should not receive PENILENTE LA if you are pregnant or breastfeeding your baby.

No fertility studies have been conducted in humans.

Driving and using machines

PENILENTE LA can impair responsiveness and the ability to drive. Due to the occurrence of possible serious side effects (e.g., anaphylactic shock with collapse and allergic-like reactions (e.g., stomach upsets), see section 4), PENILENTE LA can have a major influence on the ability to drive and use machines.

It is not always possible to predict to what extent PENILENTE LA may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machinery until you are aware of the measure to which PENILENTE LA affects you.

PENILENTE LA contains soya lecithin and sodium

PENILENTE LA contains phospholipids from soya lecithin. If you are allergic to peanut or soya, do not use this.

This medicine contains less than 1 mmol sodium (23 mg) per vial, i.e., essentially 'sodium-free'.

3. How to use PENILENTE LA

You will not be expected to give yourself PENILENTE LA. It will be given to you by a person who is qualified to do so.

Your doctor will tell you how long your treatment with PENILENTE LA will last.

If you have the impression that the effect of PENILENTE LA is too strong or too weak, tell your doctor or pharmacist.

PENILENTE LA is for **INTRAMUSCULAR USE ONLY**.

You will be administered PENILENTE LA by deep injection into a muscle once a month.

PENILENTE LA must NEVER be injected into your veins.

If you receive more PENILENTE LA than you should

Since a healthcare professional will administer PENILENTE LA, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use PENILENTE LA

Since a healthcare provider will administer PENILENTE LA it is unlikely that the dose will be missed.

4. Possible side effects

PENILENTE LA can have side effects.

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

If any of the following happens, stop using PENILENTE LA 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;
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Fungal infection (candidiasis);
- inflammation of the blood vessels (vasculitis).
- diarrhoea; nausea;
- inflammation of the lining of the mouth (stomatitis) and of the tongue (glossitis);
- being sick (vomiting);
- changes in certain test and investigation results performed by your doctor.

Less frequent side effects:

- Certain blood disorders (so called leukopenia, thrombocytopenia, agranulocytosis);
- sore mouth or tongue and black, hairy tongue;
- kidney disease (nephropathy);
- kidney inflammation (interstitial nephritis).

Side effects with unknown frequency:

- A blood disorder in which red blood cells are destroyed faster than they can be made (haemolytic anaemia);
- an abnormally low count of a type of white blood cell (neutrophils), called neutropenia, prolongation of bleeding time, defective blood platelet function;
- serum sickness (when antigens (substances that trigger an immune response) in certain medications and antiserums cause your immune system to react);
- antibiotic-associated diarrhoea caused by inflammation of the colon/ large intestines (pseudomembranous colitis);
- heartburn;
- liver inflammation (hepatitis);
- impairment of bile flow (cholestasis);
- increases in liver enzymes;

- rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease);
- pain at the injection site;
- injection site infiltrates;
- penicillin psychosis (Hoigné and Nicolau Syndrome);
- some patients with syphilis and other spirochaete infections may have a Jarisch-Herxheimer reaction shortly after starting treatment with PENILENTE LA. Symptoms can include fever, chills, headache, and reactions at the site of the lesions. (see section 2).

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

5. How to store PENILENTE LA

- Store all medicines out of reach of children.
- Store in a cool, dry place.
- Store at or below 25 °C.
- Suspensions must be used within 4 weeks when stored at or below 25 °C.
- PENILENTE LA should not be administered after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
- Any PENILENTE LA which is left over, not used or has passed its expiry date will be disposed of by hospital staff.
- Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What PENILENTE LA contains:

The active substance is benzathine benzylpenicillin.

PENILENTE LA 1,2 MU contains ± 1 111,11 mg benzathine benzylpenicillin per vial.

PENILENTE LA 2,4 MU contains ± 2 222,22 mg benzathine benzylpenicillin per vial.

After reconstitution each dose of 2 mL suspension contains 600 000 units benzathine benzylpenicillin.

The other ingredients are lecithin, polysorbate 80. As buffer: Sodium citrate 9,23 % *w/w*.

What PENILENTE LA looks like and contents of the pack

Dry: White powder

Reconstituted: White uniform suspension after mild agitation

PENILENTE LA 1,2 MU (Powder for suspension for injection) - 10 x 10 mL vials containing a white powder which after reconstitution yields a 4 mL suspension.

PENILENTE LA 2,4 MU (Powder for suspension for injection) - 10 x 10 mL vials containing a white powder which after reconstitution yields a 8 mL suspension.

Holder of Certificate of Registration

Biotech Laboratories (Pty) Ltd.

Block K West, Central Park

400 16th Road, Halfway House

Midrand

1685

Tel: (011) 848 3050

This leaflet was last revised in

31 January 2025.

Registration number

PENILENTE LA 1,2 MU: A/20.1.2/435

PENILENTE LA 2,4 MU: A/20.1.2/823