

Direct Healthcare Professional Communication (DHPC)**PENILEVEL (Sodium Benzylpenicillin): Presence of Foreign Language on the Outer Packaging and Package Leaflet of a Specific Batch**

Date: 08/06/2026

Dear Healthcare Professionals,
Greetings,

This information is being communicated by ERN Laboratories, S.A. in agreement with the Saudi Food and Drug Authority (SFDA).

With reference to a quality report received regarding the packaging and leaflet language of PENILEVEL (Sodium Benzylpenicillin), and following review of the affected batch information, we would like to inform you of the following:

Summary:

- It has been reported that the outer packaging and internal leaflet of the affected batch include information in a foreign language.
- To ensure clarity of information for healthcare professionals and safe and effective use of the product, the English Patient Information Leaflet is provided in Annex 1 of this DHPC.
- Based on the information received, an English sticker is available on the pack and the English leaflet is supplied with each delivery.

Further information on the Safety concern and recommendations:

- The issue relates to the availability and clarity of product information due to the presence of foreign-language information on the outer packaging and internal leaflet of the affected batch.
- No new safety concern has been identified from this quality notification. The purpose of this communication is to ensure that healthcare professionals have access to the English leaflet and the required product information.
- The English Patient Information Leaflet is attached in Annex 1 and should be used as the reference for product information for the affected batch.



Recommendations:

- All healthcare professionals are kindly requested to refer to the English version of the Patient Information Leaflet provided in Annex 1 to ensure that all necessary information is clearly communicated for safe and effective use.
- Healthcare institutions are requested to ensure that the English leaflet is available to relevant healthcare professionals handling or administering the affected batch.
- If you require more details regarding this batch, please contact Delta international medical company at 0507485930 or via email at regulatory.affair@delta-me.com.
- If you notice any packaging or leaflet with unclear or missing information for any other batch, please report it immediately to the SFDA reporting system: <https://ade.sfda.gov.sa/Home/Report>.

Attachments:

Please refer to the Patient Information Leaflet provided in Annex 1.

Call for Reporting

If you experience any adverse events or have concerns related to PENILEVEL, please report via:

- **Local company contact:** Delta international medical company, Tel: 0507485930, Email: regulatory.affair@delta-me.com
- **National Pharmacovigilance Center (NPC) - Saudi Food & Drug Authority (SFDA):** Call Center: 19999, Email: npc.drug@sfda.gov.sa, Website: <https://ade.sfda.gov.sa>

We appreciate your commitment to patient safety and quality care, and we thank you for your continued cooperation.

Sincerely,

Delta international medical Company

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.



DELTA INTERNATIONAL Medical & Pharmaceutical Company

ANNEX 1**Package leaflet: information for the user****PENILEVEL****Sodium Benzylpenicillin**

600,000 IU / 1,000,000 IU / 2,000,000 IU / 5,000,000 IU / 10,000,000 IU

Read this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others, even if their symptoms are the same as yours. It may be harmful.
- If you get any side effects, including any not listed in this leaflet, talk to your doctor, pharmacist, or nurse.

Contents of this sheet:

- 1. What is PENILEVEL and what is it used for?
- 2. What you need to know before using PENILEVEL
- 3. How to use PENILEVEL
- 4. Possible side effects
- 5. How to store PENILEVEL
- 6. Package contents and other information

1. What is PENILEVEL and what is it used for?

PENILEVEL contains the active substance Sodium Benzylpenicillin, an antibiotic belonging to the penicillin group.

INDICATIONS:

Infections caused by Gram-positive microorganisms such as:

- Pneumonia, pleuritis, and meningitis due to pneumococcus.



- Tonsillitis, pharyngitis, otitis media, acute sinusitis, scarlet fever, pneumonia, lung abscess, puerperal fever, septicemia, and endocarditis due to streptococcus.
- Bronchopneumonia, osteomyelitis, septicemia, empyema, lung abscess, acute enterocolitis, septic abortion, subacute endocarditis, and meningitis due to non-penicillinase-producing staphylococci.
- Gonorrhea and its genitourinary complications due to gonococcus.
- Meningococcal meningitis, gas gangrene, diphtheria, and tetanus.
- Stomatitis and Vincent's angina caused by spirochetes, actinomycosis caused by actinomycetes, and syphilis caused by Treponema pallidum.
- As a prophylactic in well-established indications.

2. What you need to know before using PENILEVEL

Do not use PENILEVEL:

- If you are allergic to penicillin.

Warnings and precautions:

- Should be administered with caution in patients allergic to cephalosporins and in those with a prior history of allergies, primarily to medications.

Incompatibilities:

- Bacteriostatic antibiotics.

Interactions:

- Benzylpenicillin sodium is inactivated in glucose serum.

3. How to use PENILEVEL

Always use this medicine exactly as your doctor, pharmacist, or nurse has told you. The dosage and frequency must always be determined by the physician, who will assess the severity of the condition being treated and the route of administration: intramuscular, intravenous, or by adding it to intravenous solutions for drip infusion.

ADULTS:

- **By intramuscular route:** The usual therapeutic dose is 1,000,000 IU every 6 hours.
- **By intravenous route:** The usual therapeutic dose is 1,000,000 IU every 4 hours.
- **In physiological saline for drip infusion:** The usual therapeutic dose is 10-100 million IU daily.

CHILDREN:

- The dose will vary depending on age and body weight. In general, the usual dose will be calculated considering that the above doses are for a 60 kg adult.

INSTRUCTIONS FOR THE CORRECT ADMINISTRATION OF THE PREPARATION:



- PENILEVEL can be administered intramuscularly or intravenously, either directly or by dilution in IV drip sets.
- For intravenous administration of PENILEVEL, it is advisable to adjust the concentration of the injectable to 1,000,000 IU per 4 ml, diluting, if necessary, with sterile, pyrogen-free water for injection, and inject slowly.
- For administration of PENILEVEL in IV drip sets, the most appropriate dilution is up to 10,000,000 IU per 100 ml of physiological saline.
- Note: The solubility of PENILEVEL allows concentrations of approximately 1,000,000 IU per ml to be achieved.

OVERDOSE AND ITS TREATMENT:

- Since the toxicity of PENILEVEL is extremely low, it is very unlikely that an overdose will occur, in which case symptomatic treatment would be applied.
- In the event of symptoms of drug allergy (urticaria, angioedema, asthma attack, or even anaphylactic shock), treatment with soluble corticosteroids, adrenaline (1/1000 mg), aminophylline, and antihistamines is recommended.
- In case of overdose or accidental ingestion, consult the National Poison Control Center.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- Allergic hypersensitivity reactions manifested by urticaria, angioedema, asthma attack, and anaphylactic shock.
- After a few days, rashes and fever may occur, and even leukopenia, purpura, and neutropenia. Herxheimer reaction.
- Pain, induration, or peripheral nerve disorders with intramuscular administration.
- At high doses and via intravenous administration, it may cause CNS irritation.

5. How to store PENILEVEL

- **MEDICINES SHOULD BE KEPT OUT OF THE REACH AND SIGHT OF CHILDREN.**
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

6. Package contents and other information

What PENILEVEL contains:

- **Active substance:** Sodium Benzylpenicillin (600,000 IU / 1,000,000 IU / 2,000,000 IU / 5,000,000 IU / 10,000,000 IU)
- **Excipient:** Water for injection.



PRESENTATIONS & REGISTRATION NUMBERS:

Strength	Presentation Details	Registration No.
600,000 IU	with a 4 ml ampoule of water for injection	Reg. No. 33.579
1,000,000 IU	with a 4 ml ampoule of water for injection	Reg. No. 33.580
2,000,000 IU	with a 4 ml ampoule of water for injection	Reg. No. 43.504
5,000,000 IU	with one 10 ml ampoule of water for injection	Reg. No. 41.245
10,000,000 IU	with one 10 ml ampoule of water for injection	Reg. No. 48.882

PRESCRIPTION REQUIRED

Marketing Authorization Holder and Manufacturer:

ERN LABORATORIES, S.A.

Peru, 228-08020 Barcelona 2013 seq.333

Local Representative:

Delta International Medical Company

