PART III: CONSUMER INFORMATION

PRE-PEN®

Benzylpenicilloyl Polylysine Injection

This leaflet is part III of a three-part "Prescribing Information" published when PRE-PEN® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PRE-PEN®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
PRE-PEN® is a skin test for the diagnosis of penicillin allergy.

What it does:
In penicillin allergy, people can react to different parts of the penicillin molecule. These parts are named major determinants and minor determinants based on the frequency of reactions to the different parts. Testing to the major determinant is done using PRE-PEN®. PRE-PEN® reacts specifically with skin sensitizing antibodies to produce redness and swelling. This may indicate an increased risk of allergic reactions to penicillin therapy.

When it should not be used:
If you have previously experienced a general or marked skin reaction to PRE-PEN® or if you are extremely hypersensitive to penicillin you should not be skin tested with PRE-PEN®.

What the medicinal ingredient is:
Benzylpenicilloyl-polylysine

What the nonmedicinal ingredients are:
Sodium Chloride, Sodium Hydroxide, Sodium Phosphate Monobasic, Water for Injection

What dosage forms it comes in:
0.25 mL ampule containing: 6 x 10^{-5} M of benzylpenicilloyl sterile solution.

WARNINGS AND PRECAUTIONS

BEFORE you use PRE-PEN® talk to your doctor or pharmacist if:

- You or someone in your family has intolerance to penicillin or other antibiotics in the past. In this case you should only be given PRE-PEN® before using penicillin treatment or if you have a known intolerance to penicillin.
- You are extremely hypersensitive to penicillin
- You are taking any medications that will interact with this product.
- You are pregnant or trying to get pregnant
- You are nursing (breastfeeding)
- You are younger than 12 or older than 65 years old

Rarely, a systemic allergic reaction (rash, hives, swelling of the face, throat, lips, difficulty swallowing or breathing, drop of blood pressure) may follow a skin test with PRE-PEN®. To decrease this risk a scratch/puncture skin test should be performed first by your health care provider. The full intradermal skin testing should be performed only if the scratch/puncture test is entirely negative (does not react).

A negative test result with PRE-PEN does not guarantee that you will not have an allergic reaction to penicillin.

A positive test result with PRE-PEN means that you have a greater risk of allergic reaction to penicillin. Your doctor will decide if penicillin is the appropriate treatment for you.

INTERACTIONS WITH THIS MEDICATION

BEFORE you use PRE-PEN® talk to your doctor or pharmacist if are taking any other drug especially:

- antihistamines (allergy medication)
- vasopressors (medications that constrict the blood vessels)

PROPER USE OF THIS MEDICATION

Due to the risk of potential systemic allergic reactions, skin testing should be performed in an appropriate healthcare setting under direct medical supervision.

PRE-PEN® is supplied in ampules for single-use administration.

Usual dose:

Scratch test – a drop of PRE-PEN®.

Intradermal test – not more than 0.03 mL of PRE-PEN® intradermally.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Occasionally, PRE-PEN® may cause a red, itchy, local inflammatory response at the skin test site or hives.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek Immediate Emergency Medical Attention
		Only if severe	In all cases	
Uncommon	Allergic Reaction: facial swelling, itchiness, and difficulty swallowing or breathing			✓
	Low blood pressure; light headedness, dizziness			✓

This is not a complete list of side effects. For any unexpected effects while taking PRE-PEN®*, contact your doctor or pharmacist.*

HOW TO STORE IT

PRE-PEN® must be stored at 2° to 8° C. If left at room temperature for more than 24 hours PRE-PEN® should be discarded. Do not use PRE-PEN® after the expiration date shown on the ampule label. PRE-PEN® should be discarded if particulate matter, precipitate, haziness, leakage or discoloration is present.

MORE INFORMATION

This document plus the full prescribing information, prepared for health professionals can be found at:
http://www.alk-abello.com/ca/products/pre-pen
or by contacting the sponsor, ALK-Abelló Inc
at: 1-800-325-7354

This leaflet was prepared by ALK-Abelló Inc

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REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701D
    Ottawa, ON K1A 0K9

  Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of the side effects, please contact your health professional. The Canada Vigilance Program does not provide medical advice.

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