

# Penase



20ml



## THE PRODUCT

**Penase concentrate** is a highly purified enzyme-based product specifically designed for the inactivation of Penicillins. The product does not contain animal derivatives thus is TSE/BSE free and is non-toxic. **Penase concentrate** has been processed in aseptic condition and the product is certified as a sterile product as it has passed a sterility test. The process has not been validated to the level required for an injectable drug.

Before use or preparation observe the product for signs of deterioration. The recommendation of CFR 436 Subpart B, "Sterility Test Methods" should be followed, i.e. "Prior to use, or at the time of test, a representative number of the tubes containing added penicillinase are incubated at 30°-32°C for 24 to 48 hours and are examined for sterility".

## FORMULATION AND PACK SIZE

**Penase concentrate** is available in the following pack size in glass vials with flip-off cap:

### Pack size

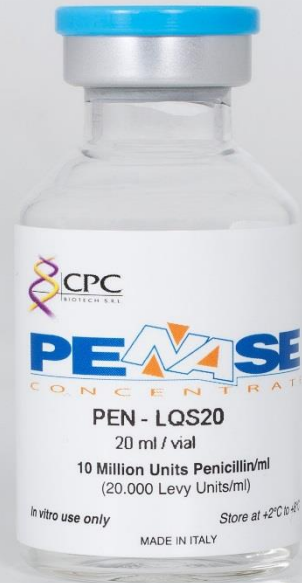
– cod. 6 PEN-LQS20: pack of 6 x 20 ml bottle

### Potency

20,000 Levy Units/ml/min  
equivalent to 10,000,000 IU Pen G/ml

## APPLICATION

**Penase concentrate** is a product specifically designed for the inactivation of penicillins, thus finds its application in beta-lactams (Penicillins) sterility testing (either environmental and antibiotics sterility testing). **Penase concentrate** can be used for the inactivation of beta-lactams from blood or tissue sample prior to routine microbiological examination. For this last application **Penase concentrate** is intended only for IVD manufacturer.



## USAGE

**Penase concentrate** is an optimized ready to use solution that can be directly added to the test samples. The amount of product to be added to the test sample should be determined and set-up case by case depending on the application, concentration of antibiotic that should be inactivated, and depending on the specific beta-lactam that should be inactivated.

Before to sample the product disinfect the cap septum with a suitable disinfectant.

## PRECAUTION

**Penase concentrate** is intended for in vitro use only.

## STABILITY OF REAGENTS

**Penase concentrate** has a stability of 48 months from manufacturing date. The product should be stored at +2°C/+8°C.

## ADDITIONAL INFORMATION

**Penase concentrate** DOES NOT CONTAIN ANIMAL DERIVATIVES and it's certified as a TSE/BSE free product.



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