▼Benepali® (etanercept): Brief training on additional Risk Minimisation Measures

Slide Deck for Healthcare Professional (HCP) Training

Version 4: March 2019

Benepali ® (etanercept)

- This medicine is subject to additional monitoring. Reporting suspected adverse events or reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse events or reactions via the national reporting systems below.

Reporting of side effects

You can report side effects directly via:

Malta

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to;

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000

E: postlicensing.medicinesauthority@gov.mt

*As per applicable national guidance

Training agenda

- Background
- Training objectives
- Educational materials for HCPs
- Resources available to HCPs for training purposes
- Overview of additional Risk Minimisation Measures (RMMs)
- Patient Alert Card
- Resources for patients
- References

Background

- Benepali is a biosimilar medicinal product. Detailed information is available on the website of the European Medicines Agency http://www.ema.europa.eu.
- In line with other etanercept products, Benepali educational materials are to be implemented as part of the additional Risk Minimisation Measures (aRMMs)
- Benepali solution for injection is available in
  - A prefilled PEN (PFP)
  - A prefilled SYRINGE (PFS)

Training objectives

- Training on important additional risk minimisation information for HCPs
  - Prevent pediatric off-label use in children and adolescents weighing less than 62.5kg
  - Prevent or reduce medication errors for pre-filled pen and pre-filled syringe

Educational materials for HCPs

- This educational training material provides additional information essential for ensuring the safe and effective use of the product and appropriate management of the important selected risks and therefore it is advised to be read carefully before prescribing/dispensing/administering the product.

- The information in this slide deck does not replace the full prescribing information in the Summary of Product Characteristics (SmPC), which should be read and understood before prescribing Benepali.

Training resources available to HCPs

Basic Training (Risk Minimisation)

Product information

- **SmPC**
- **Patient Information Leaflet**
- **Label**
- **Patient alert card (PAC) [contained in the product pack]**

Specific Training for additional RMMs

- **Slide deck for training of HCPs**

- **Quick Reference Guide (PFP)**
- **Quick Reference Guide (PFS)**

- **Training Pen**

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Summary of RMM training

Prevent Pediatric Off-Label Use

- Benepali is not approved for use in children and adolescents weighing less than 62.5 kg
- Benepali is only available at a dose which is suitable for use in children and adolescents weighing 62.5 kg or more
- Paediatric patients who require a dose other than the available full fixed dose should not receive Benepali.
- Other etanercept products suitable for children weighing less than 62.5 kg are available

Prevent/Reduce Medication Errors for the Pre-filled Pen and Pre-filled Syringe

- Patients are to be trained by the HCP using the **Training Pen**
- The **Quick Reference Guide (PFP)** and the **Quick Reference Guide (PFS)** provide step-by-step illustrated instructions how to handle and inject with the Benepali pre-filled pen and Benepali pre-filled syringe, respectively.

Patient Alert Card (PAC)

- HCPs are reminded that patients will also receive a PAC, located inside the Benepali box, which provides important safety information about:
  - The risk of opportunistic infections and tuberculosis (TB)
  - The risk of congestive heart failure (CHF)
  - Benepali is not approved for use in children and adolescents weighing less than 62.5 kg.
- The PAC should be carried by patients during treatment and for 2 months after the last dose.

If patients still have questions

TELEPHONE SUPPORT

DOCTOR OR HCP ASSISTANCE

References

- SmPC version 01/2019
- EPAR first published 28/01/2016