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

Slide Deck for Healthcare Professional (HCP) Training

BEN-HCP Training-UK and IE-v10.0
May 2017

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:
Medicines Authority ADR Reporting details:
www.medicinesauthority.gov.mt/adrportal

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
- Reminders of Benepali contraindications , special warnings and precautions of use
- 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 paediatric 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)

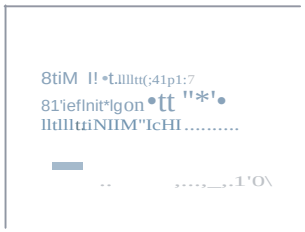
Product information

- SmPC
- Patient Information Leaflet
- Label
- Patient Alert Card (PAC)

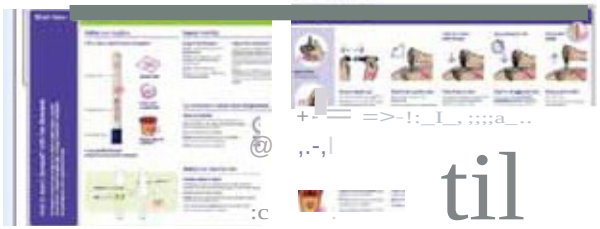
  [contained in the product pack]

Specific Training for additional RMMs

- Slide deck for training of HCPs



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



- Training Pen

Reference Materials (for Patients)

- Benepali Training Guide
- Injection demonstration video

Please note that these are being provided separately and are outside of the scope for this HCP training.

Summary of RMM training

Prevent Paediatric 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

Prevent/Reduce Medication

- Other etanercept products suitable for children weighing less than 62.5 kg are available

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.

Reminder of Benepali contraindications, special warnings and precautions of use*

Contraindications

Hypersensitivity to the active substance or to any of the excipients

Sepsis or risk of sepsis

Treatment with Benepali should not be initiated in patients with active infections, including chronic or localised infections

Special warnings and precautions for use: Tuberculosis (TB)

All patients must be evaluated for active and inactive ('latent') TB before initiation of treatment , including detailed medical history and appropriate screening tests to be recorded on the PAC (see slide 9).

If active TB is diagnosed , Benepali should not be initiated. If latent TB is diagnosed , treatment for latent TB must be started with anti-TB therapy before the initiation of Benepali, and in accordance with local recommendations .

**Please refer to Section 4.3 and 4.4 of Benepali SmPC*

Reminder of Benepali special warnings and precautions of use*

Other Special warnings and precautions for use:

./ Infections
./ Hepatitis B reactivation
./ Worsening of hepatitis C
./ Concurrent treatment with anakinra
./ Concurrent treatment with abatacept
./ Allergic reactions
./ Immunosuppression
./ Vaccinations
./ Malignancies and lymphoproliferative disorders
./ Autoantibody formation
./ Haematologic reactions
./ Neurological disorders
./ Combination therapy
./ Renal and hepatic impairment
./ Congestive heart failure
./ Alcoholic hepatitis
./ Wegener's granulomatosis
./ Hypoglycaemia in patients treated for diabetes

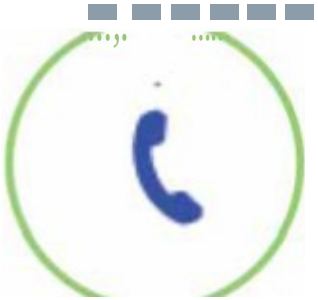
**Please refer to Section 4.3 and 4.4 of Benepali SmPC*

Resources for patients

TRAINING GUIDE

INJECTION DEMONSTRATION VIDEO

If patients still have questions



TELEPHONE SUPPORT

DOCTOR OR HCP ASSISTANCE

Resources for patients

References

- SmPC version 5/2017
- EPAR first published 28/01/2016

- **Marketing Authorisation Holder:**
  Samsung Bioepis UK Limited, 3000 Hillswood Drive, Chertsey, Surrey KT16 ORS United Kingdom.

  Manufacturer: Biogen (Denmark) A/S, Ørestads Boulevard 67, DK-2300 København S, Denmark