ADZYNMA®

(recombinant ADAMTS13 [rADAMTS13])

Healthcare Professional Guide

Important risk minimisation information for healthcare professionals prescribing ADZYNMA®

This guide contains important information about:

- The risk of hypersensitivity reactions with the use of rADAMTS13 in the home setting.
- Key elements to consider when selecting patients for home-administration/self-administration in relation to hypersensitivity.
- Key points to counsel eligible patients on hypersensitivity reactions and use of the Patient Alert Card.

Please read this guide together with the Summary of Product Characteristics (SmPC) for rADAMTS13. Please note that not all adverse reactions are listed in this Guide.

What is ADZYNMA®

ADZYNMA is an enzyme replacement therapy (ERT) indicated for the treatment of ADAMTS13 deficiency in children and adult patients with congenital thrombotic thrombocytopenic purpura (cTTP).

Important information on hypersensitivity reactions and home-administration/ self-administration

There is a risk of hypersensitivity reactions associated with the use of rADAMTS13.

- Signs of hypersensitivity reactions include but are not limited to tachycardia, tightness of the chest, wheezing and/or acute respiratory distress, hypotension, generalized urticaria, pruritus, angioedema, lethargy, nausea, vomiting, paraesthesia, restlessness and rhinoconjunctivitis.
- Hypersensitivity may progress to anaphylactic shock.
- If the patient experiences signs of hypersensitivity during home-administration/self-administration of rADAMTS13, the infusion should be stopped immediately and appropriate treatment should be initiated. Please follow up with the patient until the hypersensitivity reactions are under control.
- Ensure that subsequent injections occur in a clinical setting. Treatment should be closely monitored.

Please refer to the SmPC for additional information on hypersensitivity and other adverse reactions.

Determining patient eligibility

Consider the following in determining patient eligibility for home administration/self administration:

- Ensuring treatment is tolerated well by the patient in the clinical setting prior to initiating home-administration/self-administration.
- Ensuring the patient will be closely monitored for any hypersensitivity reaction throughout the infusion with rADAMTS13 by someone who can alert emergency medical personnel if needed.
- The patient or caregiver has been adequately trained by the treating physician and/or nurse and has been made aware of the risk of hypersensitivity.

This educational material is a requirement of the marketing authorisation of ADZYNMA and has been approved by the HPRA

Counselling patients and caregivers

Make certain to counsel your patients on symptoms of hypersensitivity reactions including anaphylaxis with rADAMTS13 and what to do in case any hypersensitivity reaction occurs.

Explain to the patient that rADAMTS13 may cause an allergic reaction called hypersensitivity. Allergic-type hypersensitivity reactions may include but are not limited to the following:

- Fast heart rate
- Tightness of the chest
- Wheezing and/or sudden onset of difficulty in breathing
- Low blood pressure
- Hives, rash and itchy skin
- Runny nose or nasal congestion
- Red eyes
- Sneezing
- Rapid swelling under the skin in areas such as the face, throat, arms and legs
- Tiredness
- Nausea (feeling sick)
- Vomiting
- Sensations like numbness, tingling, pins and needles
- Restlessness
- **Severe allergic reaction** (also called an anaphylactic reaction) can cause difficulty in swallowing and/or breathing, red or swollen face and/or hands

Instruct the patient and/or caregiver that if any symptoms of anaphylaxis occur, the patient should immediately stop the use of rADAMTS13 and seek immediate emergency medical care.

Provide the following to your patients and/or their caregivers:

- **Package Leaflet** for detailed information about rADAMTS13.
- **Patient Alert Card** for a patient-friendly easy reference for symptoms of hypersensitivity reactions and explain that it contains important information they should be aware of during home-administration/self-administration with rADAMTS13.

Instruct the patient/caregiver to:

- **Always carry the card** with them while they are receiving treatment with rADAMTS13.
- **Show this card** to any emergency service and healthcare providers should they experience hypersensitivity.

Reporting adverse reactions

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, website: www.hpra.ie.

Adverse events can also be reported to Takeda at AE.GBR-IRL@takeda.com or via phone call to Takeda UK Ltd - 0044 3333 000 181 or Takeda Products Ireland Ltd – 1800 937 970 (freephone from Ireland only)

Scan QR code or follow link https://axian.link/adz-hcp-IRL to access the Healthcare Professional website.

These materials are also available via the www.medicines.ie and www.hpra.ie websites.