Direct healthcare-professional communication (DHPC)

March 2018

Gadoversetamide, Optimark™

Gadoterate, Dotarem®

Risk of Brain Deposits Associated with Repeated Use of Gadolinium-Based Contrast Agents in Magnetic Resonance Imaging (MRI)

Dear Healthcare Professional,

Liebel-Flarsheim Company LLC, a Guerbet group company and marketing authorization holder of Optimark™ and Guerbet, marketing authorization holder of Dotarem® would like to inform you about the risk of brain deposits of gadolinium-based products associated with their multiple use in magnetic resonance imaging (MRI).

Summary

Gadolinium-based contrast agents (GBCAs) are pharmaceutical products used intravenously to enhance the images of MRI scans. They are classified into:

- Linear GBCAs (Gadopentetate, Gadobenate, Gadodiamide, Gadoversetamide) and
- Macrocyclic GBCAs (Gadobutrol, Gadoteridol, Gadoterate).

The literature shows association between repeated use of GBCAs in MRI scans and accumulation of gadolinium in the body tissues, including in the brain. Although long-term effects, clinical significance, and exact mechanism remain unclear, it might be due to the dissociation of GBCAs into free gadolinium, which is known to be highly toxic to human. In addition, research suggests that linear GBCAs are less stable and more likely to cause brain depositions than macrocyclic GBCAs.

Further information on the safety concern and the recommendations

Based on the available evidence and according to the recommendations of the Higher Pharmacovigilance Advisory Committee, the SFDA recommends HCPs to consider macrocyclic GBCAs as first choice in contrast enhanced MRI scans and limit repeated use of linear GBCAs unless there are no other alternatives.

On behalf of the SFDA, the marketing authorization holders of Dotarem® and Optimark™ are updating the summary of product characteristics of both products to reflect this risk. In addition, this letter is also part of the risk minimization activities that aims to ensure the safe use of Dotarem® and Optimark™.

The information in this letter has been approved by the SFDA.

Call for reporting

The SFDA urges both healthcare professionals and patients to report ADRs resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance and Drug Safety Center (NPC)
Saudi Food and Drug Authority-Drug sector
3292 Northern Ring Road
Al Nafal District
Riyadh 13312 – 6288
Kingdom of Saudi Arabia
Toll free number: 8002490000
Tel: 01 2038222 ext. 2317-2356-2340.
Fax: 01 2057662
Email: NPC.Drug@sfda.gov.sa
Website: https://www.sfda.gov.sa

Company contact point

According to local requirements, you can also contact the local Distributor:

TAMER GROUP,
Sh.Mohammaed Ibn Abdul Wahab – Street Ammariyah District,
P.O.Box. 180 – Jeddah – 21411 Saudi Arabia
Tel : 966 (2) 644 0099
Fax : 966 (2) 642 2669
Email: Bandar.Mezel@tamergroup.com or RAPMS@tamergroup.com

Ph. Bander Mezel
Regulatory Affairs Officer, QPPV
TAMER GROUP