PMDA Alert for Proper Use of Drugs
Pharmaceuticals and Medical Devices Agency

No. 13 October 2020

Hypercalcaemia Induced by Eldecalcitol and Adherence to Blood Testing

Eldecalcitol, an osteoporosis drug, is known to cause hypercalcaemia. Periodic monitoring of serum calcium levels as a precaution has been noted in the package insert.

Nonetheless, cases of failure to periodically monitor serum calcium levels have been identified in drug adverse reaction reports involving hypercalcaemia.

Cases of hypercalcaemia that developed in the absence of periodic blood testing may not be eligible for the payment under the Relief System for Adverse Drug Reactions because such a use of the drug is basically not considered proper.

Please check the instructions in the package insert, perform testing periodically, and ensure early detection of adverse drug reactions as well as proper treatment.

◎Periodic monitoring of serum calcium levels

- **Serum calcium levels should be monitored periodically (e.g. once every 3 to 6 months) during administration of this drug.**
- **In patients at higher risk* of hypercalcaemia, serum calcium levels should be monitored frequently at an early stage of administration.**

*** E.g. patients with renal impairment, malignant tumour, primary hyperparathyroidism, or patients co-administered this drug with calcium preparations**

◎ Symptom identification

- **Patients and their caregivers should be instructed to seek medical attention if they experience or note any symptoms of hypercalcaemia（such as malaise, irritability, queasy, thirst, declined appetite, and depressed level of consciousness）.**

Typical cases

Case 1:
Female in her 80s
Since the prescription of Edirol Capsules (eldecalcitol) was taken over from the previous physician, the drug was continuously administered even after decreased renal function was observed approximately 5 months later and serum calcium level had not been monitored within the subsequent 2 months until it was found to be high.
（partially modified from Pharmaceuticals and Medical Devices Safety Information No. 367）

Case 2:
Female in her 80s
Edirol Capsules (eldecalcitol) was initiated for osteoporosis. No blood tests were performed for 1 year. A depressed level of consciousness was gradually noted, and she was taken by ambulance to the hospital. Blood testing revealed 13.9 mg/dl of serum calcium. She was diagnosed with drug-induced hypercalcaemia. The drug was discontinued, and measures were taken such as fluid infusion. Thereafter, serum calcium levels and consciousness levels improved.

Reference

Change in number of cases involving hypercalcaemia* induced by eldecalcitol from 2015 to 2019 (compiled by Chugai Pharmaceutical Co., Ltd.)

	2015	2016	2017	2018	2019
Cases of hypercalcaemia	200	264	288	316	315
Cases of failure to periodically monitor serum calcium levels in the above cases	3	5	3	11	12

* MedDRA PT Hypercalcaemia and Blood calcium increased were counted (serious and non-serious).

Branded names (MAH)
Edirol Capsules 0.5 μg, 0.75 μg (Chugai Pharmaceutical Co., Ltd.)
Eldecalcitol Capsules [Sawai] 0.5 μg, 0.75 μg (Sawai Pharmaceutical Co., Ltd.)
Eldecalcitol Capsules [Nichi-Iko] 0.5 μg, 0.75 μg (Nichi-Iko Pharmaceutical Co., Ltd.)

About this information
- PMDA Alert for Proper Use of Drugs communicates to healthcare providers with clear information from the perspective of promoting the proper use of drugs. The information presented here includes such cases where the reporting frequencies of similar reports have not decreased despite relevant alerts provided in package inserts, among Adverse Drug Reaction/infection cases reported in accordance with the PMD Act.
- We have tried to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy in the future
- This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibility on them, but is provided to promote the proper use of the drugs.

Access to the most up to date safety information is available via the PMDA medi-navi.

Published by
the Pharmaceuticals and Medical Devices Agency
Contact：Office of Pharmacovigilance | E-mail: safety.info@pmda.go.jp