Pediatric Drugs

Sodium Thiosulfate: Adis Evaluation

Key Points

- A chemoprotectant/ antioxidant developed by Fennec Pharmaceuticals to prevent hearing loss associated with certain anticancer therapies
- Received its pediatric first approval on 20 September 2022 in the USA
- Approved for reducing the risk of ototoxicity associated with cisplatin in pediatric patients aged ≥ 1 month with localized, nonmetastatic solid tumours

Summary

Sodium thiosulfate (Pedmark[®]) is a chemoprotectant/antioxidant developed by Fennec Pharmaceuticals (formerly Adherex Technologies) to reduce to risk of hearing loss associated with cisplatin.

Sodium thiosulfate reduces the risk of ototoxicity by interacting directly with cisplatin to produce inactive platinum species, as well as by causing intracellular effects (such as increasing antioxidant glutathione levels and inhibition of oxidative stress) after entering the cells through the sodium sulfate cotransporter 2.

In September 2022, sodium thiosulfate received its first approval in the USA for reducing the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumours. Sodium thiosulfate is under regulatory review in the EU for the prevention of ototoxicity induced by cisplatin chemotherapy in patients 1 month to < 18 years of age with localised, non-metastatic, solid tumours.

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