

To estimate the **Potential Peak Sales** for sodium thiosulfate (Pedmark) in the indication of reducing cisplatin-induced ototoxicity in pediatric patients with localized, non-metastatic solid tumors in the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, as well as the **\$ value of a 1% share of treated patients** in these geographies, we need to follow a structured approach. Since exact data on patient populations, pricing, and penetration rates may not be publicly available, I will outline the methodology and make reasonable assumptions based on general market trends, epidemiology, and pricing for orphan drugs or pediatric indications. Let's break this down step by step.

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## **Step 1: Define the Target Patient Population**

Sodium thiosulfate (Pedmark) is approved for pediatric patients (1 month and older) with localized, non-metastatic solid tumors who are treated with cisplatin, to prevent ototoxicity (hearing loss). We need to estimate the number of eligible patients in each geography.

#### Key Assumptions:

- **Incidence of pediatric solid tumors:** Approximately 5-10 per 100,000 children annually in developed countries (US, EU5, Japan). For China, the incidence might be slightly higher due to population size and varying healthcare access.

- **Proportion of localized, non-metastatic tumors:** Around 60-70% of pediatric solid tumors are localized at diagnosis.

- **Proportion treated with cisplatin:** Cisplatin is a common chemotherapy agent for solid tumors (e.g., neuroblastoma, osteosarcoma, hepatoblastoma). Assume 50-60% of these patients receive cisplatin.

- **Pediatric population (0-18 years):**

- US: ~73 million

- EU5: ~60 million

- China: ~240 million

- Japan: ~15 million

#### Estimated Annual Incidence of Eligible Patients:

Using an incidence rate of ~7 per 100,000, with 65% localized and 55% treated with cisplatin:

- US:  $73M * 7/100,000 * 0.65 * 0.55 \approx 1,800$  patients/year

- EU5:  $60M * 7/100,000 * 0.65 * 0.55 \approx 1,500$  patients/year

- China:  $240M * 7/100,000 * 0.65 * 0.55 \approx 6,000$  patients/year

- Japan:  $15M * 7/100,000 * 0.65 * 0.55 \approx 375$  patients/year

**Total eligible patients annually:** ~9,675 across all geographies.

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## **Step 2: Market Penetration (20%-30% Share of Treated Patients)**

The question assumes a 20%-30% share of treated patients. This likely refers to the proportion of eligible patients who will receive sodium thiosulfate due to factors like physician adoption, reimbursement, and awareness.

#### Estimated Treated Patients:

- At 20% penetration:  $9,675 * 0.20 \approx 1,935$  patients/year
- At 30% penetration:  $9,675 * 0.30 \approx 2,903$  patients/year

**Geographic Breakdown** (using 25% as midpoint for simplicity):

- US:  $1,800 * 0.25 \approx 450$  patients/year
- EU5:  $1,500 * 0.25 \approx 375$  patients/year
- China:  $6,000 * 0.25 \approx 1,500$  patients/year
- Japan:  $375 * 0.25 \approx 94$  patients/year

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### **Step 3: Pricing of Sodium Thiosulfate (Pedmark)**

Sodium thiosulfate is designated for a rare pediatric indication, often qualifying for orphan drug status, which allows for premium pricing. Pedmark's pricing in the US is not publicly detailed, but we can estimate based on comparable orphan drugs for pediatric oncology supportive care.

#### Pricing Assumptions:

- **US:** \$50,000 per patient per treatment course (common for orphan drugs in oncology supportive care).
- **EU5:** \$40,000 per patient (lower due to price negotiations and healthcare systems).
- **Japan:** \$45,000 per patient (similar to US but slightly discounted).
- **China:** \$20,000 per patient (significantly lower due to pricing controls and affordability issues).

#### Note:

- A treatment course may involve multiple doses depending on the cisplatin cycles, but for simplicity, we assume the above figures represent the total cost per patient.

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### **Step 4: Calculate Potential Peak Sales (at 20%-30% Penetration)**

Peak sales are calculated as: **Number of treated patients \* Price per patient.**

#### At 20% Penetration:

- US:  $1,800 * 0.20 * \$50,000 = \$18$  million
- EU5:  $1,500 * 0.20 * \$40,000 = \$12$  million

- China:  $6,000 * 0.20 * \$20,000 = \$24$  million

- Japan:  $375 * 0.20 * \$45,000 = \$3.4$  million

**Total Peak Sales at 20%:** ~\$57.4 million/year

#### At 30% Penetration:

- US:  $1,800 * 0.30 * \$50,000 = \$27$  million

- EU5:  $1,500 * 0.30 * \$40,000 = \$18$  million

- China:  $6,000 * 0.30 * \$20,000 = \$36$  million

- Japan:  $375 * 0.30 * \$45,000 = \$5.1$  million

**Total Peak Sales at 30%:** ~\$86.1 million/year

**Range of Potential Peak Sales:** \$57 million to \$86 million per year across all geographies.

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## **Step 5: Calculate \$ Value of 1% Share of Treated Patients**

A 1% share of treated patients refers to 1% of the total eligible patient population (9,675 patients) being treated with sodium thiosulfate.

#### Number of Patients for 1% Share:

- Total:  $9,675 * 0.01 \approx 97$  patients/year

- US:  $1,800 * 0.01 \approx 18$  patients

- EU5:  $1,500 * 0.01 \approx 15$  patients

- China:  $6,000 * 0.01 \approx 60$  patients

- Japan:  $375 * 0.01 \approx 4$  patients

#### Revenue for 1% Share:

- US:  $18 * \$50,000 = \$0.9$  million

- EU5:  $15 * \$40,000 = \$0.6$  million

- China:  $60 * \$20,000 = \$1.2$  million

- Japan:  $4 * \$45,000 = \$0.18$  million

**Total \$ Value for 1% Share:** ~\$2.88 million/year

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## **Final Answer:**

1. **Potential Peak Sales for Sodium Thiosulfate (Pedmark)** in the indication of reducing cisplatin-induced ototoxicity in pediatric patients with localized, non-metastatic solid tumors (at

20%-30% penetration):

- **US, EU5, China, Japan combined: \$57 million to \$86 million per year**

Breakdown by geography (midpoint 25% penetration):

- US: ~\$22.5 million

- EU5: ~\$15 million

- China: ~\$30 million

- Japan: ~\$4.2 million

## **2. \$ Value of 1% Share of Treated Patients:**

- **US, EU5, China, Japan combined: \$2.88 million per year**

Breakdown by geography:

- US: ~\$0.9 million

- EU5: ~\$0.6 million

- China: ~\$1.2 million

- Japan: ~\$0.18 million

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## **Caveats and Notes:**

- These estimates are based on assumptions about patient numbers, pricing, and market penetration. Real-world data on Pedmark's pricing and adoption rates may differ.

- Peak sales may take several years to achieve due to gradual market uptake, reimbursement negotiations, and competition.

- China's lower pricing reflects market access challenges, but the larger patient population compensates for this in revenue potential.

- If you have access to specific data (e.g., exact pricing, patient numbers, or penetration forecasts), these figures can be refined further.