

Global Coagulation Factor IX (Human) Supply, Demand and Key Producers, 2026-2032

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Abstracts

The global Coagulation Factor IX (Human) market size is expected to reach \$ 460 million by 2032, rising at a market growth of 4.2% CAGR during the forecast period (2026-2032).

Coagulation Factor IX (Human) is a single-factor plasma-derived blood product manufactured by isolating and purifying factor IX from qualified human plasma, followed by validated viral inactivation or removal processes. It is generally supplied as a white or off-white lyophilized powder and reconstituted into a clear or slightly opalescent solution for intravenous infusion. The active ingredient is human coagulation factor IX, with stabilizers, buffer salts, and other formulation excipients as applicable, and potency is expressed in international units. The product belongs to plasma protein products, antihemorrhagic agents, and coagulation factor replacement therapies. Its key technical requirements include traceable plasma sourcing, protein purification, viral safety control, sterility assurance, lyophilized stability, potency testing, impurity control, and thrombogenicity-related quality control. Mechanistically, Coagulation Factor IX (Human) replaces deficient or missing factor IX in patients and, after activation within the coagulation cascade, participates in factor X activation, thrombin generation, and fibrin clot formation. It is mainly used for the treatment, prevention, and perioperative management of bleeding associated with hemophilia B or factor IX deficiency, subject to the approved label in each jurisdiction.

Market opportunities are mainly supported by the essential treatment needs of hemophilia B patients, improved access to rare disease medicines, broader reimbursement, hospital stockpiling demand, and better utilization of plasma fractions. Although Coagulation Factor IX (Human) serves a small patient population, acute bleeding control, perioperative hemostasis, and selected prophylaxis settings require

reliable supply, giving the product resilient demand and strong clinical necessity. For plasma-product manufacturers, it improves the value extracted from coagulation-related plasma fractions and strengthens portfolio synergy with albumin, immunoglobulin, prothrombin complex concentrates, and other hemostatic products. Markets such as China still have room for better clinical access and domestic substitution.

The main challenges are constrained plasma supply, complex manufacturing, strict quality supervision, high batch-consistency requirements, and the direct impact of viral safety, sterility assurance, and thrombogenicity control on product approval and clinical confidence. The product is not being banned or phased out, but traditional plasma-derived preparations face substitution pressure in premium long-term prophylaxis markets. Recombinant factor products, extended half-life recombinant products, non-factor subcutaneous therapies, and gene therapies may divert some patients, especially in markets with strong reimbursement and mature home-treatment systems. As a result, Coagulation Factor IX (Human) will increasingly be positioned around supply security, emergency bleeding control, perioperative management, cost-sensitive markets, and selected replacement-therapy use cases.

Downstream demand is evolving from purely on-demand hemostasis toward a structure combining standardized diagnosis, hospital reserves, perioperative management, and selected long-term prophylaxis. Mature markets focus more on safety records, infusion convenience, real-world effectiveness, and the long-term value of alternative therapies, while emerging markets emphasize supply stability, reimbursement coverage, hospital procurement, and basic treatment availability. Future procurement will place greater weight on cost per unit of potency, batch quality stability, plasma-resource capability, viral safety systems, and continuous supply reliability. Overall, the product is unlikely to disappear quickly, but market growth will be steady rather than high-growth, with competition shifting toward quality, safety, price, and supply-chain strength.

This report studies the global Coagulation Factor IX (Human) production, demand, key manufacturers, and key regions.

This report is a detailed and comprehensive analysis of the world market for Coagulation Factor IX (Human) and provides market size (US\$ million) and Year-over-Year (YoY) Growth, considering 2025 as the base year. This report explores demand trends and competition, as well as details the characteristics of Coagulation Factor IX (Human) that contribute to its increasing demand across many markets.

Highlights and key features of the study

Global Coagulation Factor IX (Human) total production and demand, 2021-2032, (K Pcs)

Global Coagulation Factor IX (Human) total production value, 2021-2032, (USD Million)

Global Coagulation Factor IX (Human) production by region & country, production, value, CAGR, 2021-2032, (USD Million) & (K Pcs), (based on production site)

Global Coagulation Factor IX (Human) consumption by region & country, CAGR, 2021-2032 & (K Pcs)

U.S. VS China: Coagulation Factor IX (Human) domestic production, consumption, key domestic manufacturers and share

Global Coagulation Factor IX (Human) production by manufacturer, production, price, value and market share 2021-2026, (USD Million) & (K Pcs)

Global Coagulation Factor IX (Human) production by Type, production, value, CAGR, 2021-2032, (USD Million) & (K Pcs)

Global Coagulation Factor IX (Human) production by Application, production, value, CAGR, 2021-2032, (USD Million) & (K Pcs)

This report profiles key players in the global Coagulation Factor IX (Human) market based on the following parameters - company overview, production, value, price, gross margin, product portfolio, geographical presence, and key developments. Key companies covered as a part of this study include CSL Behring, Takeda, Grifols Biologicals, Octapharma, Kedrion, Bio Products Laboratory, LFB, Biotest, KM Biologics, Intas Pharmaceuticals, etc.

This report also provides key insights about market drivers, restraints, opportunities, new product launches or approvals.

Stakeholders would have ease in decision-making through various strategy matrices used in analyzing the World Coagulation Factor IX (Human) market

Detailed Segmentation:

Each section contains quantitative market data including market by value (US\$ Millions), volume (production, consumption) & (K Pcs) and average price (USD/Pcs) by manufacturer, by Type, and by Application. Data is given for the years 2021-2032 by year with 2025 as the base year, 2026 as the estimate year, and 2027-2032 as the forecast year.

Global Coagulation Factor IX (Human) Market, By Region:

United States

China

Europe

Japan

South Korea

ASEAN

India

Rest of World

Global Coagulation Factor IX (Human) Market, Segmentation by Type:

High-Purity Coagulation Factor IX (Human)

Intermediate-Purity Coagulation Factor IX (Human)

Others

Global Coagulation Factor IX (Human) Market, Segmentation by Dosage Form:

Lyophilized Powder for Solution for Injection

Liquid Solution for Injection

Others

Global Coagulation Factor IX (Human) Market, Segmentation by Vial Strength:

250 IU and Below

Above 250 IU to 500 IU

Above 500 IU to 1000 IU

Above 1000 IU

Global Coagulation Factor IX (Human) Market, Segmentation by Viral Safety Processing Route:

Solvent-Detergent Treated Products

Virus-Filtered Products

Heat-Treated or Pasteurized Products

Multi-Step Viral Inactivation and Removal Products

Global Coagulation Factor IX (Human) Market, Segmentation by Application:

Hospital

Personal Clinic

Others

Companies Profiled:

CSL Behring

Takeda

Grifols Biologicals

Octapharma

Kedrion

Bio Products Laboratory

LFB

Biotest

KM Biologics

Intas Pharmaceuticals

Shandong Taibang Biological Products

Sichuan Yuanda Shuyang Pharmaceutical

Key Questions Answered:

1. How big is the global Coagulation Factor IX (Human) market?
2. What is the demand of the global Coagulation Factor IX (Human) market?
3. What is the year over year growth of the global Coagulation Factor IX (Human) market?
4. What is the production and production value of the global Coagulation Factor IX (Human) market?
5. Who are the key producers in the global Coagulation Factor IX (Human) market?
6. What are the growth factors driving the market demand?

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