

# **Global Enzyme Replacement Therapy Market Size study, by Product (Imiglucerase), by Therapeutic Condition (MPS), by Route of Administration (Oral), by End-use, and Regional Forecasts 2022-2032**

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## **Abstracts**

Global Enzyme Replacement Therapy (ERT) Market is valued at approximately USD 9.51 billion in 2023 and is projected to expand with a robust compound annual growth rate (CAGR) of 9.00% over the forecast period from 2024 to 2032. Enzyme replacement therapy is revolutionizing the treatment of rare genetic disorders, particularly lysosomal storage diseases like mucopolysaccharidosis (MPS), Gaucher disease, and Pompe disease. This therapy substitutes deficient or malfunctioning enzymes with biologically active counterparts, offering life-altering benefits for patients who once faced debilitating symptoms and significantly shortened life expectancy. With advancements in biopharmaceutical manufacturing and a rising tide of orphan drug approvals, ERT is shifting from being an experimental therapy to a clinically validated mainstay in personalized medicine.

A wave of scientific innovation, especially in recombinant enzyme formulations such as Imiglucerase, is propelling the ERT market forward. These biologics are not only enhancing treatment efficacy but are also engineered to reduce immunogenicity and improve cellular uptake. The increasing prevalence of inherited metabolic conditions, coupled with the expansion of newborn screening programs, has led to earlier diagnosis and better long-term outcomes, thereby boosting demand for ERT. Despite its promise, the therapy still faces barriers such as exorbitant costs, complex cold-chain logistics, and limited availability in low-resource settings, all of which call for strategic interventions in manufacturing and policy reforms.

The landscape of ERT is also evolving due to the growing emphasis on oral

administration methods. While intravenous infusions remain the dominant route, oral alternatives are gaining traction due to their convenience and improved patient compliance, especially among pediatric populations. Pharmaceutical companies are exploring nanoparticle delivery systems and enzyme encapsulation technologies to enable bioavailability through oral pathways. This aligns with a broader trend of enhancing patient-centric therapies, reducing hospitalization frequency, and minimizing systemic side effects—an area increasingly prioritized by healthcare providers and payers alike.

Regionally, North America is at the forefront of ERT adoption due to its advanced biotechnology sector, regulatory incentives for orphan drug development, and expansive insurance coverage. Europe follows closely, backed by strong healthcare infrastructure and public funding for rare disease treatment. Meanwhile, Asia Pacific is emerging as a high-growth market, driven by increasing awareness, expanding healthcare access, and the rise of local biopharma manufacturers in nations such as India, Japan, and South Korea. Countries across Latin America and the Middle East & Africa are gradually integrating ERT into their public health strategies through international collaborations and donor-funded initiatives.

Major market player included in this report are:

Sanofi S.A.

Takeda Pharmaceutical Company Limited

BioMarin Pharmaceutical Inc.

Amicus Therapeutics, Inc.

Pfizer Inc.

Alexion Pharmaceuticals, Inc.

Protalix BioTherapeutics, Inc.

Genzyme Corporation

Horizon Therapeutics plc

Shire (Now part of Takeda)

Eli Lilly and Company

EnzymeRx LLC

Sigilon Therapeutics, Inc.

Greenovation Biotech GmbH

JCR Pharmaceuticals Co., Ltd.

The detailed segments and sub-segment of the market are explained below:

#### By Product

Imiglucerase

#### By Therapeutic Condition

Mucopolysaccharidosis (MPS)

#### By Route of Administration

Oral

#### By End-use

Hospitals

Clinics

Homecare

Others

## By Region:

### North America

U.S.

Canada

### Europe

UK

Germany

France

Spain

Italy

Rest of Europe

### Asia Pacific

China

India

Japan

Australia

South Korea

Rest of Asia Pacific

## Latin America

Brazil

Mexico

Rest of Latin America

## Middle East & Africa

Saudi Arabia

South Africa

Rest of Middle East & Africa

Years considered for the study are as follows:

Historical Year – 2022

Base Year – 2023

Forecast Period – 2024 to 2032

## Key Takeaways:

Market Estimates & Forecast for 10 years from 2022 to 2032

Annualized revenues and regional level analysis for each market segment

Detailed analysis of geographical landscape with country-level analysis of major regions

Competitive landscape with information on major players in the market

Analysis of key business strategies and recommendations on future market approach

Analysis of competitive structure of the market

Demand side and supply side analysis of the market

## Contents

### **CHAPTER 1. GLOBAL ENZYME REPLACEMENT THERAPY MARKET EXECUTIVE SUMMARY**

- 1.1. Global Enzyme Replacement Therapy Market Size & Forecast (2022–2032)
- 1.2. Regional Summary
- 1.3. Segmental Summary
  - 1.3.1. By Product
  - 1.3.2. By Therapeutic Condition
  - 1.3.3. By Route of Administration
  - 1.3.4. By End-use
- 1.4. Key Trends
- 1.5. Recession Impact
- 1.6. Analyst Recommendation & Conclusion

### **CHAPTER 2. GLOBAL ENZYME REPLACEMENT THERAPY MARKET DEFINITION AND RESEARCH ASSUMPTIONS**

- 2.1. Research Objective
- 2.2. Market Definition
- 2.3. Research Assumptions
  - 2.3.1. Inclusion & Exclusion
  - 2.3.2. Limitations
  - 2.3.3. Supply Side Analysis
    - 2.3.3.1. Availability
    - 2.3.3.2. Infrastructure
    - 2.3.3.3. Regulatory Environment
    - 2.3.3.4. Market Competition
    - 2.3.3.5. Economic Viability (Consumer's Perspective)
  - 2.3.4. Demand Side Analysis
    - 2.3.4.1. Regulatory Frameworks
    - 2.3.4.2. Technological Advancements
    - 2.3.4.3. Environmental Considerations
    - 2.3.4.4. Consumer Awareness & Acceptance
- 2.4. Estimation Methodology
- 2.5. Years Considered for the Study
- 2.6. Currency Conversion Rates

## **CHAPTER 3. GLOBAL ENZYME REPLACEMENT THERAPY MARKET DYNAMICS**

### **3.1. Market Drivers**

- 3.1.1. Rising Prevalence of Lysosomal Storage Disorders
- 3.1.2. Advances in Recombinant Enzyme Technology
- 3.1.3. Expansion of Newborn Screening Programs

### **3.2. Market Challenges**

- 3.2.1. High Treatment Costs and Reimbursement Hurdles
- 3.2.2. Cold-Chain and Distribution Complexities
- 3.2.3. Limited Access in Low-Resource Settings

### **3.3. Market Opportunities**

- 3.3.1. Development of Oral and Less-Invasive Formulations
- 3.3.2. Emergence of Biosimilars to Reduce Costs
- 3.3.3. Digital Health Solutions for Adherence Monitoring

## **CHAPTER 4. GLOBAL ENZYME REPLACEMENT THERAPY MARKET INDUSTRY ANALYSIS**

### **4.1. Porter's Five Forces Model**

- 4.1.1. Bargaining Power of Suppliers
- 4.1.2. Bargaining Power of Buyers
- 4.1.3. Threat of New Entrants
- 4.1.4. Threat of Substitutes
- 4.1.5. Competitive Rivalry
- 4.1.6. Futuristic Approach to Porter's Model
- 4.1.7. Porter's Impact Analysis

### **4.2. PESTEL Analysis**

- 4.2.1. Political
- 4.2.2. Economic
- 4.2.3. Social
- 4.2.4. Technological
- 4.2.5. Environmental
- 4.2.6. Legal

### **4.3. Top Investment Opportunities**

### **4.4. Top Winning Strategies**

### **4.5. Disruptive Trends**

### **4.6. Industry Expert Perspective**

### **4.7. Analyst Recommendation & Conclusion**



## **CHAPTER 5. GLOBAL ENZYME REPLACEMENT THERAPY MARKET SIZE & FORECASTS BY PRODUCT, 2022–2032**

5.1. Segment Dashboard

5.2. Imiglucerase Revenue Trend Analysis, 2022 & 2032 (USD Million)

## **CHAPTER 6. GLOBAL ENZYME REPLACEMENT THERAPY MARKET SIZE & FORECASTS BY THERAPEUTIC CONDITION, 2022–2032**

6.1. Segment Dashboard

6.2. Mucopolysaccharidosis (MPS) Revenue Trend Analysis, 2022 & 2032 (USD Million)

## **CHAPTER 7. GLOBAL ENZYME REPLACEMENT THERAPY MARKET SIZE & FORECASTS BY ROUTE OF ADMINISTRATION, 2022–2032**

7.1. Segment Dashboard

7.2. Oral Administration Revenue Trend Analysis, 2022 & 2032 (USD Million)

## **CHAPTER 8. GLOBAL ENZYME REPLACEMENT THERAPY MARKET SIZE & FORECASTS BY END-USE, 2022–2032**

8.1. Segment Dashboard

8.2. Hospitals Revenue Trend Analysis, 2022 & 2032 (USD Million)

8.3. Clinics Revenue Trend Analysis, 2022 & 2032 (USD Million)

8.4. Homecare Revenue Trend Analysis, 2022 & 2032 (USD Million)

8.5. Others Revenue Trend Analysis, 2022 & 2032 (USD Million)

## **CHAPTER 9. GLOBAL ENZYME REPLACEMENT THERAPY MARKET SIZE & FORECASTS BY REGION, 2022–2032**

9.1. North America Market

9.1.1. U.S. Market

9.1.1.1. Product & Condition Breakdown & Forecasts, 2022–2032

9.1.1.2. Route & End-use Breakdown & Forecasts, 2022–2032

9.1.2. Canada Market

9.2. Europe Market

9.2.1. UK Market

9.2.2. Germany Market

9.2.3. France Market

- 9.2.4. Spain Market
- 9.2.5. Italy Market
- 9.2.6. Rest of Europe Market
- 9.3. Asia Pacific Market
  - 9.3.1. China Market
  - 9.3.2. India Market
  - 9.3.3. Japan Market
  - 9.3.4. Australia Market
  - 9.3.5. South Korea Market
  - 9.3.6. Rest of Asia Pacific Market
- 9.4. Latin America Market
  - 9.4.1. Brazil Market
  - 9.4.2. Mexico Market
  - 9.4.3. Rest of Latin America Market
- 9.5. Middle East & Africa Market
  - 9.5.1. Saudi Arabia Market
  - 9.5.2. South Africa Market
  - 9.5.3. Rest of Middle East & Africa Market

## **CHAPTER 10. COMPETITIVE INTELLIGENCE**

- 10.1. Key Company SWOT Analysis
  - 10.1.1. Sanofi S.A.
  - 10.1.2. Takeda Pharmaceutical Company Limited
  - 10.1.3. BioMarin Pharmaceutical Inc.
- 10.2. Top Market Strategies
- 10.3. Company Profiles
  - 10.3.1. Sanofi S.A.
    - 10.3.1.1. Key Information
    - 10.3.1.2. Overview
    - 10.3.1.3. Financial (Subject to Data Availability)
    - 10.3.1.4. Product Summary
    - 10.3.1.5. Market Strategies
  - 10.3.2. Takeda Pharmaceutical Company Limited
  - 10.3.3. BioMarin Pharmaceutical Inc.
  - 10.3.4. Amicus Therapeutics, Inc.
  - 10.3.5. Pfizer Inc.
  - 10.3.6. Alexion Pharmaceuticals, Inc.
  - 10.3.7. Protalix BioTherapeutics, Inc.

- 10.3.8. Genzyme Corporation
- 10.3.9. Horizon Therapeutics plc
- 10.3.10. Shire (Now part of Takeda)
- 10.3.11. Eli Lilly and Company
- 10.3.12. EnzymeRx LLC
- 10.3.13. Sigilon Therapeutics, Inc.
- 10.3.14. Greenovation Biotech GmbH
- 10.3.15. JCR Pharmaceuticals Co., Ltd.

## **CHAPTER 11. RESEARCH PROCESS**

- 11.1. Research Process
  - 11.1.1. Data Mining
  - 11.1.2. Analysis
  - 11.1.3. Market Estimation
  - 11.1.4. Validation
  - 11.1.5. Publishing
- 11.2. Research Attributes

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