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Recombinant Human Insulin Market Forecasts to 2030 – Global Analysis By Product (Short-Acting Human Insulin, Intermediate-Acting Human Insulin and Premixed Human Insulin), Brand (Humulin R, Novolin R, Humulin N, Novolin N and Other Brands), Distribution Channel and By Geography

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Abstracts

According to Stratistics MRC, the Global Recombinant Human Insulin Market is accounted for $20.97 billion in 2024 and is expected to reach $28.91 billion by 2030 growing at a CAGR of 5.5% during the forecast period. Recombinant human insulin is a synthetic form of the hormone that is made using recombinant DNA technology, mostly in yeast (Saccharomyces cerevisiae) or genetically modified bacteria like Escherichia coli. It was created as a more effective and safe substitute for the widely used insulin derived from animal sources prior to its introduction. Moreover, recombinant human insulin helps diabetics control their blood glucose levels by simulating the body's natural production of the hormone. In order to produce it, the human insulin gene is inserted into microbial cells, which subsequently use regulated fermentation processes to synthesize the protein.

According to the International Diabetes Federation (IDF), the number of adults with diabetes is projected to reach 643 million by 2030.

Market Dynamics:

Driver:

Growing prevalence of diabetes

The market for recombinant human insulin is largely driven by the rising prevalence of diabetes worldwide, especially type 1 and insulin-dependent type-2 diabetes. The demand for insulin-based treatments is predicted to rise dramatically as the number of people with diabetes rises to 643 million by 2030 and 783 million by 2045, according to the International Diabetes Federation (IDF). Additionally, diabetes is also becoming more common due to sedentary lifestyles, poor diets, and altered lifestyles, which increases the need for insulin to maintain glycemic control.

Restraint:

Expensive insulin therapy

The high cost of recombinant human insulin is one of the biggest barriers to its market, limiting accessibility, particularly in low#- #and middle-income countries (LMICs). Because of costly production methods, monopolistic pricing tactics by large pharmaceutical companies, and patent protections, prices are still an issue even with the availability of bio-similar insulin. The World Health Organization (WHO) claims that a large number of people in developing nations cannot afford insulin, which results in inadequate disease management and a rise in complications associated with diabetes. Furthermore, limiting the widespread use of insulin therapy is the high out-of-pocket costs, which can strain healthcare systems.

Opportunity:

Developments in insulin delivery system technology

Technological advancements in insulin delivery present substantial growth prospects. Precision, convenience, and patient adherence are all improved by the development of artificial pancreas systems, insulin pumps, smart insulin pens, and continuous glucose monitoring (CGM) devices. By offering automated dosing adjustments and real-time glucose monitoring, wearable and automated insulin delivery systems lower the risk of hypoglycemia and blood sugar swings. Moreover, the use of recombinant human insulin in sophisticated therapeutic solutions will be fueled by advancements in digital healthcare and smart medical devices.

Threat:

Strict approval procedure for regulation

Strict regulatory oversight of recombinant human insulin products results in lengthy approval processes and expensive compliance expenses. Insulin production must meet strict safety, efficacy, and quality standards set by regulatory bodies like the European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA), and China's National Medical Products Administration (NMPA). Additionally, the lengthy comparability studies, clinical trials, and post-market surveillance required for bio-similar insulin approvals can cause delays in product launches and raise operating expenses.

Covid-19 Impact:

Due to the disruption of global supply chains, the delay of clinical trials, and the strain on healthcare systems, the COVID-19 pandemic had a major effect on the market for recombinant human insulin. Insulin production and distribution were delayed, and raw material shortages resulted from lockdowns and transportation restrictions, which impacted market availability, especially in low#- #and middle-income nations. Financial limitations and job losses also made it harder for patients to afford insulin therapy, which decreased adherence. However, the pandemic also hastened the adoption of home-based diabetes management programs and telemedicine, which has increased demand for insulin delivery devices that can be used by the patients themselves, such as insulin pumps and pens.

The Premixed Human Insulin segment is expected to be the largest during the forecast period

The Premixed Human Insulin segment is expected to account for the largest market share during the forecast period. Premixed human insulin improves patient compliance by reducing the number of daily injections and simplifying dosing schedules by combining precise ratios of short-acting and intermediate-acting insulin. For people with type 2 diabetes who need both basal and prandial glycemic control, this formulation is especially helpful. Moreover, the use of premixed human insulin has increased due to the rising incidence of diabetes worldwide and the growing need for insulin treatments that are easy to use, thereby securing its market leadership.

The Humulin R segment is expected to have the highest CAGR during the forecast period

Over the forecast period, the Humulin R segment is predicted to witness the highest growth rate. Humulin R is short-acting insulin that is frequently used to control

postprandial blood glucose levels. Because of its quick onset of action, it is an essential part of intensive insulin therapy. Key drivers of its market expansion include the rising incidence of type 2 diabetes, the growing use of self-administration insulin delivery systems, and the rising need for bio-similar insulin formulations. Additionally, its robust growth trajectory has also been aided by continuous developments in insulin pump technology and the incorporation of Humulin R into hybrid closed-loop systems.

Region with largest share:

During the forecast period, the North America region is expected to hold the largest market share, driven by the high rate of diabetes, the sophisticated medical system, and the widespread use of cutting-edge insulin delivery technologies. The region benefits from a growing number of diabetics, especially in the US, well-established reimbursement policies, and rising demand for biosimilar insulin. North America's dominance is further reinforced by the existence of top insulin producers, ongoing R&D expenditures, and government programs to improve diabetes care. Furthermore, the region's market is growing steadily due in part to consumers' growing preference for smart insulin pens and pumps.

Region with highest CAGR:

Over the forecast period, the Asia Pacific region is anticipated to exhibit the highest CAGR, driven by nations like China, India, and Japan's expanding access to insulin therapies, rising healthcare costs, and the fast-growing number of people with diabetes. Growing use of bio-similar insulin, government programs to upgrade the infrastructure for diabetes care and the existence of a sizable untapped patient base are all driving market expansion. Moreover, growing urbanization, lifestyle changes that contribute to a higher prevalence of diabetes and growing awareness of self-administration insulin delivery devices all support the market's robust growth trajectory in this region.

Key players in the market

Some of the key players in Recombinant Human Insulin market include AstraZeneca Ltd, Eli Lilly and Company, Sanofi S.A, Gan & Lee Pharmaceuticals, Ltd, Dongbao Enterprise Group Co Ltd., Merck KGaA, Biocon Limited, Zhuhai United Laboratories Co., Ltd, Duopharma Marketing Sdn Bhd, Julphar Gulf Pharmaceutical Industries, Novo Nordisk A/S, Sigma-Aldrich Inc, Bioton S.A, Pfizer Inc and Wanbang Biopharmaceuticals Co., Ltd.

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Key Developments:

In September 2024, Biocon Ltd said it has signed a licensing and supply agreement with Tabuk Pharmaceutical Manufacturing Company to commercialise its 'GLP-1' products for treating diabetes and chronic weight management in select countries of the Middle East. Under the agreement, the company will develop and manufacture the products and Tabuk Pharmaceuticals -#- #a fully-owned subsidiary of Astra Industrial Group, a leading pharmaceutical company in the Middle East and North Africa (MENA) region.

In July 2024, Merck has signed an agreement to sell its global Surface Solutions business unit to Global New Material International Holdings Ltd. for € 665 million in cash. Merck intends to use the net proceeds from the divestment to further strengthen its strategic core businesses.

In March 2024, AstraZeneca Pharma India and Mankind Pharma has entered into an agreement for exclusive distribution of AstraZeneca's budesonide and formoterol fumarate dihydrate brand Symbicort in India. AstraZeneca will retain the intellectual property rights to budesonide and formoterol fumarate dihydrate and long-acting beta-agonist and will continue to be the marketing authorisation holder (MAH) and import license.

Products Covered:

Short-Acting Human Insulin

Intermediate-Acting Human Insulin

Premixed Human Insulin

Brands Covered:

Humulin R

Novolin R

Humulin N

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- Novolin N
- Other Brands

Distribution Channels Covered:

- Hospitals
- Retail Pharmacies
- Online Pharmacies
- Other Distribution Channels

Regions Covered:

- North America
  - US
  - Canada
  - Mexico
- Europe
  - Germany
  - UK
  - Italy
  - France
  - Spain
  - Rest of Europe

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Asia Pacific

- Japan
- China
- India
- Australia
- New Zealand
- South Korea
- Rest of Asia Pacific

South America

- Argentina
- Brazil
- Chile
- Rest of South America

Middle East & Africa

- Saudi Arabia
- UAE
- Qatar
- South Africa
- Rest of Middle East & Africa

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What our report offers:
- Market share assessments for the regional and country-level segments
- Strategic recommendations for the new entrants
- Covers Market data for the years 2022, 2023, 2024, 2026, and 2030
- Market Trends (Drivers, Constraints, Opportunities, Threats, Challenges, Investment Opportunities, and recommendations)
- Strategic recommendations in key business segments based on the market estimations
- Competitive landscaping mapping the key common trends
- Company profiling with detailed strategies, financials, and recent developments
- Supply chain trends mapping the latest technological advancements

Free Customization Offerings:

All the customers of this report will be entitled to receive one of the following free customization options:

Company Profiling

Comprehensive profiling of additional market players (up to 3)

SWOT Analysis of key players (up to 3)

Regional Segmentation

Market estimations, Forecasts and CAGR of any prominent country as per the client's interest (Note: Depends on feasibility check)

Competitive Benchmarking

Benchmarking of key players based on product portfolio, geographical presence, and strategic alliances

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10.9 Duopharma Marketing Sdn Bhd
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10.12 Sigma-Aldrich Inc
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