

Phenylketonuria Treatment Market Size, Share & Trends Analysis Report By Drug (Kuvan, Palynziq), By Mode of Administration (Oral Administration, Parenteral Administration), By Region, And Segment Forecasts, 2025 - 2030

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Abstracts

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Phenylketonuria Treatment Market Growth & Trends

The global phenylketonuria treatment market size is expected to reach USD 851.0 million by 2030, registering a CAGR of 9.4% from 2025 to 2030, according to a new report by Grand View Research, Inc. Rising prevalence of PKU across the world and favorable government regulations are the factors expected to spur the market growth over the forecast period.

For instance, according to the FDA, in 2018, phenylketonuria affected about 1 in 10,000 to 15,000 people in U.S. Furthermore, according to the Orphanet, it was estimated that 1 in 10,000 newborns in Europe is suffering from PKU. The target disease is highly prevalent in European countries, such as Italy, Ireland, and Turkey. It was estimated that around 1 in 4000 individuals in Turkey were diagnosed with PKU.

Various awareness programs conducted by private and public organizations are also projected to fuel market growth. Some of the organizations conducting such programs are SickKids, Children's Hospital of Wisconsin, CHOC Children's, and Boston Children's Hospital. These programs aim to promote optimal emotional, developmental, and physical health PKU patients.

Furthermore, continuous R&D for the disease treatment is estimated to enhance the market growth. For instance, Synlogic, Inc.'s SYN161 drug is undergoing Phase 1/2a clinical trials and also received fast-track designation from FDA. In addition, other companies, such as Rubius Therapeutics, Inc., Retrophin, Inc., and Homology Medicines, Inc. are also conducting research to develop novel therapies, such as oral, enzyme therapy, gene therapy.

Availability of reimbursement policies for high-cost treatments of PKU is also projected to boost the market growth. Kuvan is currently approved for use and reimbursed in many European countries, such as Germany, Belgium, France, Italy, and Austria. Furthermore, increasing number of funding programs for R&D by various organizations is anticipated to drive the market. For instance, the National PKU Alliance provides funding for research projects that helps in promoting advances in the management and treatment of PKU.

Phenylketonuria Treatment Market Report Highlights

Palynziq accounted for the largest share of 67.9% in 2024 and is also expected to grow at a significant CAGR over the forecast period.

North America dominated the phenylketonuria treatment market in 2024 owing to the presence of well-established healthcare infrastructure, high healthcare expenditure, and favorable government regulations.

Europe region is expected to exhibit the fastest CAGR over the forecast period owing to rising R&D activities for the development of new PKU drugs.

Contents

CHAPTER 1. METHODOLOGY AND SCOPE

- 1.1. Market Segmentation & Scope
- 1.2. Segment Definitions
 - 1.2.1. Drug
 - 1.2.2. Mode of Administration
- 1.3. Estimates and Forecast Timeline
- 1.4. Research Methodology
- 1.5. Information Procurement
 - 1.5.1. Purchased Database
 - 1.5.2. GVR's Internal Database
 - 1.5.3. Secondary Sources
 - 1.5.4. Primary Research
- 1.6. Information Analysis
 - 1.6.1. Data Analysis Models
- 1.7. Market Formulation & Data Visualization
- 1.8. Model Details
 - 1.8.1. Commodity Flow Analysis
- 1.9. List of Secondary Sources
- 1.10. Objectives

CHAPTER 2. EXECUTIVE SUMMARY

- 2.1. Market Snapshot
- 2.2. Segment Snapshot
- 2.3. Competitive Landscape Snapshot

CHAPTER 3. PHENYLKETONURIA TREATMENT MARKET VARIABLES, TRENDS, & SCOPE

- 3.1. Market Lineage Outlook
- 3.2. Market Dynamics
 - 3.2.1. Market Driver Analysis
 - 3.2.2. Market Restraint Analysis
- 3.3. Business Environment Analysis
 - 3.3.1. Industry Analysis - Porter's Five Forces Analysis
 - 3.3.1.1. Supplier power

- 3.3.1.2. Buyer power
- 3.3.1.3. Substitution threat
- 3.3.1.4. Threat of new entrant
- 3.3.1.5. Competitive rivalry
- 3.3.2. PESTLE Analysis

CHAPTER 4. PHENYLKETONURIA TREATMENT MARKET: DRUG BUSINESS ANALYSIS

- 4.1. Drug Market Share, 2024 & 2030
- 4.2. Drug Segment Dashboard
- 4.3. Market Size & Forecasts and Trend Analysis, by Drug, 2018 to 2030 (USD Million)
- 4.4. Kuvan
 - 4.4.1. Kuvan market, 2018 - 2030 (USD Million)
- 4.5. Palynziq
 - 4.5.1. Palynziq market, 2018 - 2030 (USD Million)
- 4.6. Others
 - 4.6.1. Others market, 2018 - 2030 (USD Million)

CHAPTER 5. PHENYLKETONURIA TREATMENT MARKET: MODE OF ADMINISTRATION BUSINESS ANALYSIS

- 5.1. Mode of Administration Market Share, 2024 & 2030
- 5.2. Mode of Administration Segment Dashboard
- 5.3. Market Size & Forecasts and Trend Analysis, by Mode of Administration, 2018 to 2030 (USD Million)
- 5.4. Oral Administration
 - 5.4.1. Oral administration market, 2018 - 2030 (USD Million)
- 5.5. Parenteral Administration
 - 5.5.1. Parenteral administration market, 2018 - 2030 (USD Million)

CHAPTER 6. PHENYLKETONURIA TREATMENT MARKET: REGIONAL ESTIMATES & TREND ANALYSIS BY DRUG AND MODE OF ADMINISTRATION

- 6.1. Regional Market Share Analysis, 2024 & 2030
- 6.2. Regional Market Dashboard
- 6.3. Market Size, & Forecasts Trend Analysis, 2018 to 2030:
- 6.4. North America
 - 6.4.1. North America phenylketonuria treatment market estimates and forecasts, 2018

- 2030 (USD Million)

6.4.2. U.S.

6.4.2.1. Key country dynamics

6.4.2.2. Regulatory framework

6.4.2.3. Competitive insights

6.4.2.4. U.S. phenylketonuria treatment market estimates and forecasts, 2018 - 2030

(USD Million)

6.4.3. Canada

6.4.3.1. Key country dynamics

6.4.3.2. Regulatory framework

6.4.3.3. Competitive insights

6.4.3.4. Canada phenylketonuria treatment market estimates and forecasts, 2018 -

2030 (USD Million)

6.4.4. Mexico

6.4.4.1. Key country dynamics

6.4.4.2. Regulatory framework

6.4.4.3. Competitive insights

6.4.4.4. Mexico phenylketonuria treatment market estimates and forecasts, 2018 -

2030 (USD Million)

6.5. Europe

6.5.1. Europe phenylketonuria treatment market estimates and forecasts, 2018 - 2030

(USD Million)

6.5.2. UK

6.5.2.1. Key country dynamics

6.5.2.2. Regulatory framework

6.5.2.3. Competitive insights

6.5.2.4. UK phenylketonuria treatment market estimates and forecasts, 2018 - 2030

(USD Million)

6.5.3. Germany

6.5.3.1. Key country dynamics

6.5.3.2. Regulatory framework

6.5.3.3. Competitive insights

6.5.3.4. Germany phenylketonuria treatment market estimates and forecasts, 2018 -

2030 (USD Million)

6.5.4. France

6.5.4.1. Key country dynamics

6.5.4.2. Regulatory framework

6.5.4.3. Competitive insights

6.5.4.4. France phenylketonuria treatment market estimates and forecasts, 2018 -

2030 (USD Million)

6.5.5. Italy

6.5.5.1. Key country dynamics

6.5.5.2. Regulatory framework

6.5.5.3. Competitive insights

6.5.5.4. Italy phenylketonuria treatment market estimates and forecasts, 2018 - 2030

(USD Million)

6.5.6. Spain

6.5.6.1. Key country dynamics

6.5.6.2. Regulatory framework

6.5.6.3. Competitive insights

6.5.6.4. Spain phenylketonuria treatment market estimates and forecasts, 2018 -

2030 (USD Million)

6.5.7. Denmark

6.5.7.1. Key country dynamics

6.5.7.2. Regulatory framework

6.5.7.3. Competitive insights

6.5.7.4. Denmark phenylketonuria treatment market estimates and forecasts, 2018 -

2030 (USD Million)

6.5.8. Sweden

6.5.8.1. Key country dynamics

6.5.8.2. Regulatory framework

6.5.8.3. Competitive insights

6.5.8.4. Sweden phenylketonuria treatment market estimates and forecasts, 2018 -

2030 (USD Million)

6.5.9. Norway

6.5.9.1. Key country dynamics

6.5.9.2. Regulatory framework

6.5.9.3. Competitive insights

6.5.9.4. Norway phenylketonuria treatment market estimates and forecasts, 2018 -

2030 (USD Million)

6.6. Asia Pacific

6.6.1. Asia Pacific phenylketonuria treatment market estimates and forecasts, 2018 -

2030 (USD Million)

6.6.2. Japan

6.6.2.1. Key country dynamics

6.6.2.2. Regulatory framework

6.6.2.3. Competitive insights

6.6.2.4. Japan phenylketonuria treatment market estimates and forecasts, 2018 -

2030 (USD Million)

6.6.3. China

6.6.3.1. Key country dynamics

6.6.3.2. Regulatory framework

6.6.3.3. Competitive insights

6.6.3.4. China phenylketonuria treatment market estimates and forecasts, 2018 -

2030 (USD Million)

6.6.4. India

6.6.4.1. Key country dynamics

6.6.4.2. Regulatory framework

6.6.4.3. Competitive insights

6.6.4.4. India phenylketonuria treatment market estimates and forecasts, 2018 - 2030

(USD Million)

6.6.5. Australia

6.6.5.1. Key country dynamics

6.6.5.2. Regulatory framework

6.6.5.3. Competitive insights

6.6.5.4. Australia phenylketonuria treatment market estimates and forecasts, 2018 -

2030 (USD Million)

6.6.6. South Korea

6.6.6.1. Key country dynamics

6.6.6.2. Regulatory framework

6.6.6.3. Competitive insights

6.6.6.4. South Korea phenylketonuria treatment market estimates and forecasts,

2018 - 2030 (USD Million)

6.6.7. Thailand

6.6.7.1. Key country dynamics

6.6.7.2. Regulatory framework

6.6.7.3. Competitive insights

6.6.7.4. Thailand phenylketonuria treatment market estimates and forecasts, 2018 -

2030 (USD Million)

6.7. Latin America

6.7.1. Latin America phenylketonuria treatment market estimates and forecasts, 2018 -

2030 (USD Million)

6.7.2. Brazil

6.7.2.1. Key country dynamics

6.7.2.2. Regulatory framework

6.7.2.3. Competitive insights

6.7.2.4. Brazil phenylketonuria treatment market estimates and forecasts, 2018 -

2030 (USD Million)

6.7.3. Argentina

6.7.3.1. Key country dynamics

6.7.3.2. Regulatory framework

6.7.3.3. Competitive insights

6.7.3.4. Argentina phenylketonuria treatment market estimates and forecasts, 2018 -

2030 (USD Million)

6.8. MEA

6.8.1. MEA phenylketonuria treatment market estimates and forecasts, 2018 - 2030

(USD Million)

6.8.2. South Africa

6.8.2.1. Key country dynamics

6.8.2.2. Regulatory framework

6.8.2.3. Competitive insights

6.8.2.4. South Africa phenylketonuria treatment market estimates and forecasts, 2018

- 2030 (USD Million)

6.8.3. Saudi Arabia

6.8.3.1. Key country dynamics

6.8.3.2. Regulatory framework

6.8.3.3. Competitive insights

6.8.3.4. Saudi Arabia phenylketonuria treatment market estimates and forecasts,

2018 - 2030 (USD Million)

6.8.4. UAE

6.8.4.1. Key country dynamics

6.8.4.2. Regulatory framework

6.8.4.3. Competitive insights

6.8.4.4. UAE phenylketonuria treatment market estimates and forecasts, 2018 - 2030

(USD Million)

6.8.5. Kuwait

6.8.5.1. Key country dynamics

6.8.5.2. Regulatory framework

6.8.5.3. Competitive insights

6.8.5.4. Kuwait phenylketonuria treatment market estimates and forecasts, 2018 -

2030 (USD Million)

CHAPTER 7. COMPETITIVE LANDSCAPE

7.1. Participant Overview

7.2. Company Market Position Analysis

- 7.3. Company Categorization
- 7.4. Strategy Mapping
- 7.5. Company Profiles/Listing
 - 7.5.1. BioMarin
 - 7.5.1.1. Overview
 - 7.5.1.2. Financial performance
 - 7.5.1.3. Product benchmarking
 - 7.5.1.4. Strategic initiatives
 - 7.5.2. Synlogic
 - 7.5.2.1. Overview
 - 7.5.2.2. Financial performance
 - 7.5.2.3. Product benchmarking
 - 7.5.2.4. Strategic initiatives
 - 7.5.3. Travele Therapeutics, Inc.
 - 7.5.3.1. Overview
 - 7.5.3.2. Financial performance
 - 7.5.3.3. Product benchmarking
 - 7.5.3.4. Strategic initiatives
 - 7.5.4. DAIICHI SANKYO COMPANY, LIMITED.
 - 7.5.4.1. Overview
 - 7.5.4.2. Financial performance
 - 7.5.4.3. Product benchmarking
 - 7.5.4.4. Strategic initiatives
 - 7.5.5. Codexis, Inc.
 - 7.5.5.1. Overview
 - 7.5.5.2. Financial performance
 - 7.5.5.3. Product benchmarking
 - 7.5.5.4. Strategic initiatives
 - 7.5.6. SOM BIOTECH
 - 7.5.6.1. Overview
 - 7.5.6.2. Financial performance
 - 7.5.6.3. Product benchmarking
 - 7.5.6.4. Strategic initiatives
 - 7.5.7. Homology Medicines, Inc. (Q32 Bio Inc.)
 - 7.5.7.1. Overview
 - 7.5.7.2. Financial performance
 - 7.5.7.3. Product benchmarking
 - 7.5.7.4. Strategic initiatives

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