Taliglucerase alfa

Targets (1)

IDENTIFICATION

Name

Taliglucerase alfa

Accession Number

DB08876 (DB06667)

Type

Biotech

Groups

Approved, Investigational

Biologic Classification

Protein Based Therapies
Recombinant Enzymes

Description

Taliglucerase alfa is the recombinant active form of the human lysosomal enzyme, β-glucocerebrosidase. It was approved in 2012 and is marketed under the name Elelyso for use in patients with type 1 Gaucher's disease.

Protein chemical formula

$C_{2580}H_{3918}N_{680}O_{727}S_{17}$

Protein average weight

56637.9397 Da

Synonyms

Glucosylcerebrosidase

prGC-D

prGCD

External IDs

PRX-112

Prescription Products

Search

NAME	DOSAGE	STRENGTH	ROUTE	LABELLER	MARKETING START	MARKETING END		
Elelyso	Powder, for solution	200 unit	Intravenous	Pfizer	2014-09-08	Not applicable		
Elelyso	Injection, powder, lyophilized, for solution	200 U/5mL	Intravenous	Pfizer Laboratories Div Pfizer Inc.	2012-05-01	Not applicable		

Showing 1 to 2 of 2 entries

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International/Other Brands

Uplyso (PFIZER)

Categories

Alimentary Tract and Metabolism

Enzyme Replacement Therapy

Enzymes

Enzymes and Coenzymes

Gaucher Disease

Glucosidases

Hydrolases

Hydrolytic Lysosomal Glucocerebroside-specific Enzyme

Recombinant Proteins

UNII

0R4NLX88O4

CAS number

37228-64-1

PHARMACOLOGY

Indication

For the treatment of adult Type 1 Gaucher disease.

Associated Conditions

Gaucher's Disease Type 1

Type 3 Gaucher disease

Pharmacodynamics

Patient's with Type 1 Gaucher disease have a long-term deficiency in the enzyme, glucocerebrosidase. Taliglucerase alfa is a modified form of glucocerebrosidase and is provided to counter this enzyme deficiency, resulting in smaller liver and spleen size, and improved thrombocytopenia and anemia.

Mechanism of action

Taliglucerase alfa is different from human glucocerebrosidase by two amino acids at the N terminal and up to 7 amino acids at the C terminal. This recombinant enzyme allows the hydrolysis reaction of glucocerebroside to glucose and ceramide that naturally occurs in healthy individuals.

(U) Glucocerebroside	
Not Available	
Human	

Taliglucerase alfa is administered IV so absorption is 100%.

Volume of distribution

The steady state volume of distribution is between 7.30 to 11.7 L.

Protein binding

Plasma protein binding was not quantified.

Metabolism

Metabolism was not determined.

Route of elimination

Route of elimination was not determined.

Half life

The half life is between 18.9 to 28.7 min.

Clearance

The systemic clearance was approximately 30 L/hr and 20 L/hr for 30 and 60 units/kg, respectively.

Toxicity

The most common toxic reaction seen was infusion reactions such as urticaria, arthralgia, headache, and chest pain due to IV administration.

Affected organisms

Humans and other mammals

Pathways

Not Available

Pharmacogenomic Effects/ADRs

Not Available

INTERACTIONS

No interactions found.

Food Interactions

No food effects found.

REFERENCES

Synthesis Reference

Shaaltiel Y, Bartfeld D, Hashmueli S, Baum G, Brill-Almon E, Galili G, Dym O, Boldin-Adamsky SA, Silman I, Sussman JL, Futerman AH, Aviezer D: Production of glucocerebrosidase with terminal mannose glycans for enzyme replacement therapy of Gaucher's disease using a plant cell system. Plant Biotechnol J. 2007 Sep;5(5):579-90. Epub 2007 May 24.

General References

1. Zimran A, Brill-Almon E, Chertkoff R, Petakov M, Blanco-Favela F, Munoz ET, Solorio-Meza SE, Amato D, Duran G, Giona F, Heitner R, Rosenbaum H, Giraldo P, Mehta A, Park G, Phillips M, Elstein D, Altarescu G, Szleifer M, Hashmueli S, Aviezer D: Pivotal trial with plant cell-expressed recombinant glucocerebrosidase, taliglucerase alfa, a novel enzyme replacement therapy for Gaucher disease. Blood. 2011 Nov 24;118(22):5767-73. doi: 10.1182/blood-2011-07-366955. Epub 2011 Sep 6. [PubMed:21900191]
2. Aviezer D, Brill-Almon E, Shaaltiel Y, Hashmueli S, Bartfeld D, Mizrachi S, Liberman Y, Freeman A, Zimran A, Galun E: A plant-derived recombinant human glucocerebrosidase enzyme--a preclinical and phase I investigation. PLoS One. 2009;4(3):e4792. doi: 10.1371/journal.pone.0004792. Epub 2009 Mar 11. [PubMed:19277123]

External Links

KEGG Drug

D09675

PubChem Substance

347910377

ChEMBL

CHEMBL1964120

RxList

RxList Drug Page

Drugs.com

Drugs.com Drug Page

Taliglucerase_alfa

ATC Codes

A16AB11 — Taliglucerase alfa

- A16AB — Enzymes
- A16A — OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS
- A16 — OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS
- A — ALIMENTARY TRACT AND METABOLISM

AHFS Codes

44:00.00 — Enzymes

FDA label

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MSDS

Download (28.3 KB)

CLINICAL TRIALS

Clinical Trials

Search

PHASE	STATUS	PURPOSE	CONDITIONS	COUNT
1	Completed	Treatment	Gaucher's Disease	2
2	Completed	Treatment	Gaucher's Disease	1
2	Unknown Status	Treatment	Gaucher's Disease	1
3	Completed	Treatment	Gaucher's Disease	5
4	Completed	Treatment	Gaucher's Disease	1
Not Available	No Longer Available	Not Available	Gaucher's Disease	1

Showing 1 to 6 of 6 entries

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PHARMACOECONOMICS

Not Available

Packagers

Not Available

Dosage forms

Search

FORM	ROUTE	STRENGTH
Injection, powder, lyophilized, for solution	Intravenous	200 U/5mL
Powder, for solution	Intravenous	200 unit

Showing 1 to 2 of 2 entries

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Prices

Not Available

Patents

Search

PATENT NUMBER	PEDIATRIC EXTENSION	APPROVED	EXPIRES (ESTIMATED)	
US8790641	No	2005-10-18	2025-10-18	
US8741620	No	2004-02-24	2024-02-24	
US8227230	No	2004-02-24	2024-02-24	

Showing 1 to 3 of 3 entries

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PROPERTIES

State

Solid

Experimental Properties

TAXONOMY

Description

Not Available

Kingdom

Organic Compounds

Super Class

Organic Acids

Class

Carboxylic Acids and Derivatives

Sub Class

Amino Acids, Peptides, and Analogues

Direct Parent

Peptides

Alternative Parents

Not Available

Substituents

Not Available

Molecular Framework

Not Available

External Descriptors

Not Available

TARGETS

Kind
Small molecule

Organism
Human

Pharmacological action
Unknown

References

1. Haddley K: Taliglucerase alfa for the treatment of Gaucher's disease. Drugs Today (Barc). 2012 Aug;48(8):525-32. doi: 10.1358/dot.2012.48.8.1844808. [PubMed:22916340]
2. Shaaltiel Y, Bartfeld D, Hashmueli S, Baum G, Brill-Almon E, Galili G, Dym O, Boldin-Adamsky SA, Silman I, Sussman JL, Futerman AH, Aviezer D: Production of glucocerebrosidase with terminal mannose glycans for enzyme replacement therapy of Gaucher's disease using a plant cell system. Plant Biotechnol J. 2007 Sep;5(5):579-90. Epub 2007 May 24. [PubMed:17524049]

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