

Public FDA GSRS Version

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Panagiotis Telonis, EMA; Alex Welsch NLM

New Additions to Current Data

- Orphan Drug Application Codes
 - Status and Disease
 - Captured as a code
 - US and EMA
- Group 1 Specified Substances
 - Excipients
 - Microcrystalline Cellulose
 - Aluminum Lakes
 - Multiple substance ingredients
 - Opacoats
 - Flavorants

FDA System Public Version

- Query Version to be Deployed
 - Open FDA
 - NLM (SIS)
 - Time Frame September
- Working on a Secure Portal to Allow Secure Registration (UNII Request)
 - Fourth Quarter
- Full Deployable Version of FDA/NCATS GSRS
 - Fourth Quarter

Deployable Version Inclusions

- Links to Product Data, Clinical Trial (CT.gov and Eu-CT); Adverse Event Data
- Product Registration Module (more consistent with IDMP)
- Application Registration
- Pharmacopeial Specification Data (International Pharmacopeia; USP?; EP?)
- Non-clinical in-vitro pharmacology data
- Indications and more Integration with NCATS Insight and Pharos
- Tools to Analyse Adverse Events based on Structure, Target etc.

GSRS



version 2.2.1

WELCOME: GALLAGHER - HOMS (Juvenile, Unsatatty, superUnsatatty, Updatet, superUpdatet, Approver, Admin)

Search ...



Adv

[Browse Substances](#) [Search](#) [Register](#) [FARM Integration](#) [Admin](#) [Help](#)

Search

- [Browse All Substances](#)
- [Substance](#)
- [Product](#)
- [Application](#)
- [Clinical Trial](#)
- [Adverse Event](#)
- [Advanced Search](#)

Register

- [Register a Substance](#)
 - Chemical
 - Protein
 - Nucleic Acid
 - Polymer
 - Structurally Diverse
 - Mixture
 - Concept
- Specified Substance Group 1
- Specified Substance Group 2
- Specified Substance Group 3
- Specified Substance Group 4
- Product
- Application

Orphan drug

Show Deprecated Records

Code System

Search Code System...

- FDA ORPHAN DRUG 2,235
- BONUM 181,079
- CAS 137,787
- PUBCHEM 194,731
- EPA CompTox 66,504

Exclude Selected

[More ...](#) [Clear](#)

Record Status

Substance Type

Source Tag

Relationships

ATC Level 1

ATC Level 2

ATC Level 3

ATC Level 4

Annotation Status

Code System: **FDA ORPHAN DRUG** [X](#)

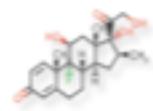
2,235 < 1 2 3 4 5 6 7 8 - 139 140 > >

[Sort By](#) Sort By [Sort By](#)

[grid](#) [list](#) [grid](#)

BETAMETHASONE UNII:9842X06Q6M

ABSOLUTE



Names: BETAMETHASONE
CELESTONE
SCH-4831
FLUBENISOLONE
PREGNA-1,4-DIENE-3,20-DIONE, 9-FLUORO-11...

Codes: BONUM: 0025365AA
CAS: 378-44-9 [edit](#)

WHO-ATC: D07KD01 [edit](#) R03BA04 [edit](#) S007AC01 [edit](#)
A07EA04 [edit](#) R01AD06 [edit](#) S03BA03 [edit](#) S01BA06 [edit](#)
H02AB01 [edit](#) S02BA07 [edit](#) S01CB04 [edit](#) C05AA05 [edit](#)
S03CA06 [edit](#) S01CA05 [edit](#) S01BB04 [edit](#) D07CC01 [edit](#)
D07BC01 [edit](#)

EVMPD: SUB05797MG

Relationships: [24](#)

Formula: C₂₂H₂₉F₅

Mol Weight: 392.46

Product Count: [Active: 3](#) **Application Count:** [CDER: 24](#) **Clinical Trial Count:** [29](#) **Adverse Event Count:** [7564](#)

Inactive: 0 [SRS: 24](#)

Orphan drug

BETAMETH...

9842X06Q6M

- [➤ Overview](#)
- [Product, Application,](#)
- [➤ Clinical Trial, Adverse Event](#)
- [➤ Structure](#)
- [➤ Names](#)
- [➤ Classification](#)
- [➤ Identifiers](#)
- [➤ Relationships](#)
- [➤ Metabolites](#)

Showing 1 to 5 of 31 entries

Classification Tree	Code System	Code
ORPHAN DRUG Designated: Treatment of Ataxia Telangiectasia.	FDA ORPHAN DRUG	492415
VATC CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS CORTICOSTEROIDS, COMBINATIONS WITH ANTIBIOTICS Corticosteroids, potent, combinations with antibiotics betamethasone and antibiotics	WHO-VATC	QD07CC01
VATC NASAL PREPARATIONS DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE Corticosteroids betamethasone	WHO-VATC	QR01AD05
VATC OTOLOGICALS CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION Corticosteroids and antiinfectives in combination betamethasone and antiinfectives	WHO-VATC	QS02CA90
Established Pharmacologic Class [EPC] Corticosteroid [EPC]	NDF-RT	N0000175576

Showing 1 to 5 of 43 entries

Previous [1](#) [2](#) [3](#) [4](#) [5](#) ... [9](#) Next

Clinical trial

Product Application Clinical Trial Adverse PT Adverse DME

Clinical Trial US Clinical Trial EU

Clinical Trial EU  Clinical Trial EU Export to Excel

Show 10 entries Previous 1 Next

Showing 1 to 1 of 1 entries

Details	EudraCT Number	Title	Sponsor	Product Name/Trade Name - Substances
View Details	2010-022120-72	The metabolic impact of Darunavir/ritonavir maintenance monotherapy after successful viral suppression with standard Atripla in HIV-1-infected patients (MIDAs).	Guy's & St. Thomas' NHS Foundation Trust	<ul style="list-style-type: none">Prezista• DARUNAVIR ETHANOLATE• DARUNAVIRNorvir• RITONAVIRAtripla• EFAVIRENZ• EMTRICITABINE• TENOFOVIR DISOPROXIL FUMARATE

Clinical trial

Clinical Trial Europe Details

EudraCT Number: [2010-022120-72-GB](#)

Title: The metabolic impact of Darunavir/ritonavir maintenance monotherapy after successful viral suppression with standard Atripla in HIV-1-infected patients (MDAs).

Sponsor Name: Guy's & St. Thomas' NHS Foundation Trust

Clinical Trial Europe

Product (3)

Medical (1)

Meddra (4)

Products in Clinical Trial

#	Product Name	Trade Name	Substances	IMP Route of Administration	Pharmaceutical Form	IMP Section	IMP Role
1		Prezista	<ul style="list-style-type: none">• DARUNAVIR ETHANOLATE• DARUNAVIR	Oral use	Tablet	1	Test
2		Norvir	<ul style="list-style-type: none">• RITONAVIR	Oral use	Tablet	2	Test
3		Atripla	<ul style="list-style-type: none">• EFAVIRENZ• EMTRICARTABINE• TENOFOVIR DISOPROXIL FUMARATE	Oral use	Tablet	3	Comparator

Clinical trial

Clinical Trial Europe Details

EudraCT Number: [2010-022120-72-GB](#)

Title: The metabolic impact of Darunavir/ritonavir maintenance monotherapy after successful viral suppression with standard Atripla in HIV-1-infected patients (MDAs).

Sponsor Name: Guy's & St. Thomas' NHS Foundation Trust

Clinical Trial Europe

Product (3)

Medical (1)

Meddra (4)

Products in Clinical Trial

#	Product Name	Trade Name	Substances	IMP Route of Administration	Pharmaceutical Form	IMP Section	IMP Role
1		Prezista	<ul style="list-style-type: none">• DARUNAVIR ETHANOLATE• DARUNAVIR	Oral use	Tablet	1	Test
2		Nonvir	<ul style="list-style-type: none">• RITONAVIR	Oral use	Tablet	2	Test
3		Atripla	<ul style="list-style-type: none">• EFAVIRENZ• EMTRICARTABINE• TENOFOVIR DISOPROXIL FUMARATE	Oral use	Tablet	3	Comparator

Clinical trial

Clinical Trial Europe Details

EudraCT Number: [2010-022120-72-GB](#)

Title: The metabolic impact of Darunavir/ritonavir maintenance monotherapy after successful viral suppression with standard Abcila in HIV-1-infected patients (MDAs).

Sponsor Name: Guy's & St. Thomas' NHS Foundation Trust

Clinical Trial Europe

Product (3)

Medical (1)

Meddra (4)

Meddra in Clinical Trial

#	Meddra Version	Meddra Class Code	Meddra Term	Meddra System Organ Class
1	14.1	10068341	HIV-1 infection	10021881 - Infections and infestations
2	14.1	10020180	HIV positive	10022891 - Investigations
3	14.1	10020188	HIV test positive	10022891 - Investigations
4	14.1	10020161	HIV infection	10021881 - Infections and infestations