

Copy of FOIA Report 2025-894: FOIA Case Form Template

Case Number - Version #: 24881936 - 1

FOIA Case Information

FDA Received Date	Case Type	HP?	Outcomes	Age in Years	Sex	503B?	Country	MCN#
24-JAN-2025	1	Y	HO				RUS	RU-SAREPTA THERAPEUTICS INC.- SRP2025-005549

FOIA Product Information

Event Preferred Terms (All)	Product Name	Role	Comp.	OTC	Route	Dosage Text	Duration	Manufacturer
1)Transaminases increased;	Elevidys	S	No	No	UNK	Unk		Sarepta Therapeutics

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Case Number - Version #: 24826867 - 2

FOIA Case Information

FDA Received Date	Case Type	HP?	Outcomes	Age in Years	Sex	503B?	Country	MCN#
23-JAN-2025	1	Y	HO				USA	US-SAREPTA THERAPEUTICS INC.- SRP2025-005458

FOIA Product Information

Event Preferred Terms (All)	Product Name	Role	Comp.	OTC	Route	Dosage Text	Duration	Manufacturer
1)Gamma-glutamyltransferase increased;2)Aspartate aminotransferase increased;3) Alanine aminotransferase increased;	Prednisone	C	No	No		1 Mg/Kg/Day		
	Deflazacort	C	No	No		Unk		
	Elevidys	S	No	No	IV	Unk, Single	1 DAY	Sarepta Therapeutics

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Case Number - Version #: 24806104 - 2

FOIA Case Information

FDA Received Date	Case Type	HP?	Outcomes	Age in Years	Sex	503B?	Country	MCN#
23-JAN-2025	1	Y	OT	15(b) (6)			USA	US-SAREPTA THERAPEUTICS INC.- SRP2024-005442

FOIA Product Information

Event Preferred Terms (All)	Product Name	Role	Comp.	OTC	Route	Dosage Text	Duration	Manufacturer
1)Liver injury;	Elevidys	S	No	No	IV	Unk, Single	1 DAY	Sarepta Therapeutics
	Prednisone	C	No	No		1 Mg/Kg/Day		
	Prednisone	C	No	No		2 Mg/Kg/Day		

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Case Number - Version #: 24777459 - 2

FOIA Case Information

FDA Received Date	Case Type	HP?	Outcomes	Age in Years	Sex	503B?	Country	MCN#
22-JAN-2025	1		HO	11(b) (6)	MALE		USA	US-SAREPTA THERAPEUTICS INC.- SRP2024-005409

FOIA Product Information

Event Preferred Terms (All)	Product Name	Role	Comp.	OTC	Route	Dosage Text	Duration	Manufacturer
1)Troponin I increased;2)Dyspepsia; 3)Headache;4)Nausea;5)Vomiting;	Elevidys	S	No	No	IV	Unk, Single	1 DAY	Sarepta Therapeutics

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Case Number - Version #: 24771071 - 2

FOIA Case Information

FDA Received Date	Case Type	HP?	Outcomes	Age in Years	Sex	503B?	Country	MCN#
10-JAN-2025	1		HO		MALE		USA	US-SAREPTA THERAPEUTICS INC.- SRP2024-005337

FOIA Product Information

Event Preferred Terms (All)	Product Name	Role	Comp.	OTC	Route	Dosage Text	Duration	Manufacturer
1)Gamma-glutamyltransferase increased;2)Troponin I increased;3) Alanine aminotransferase increased; 4)Aspartate aminotransferase increased;	Elevidys	S	No	No		Unk, Single	1 DAY	Sarepta Therapeutics
	Emflaza	C	No	No				
	Prednisone	C	No	No		1mg/Kg/Day		
	Prednisone	C	No	No		2.3mg/Kg/Day		

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Case Number - Version #: 24748510 - 3

FOIA Case Information

FDA Received Date	Case Type	HP?	Outcomes	Age in Years	Sex	503B?	Country	MCN#
17-JAN-2025	1						DEU	DE-SAREPTA THERAPEUTICS INC.- SRP2024-005349

FOIA Product Information

Event Preferred Terms (All)	Product Name	Role	Comp.	OTC	Route	Dosage Text	Duration	Manufacturer
1)Glutamate dehydrogenase increased;	Ondansetron	C	No	No	Oral	4 Milligram, Qd	3 DAY	
	Acetaminophen	C	No	No	Oral	200 Milligram, Prn		
	Deflazacort	C	No	No	Oral	18 Milligram, Qd		
	Ondansetron	C	No	No				
	Prednisolone	C	No	No	Oral	25 Milligram, Qd	3 DAY	
	Prednisolone	C	No	No	Oral	25 Milligram, Qd		
	Influvac Tetra	C	No	No	Intramuscular	0.5 Milliliter, Single	1 DAY	
	Cholecalciferol	C	No	No	Oral	2000 International Unit, Qd		
	Delandistrogene Moxeparvovec	S	No	No	IV	250 Milliliter, Single	1 DAY	Sarepta Therapeutics
	Investigational Product	S	No	No	IV	250 Milliliter, Single	1 DAY	Sarepta Therapeutics

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Case Number - Version #: 24707543 - 5

FOIA Case Information

FDA Received Date	Case Type	HP?	Outcomes	Age in Years	Sex	503B?	Country	MCN#
29-JAN-2025	1	Y	DE	11(b) (6)	MALE		USA	US-SAREPTA THERAPEUTICS INC.- SRP2024-005342

FOIA Product Information

Event Preferred Terms (All)	Product Name	Role	Comp.	OTC	Route	Dosage Text	Duration	Manufacturer
1)Disease progression;2)Muscle spasms;3)Myalgia;	Elevidys	S	No	No	IV	30 Milliliter, Single (Srp-9001)	1 DAY	Sarepta Therapeutics
	Lisinopril	C	No	No	Oral	2.5 Milligram, Qd		
	Givinostat	C	No	No	Oral	44.3 Milligram, Bid		
	Prednisone	C	No	No	Oral	150 Milligram, Saturday And Sunday		

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Case Number - Version #: 24679098 - 3

FOIA Case Information

FDA Received Date	Case Type	HP?	Outcomes	Age in Years	Sex	503B?	Country	MCN#
15-JAN-2025	1	Y	HO		MALE		USA	US-SAREPTA THERAPEUTICS INC.- SRP2024-005255

FOIA Product Information

Event Preferred Terms (All)	Product Name	Role	Comp.	OTC	Route	Dosage Text	Duration	Manufacturer
1)Hepatitis;2)Gamma-glutamyltransferase increased;3)Aspartate aminotransferase increased;4)Alanine aminotransferase increased;5)Liver injury;6)Irritability;7)Gait disturbance;	Elevidys	S	No	No	IV	Unk, Single	1 DAY	Sarepta Therapeutics

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Case Number - Version #: 24657565 - 2

FOIA Case Information

FDA Received Date	Case Type	HP?	Outcomes	Age in Years	Sex	503B?	Country	MCN#
15-JAN-2025	1	Y	HO		MALE		USA	US-SAREPTA THERAPEUTICS INC.- SRP2024-005274

FOIA Product Information

Event Preferred Terms (All)	Product Name	Role	Comp.	OTC	Route	Dosage Text	Duration	Manufacturer
1)Hepatitis;2)Liver injury;3)Hepatic enzyme increased;	Elevidys	S	No	No	UNK	Unk	1 DAY	Sarepta Therapeutics
	Prednisolone	C	No	No		45 Milligram, 1mg/Kg		
	Emflaza	C	No	No		40.95 Milligram, Qd		

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Case Number - Version #: 24544423 - 2

FOIA Case Information

FDA Received Date	Case Type	HP?	Outcomes	Age in Years	Sex	503B?	Country	MCN#
16-JAN-2025	1	Y	OT				RUS	RU-SAREPTA THERAPEUTICS INC.- SRP2024-005185

FOIA Product Information

Event Preferred Terms (All)	Product Name	Role	Comp.	OTC	Route	Dosage Text	Duration	Manufacturer
1)Drug-induced liver injury;2) Asthenia;3)Hepatitis;4)Alanine aminotransferase increased;5) Gamma-glutamyltransferase increased;6)Blood bilirubin increased;	Captopril Per Os	C	No	No		6.25 Milligram	26 DAY	
	Elevidys	S	No	No	IV	Form: Liquid, Ampoules, Unites Affected:30		Sarepta Therapeutics

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Case Number - Version #: 24044727 - 12

FOIA Case Information

FDA Received Date	Case Type	HP?	Outcomes	Age in Years	Sex	503B?	Country	MCN#
17-JAN-2025	1		HO	10(b) (6)	MALE		USA	US-SAREPTA THERAPEUTICS INC.- SRP2024-004773

FOIA Product Information

Event Preferred Terms (All)	Product Name	Role	Comp.	OTC	Route	Dosage Text	Duration	Manufacturer
1)Myopericarditis;2)Troponin I increased;	Delandistrogene Moxeparvovec	S	No	No	IV	235 Milliliter, Single	1 DAY	Sarepta Therapeutics
	Edg-5506	C	No	No	Oral	10 Milligram, Qd		
	Deflazacort	C	No	No	Oral	15.9 Milligram, Qd		
	Acetaminophen	C	No	No	Oral	10 Milliliter, Prn	534 DAY	
	Edg-5506/ Placebo	C	No	No	Oral	10 Milligram, Qd	1 MONTH	
	Proventil	C	No	No		25 Milligram, Prn		
	Acetaminophen	C	No	No	Oral	325 Milligram, Prn		