Drug Information Fulltext

Date revised: 4 August 2021

Description

Drug Information Fulltext provides complete evaluative drug descriptions of thousands of drug products available in the U.S. The file contains monographs on drugs marketed in the U.S. and some abbreviated descriptions of investigational injectable drugs. Each drug monograph provides: trade names, generic name, manufacturer, therapeutic classification and CAS® Registry Number, as well as information on pharmacology, pharmacokinetics, toxicity, dosage and administration and references to the literature. Coverage is current.

Subject Coverage

Use Drug Information Fulltext to answer questions such as:

- Are there any side effects known for the antihistamine drug Seldane?
- What drugs can be used to treat “panic disorder”?
- What drugs does Pfizer have on the market?
- When Thiopental is administered as a drug added to large volume parenteral therapy, can Amikacin also be added to the injection?

Date Coverage

Current

Update Frequency

Monthly

Geographic Coverage

United States

Document Types

- Monographs

Publisher

Drug Information Fulltext is provided by American Society of Health-System Pharmacists. Questions concerning file content should be directed to:

American Society of Health-System Pharmacists
7272 Wisconsin Avenue
Bethesda MD 20814
USA

Sample document

ProQuest Dialog

Drug Information Fulltext

Basic Search | Advanced | Command Line

Full text « Back to results

Add to selected items Save to My Research Ema

TI

Mipomersen Sodium

Nov 24, 2014.

Highlighting: Off | Single | Multi

Full Text Translate

314018

Mipomersen Sodium

TX,FT

REMS:

FDA approved a REMS for mipomersen to ensure that the benefits outweigh the risks. The REMS may apply to one or more preparations of mipomersen and consists of the following: elements to assure safe use and implementation system. See the FDA REMS page ([Web]) or the ASHP REMS Resource Center ([Web]). Also see Restricted Distribution Program under Dosage and Administration: General.

Introduction

Mipomersen sodium, a synthetic antisense oligonucleotide inhibitor of human apolipoprotein B (apo B)-100 synthesis, is an antilipemic agent. [1 4 5 6 7 8 11 12 14 15]

Uses

Dyslipidemias

Homozygous Familial Hypercholesterolemia

Mipomersen is used as an adjunct to other antilipemic agents and diet to reduce LDL-cholesterol, apolipoprotein B (apo B), total cholesterol, and non-high-density lipoprotein (non-HDL)-cholesterol concentrations in the management of homozygous familial hypercholesterolemia. [1 4] Mipomersen has been designated an orphan drug by US FDA for use in this condition. [2]

Homozygous familial hypercholesterolemia, a rare autosomal codominant disorder of lipoprotein metabolism, is a severe subtype of a group of inherited genetic defects characterized by extreme elevations of serum cholesterol concentrations (low-density lipoprotein [LDL]-cholesterol concentrations typically in excess of 500 mg/dL) occurring primarily as a result of mutations in both LDL-receptor gene loci. [4 5 13 14 15] Such excessive elevations in cholesterol concentrations put patients at high risk for premature development of atherosclerosis, cardiovascular disease, and death, if untreated. [4 5 13 14 15] Current treatments for patients with homozygous familial hypercholesterolemia include lifestyle modifications (e.g., low-fat diet, maintenance of a healthy body weight, smoking cessation), maximally tolerated dosages of hydroxymethylglutaryl-CoA (HMG-CoA) reductase inhibitors (statins), and, if necessary, combination therapy with other lipid-lowering medications (e.g., ezetimibe, bile acid sequestrants, niacin). [4 5 13 14 15] Because there is some variability among the level of residual LDL-receptor activity in those with homozygous familial hypercholesterolemia and because statins rely on the upregulation of the LDL-receptor to clear LDL particles, even maximum tolerated dosages of statins often do not result in sufficient reduction of LDL-cholesterol concentration in this population. [4 12 13 14 15] Other non-pharmacologic treatment modalities, each with its own limitations, include LDL apheresis, portocaval shunting, and liver transplantation. [4 5 13 14] Mipomersen provides an LDL-receptor independent option in the treatment of homozygous familial hypercholesterolemia. [1 12 15]

The current indication for use of mipomersen in the management of homozygous familial hypercholesterolemia is based principally on the results of a 26-week randomized, double-blind, placebo-controlled phase 3 study in patients with homozygous familial hypercholesterolemia. [1 4] This study defined homozygous familial hypercholesterolemia as 1) presence of documented mutations in both LDL-receptor alleles or 2) untreated LDL-cholesterol concentration greater than 500 mg/dL with a) tendinous and/or cutaneous xanthoma prior to age 10 and/or b) LDL-cholesterol concentration greater than 190 mg/dL in both parents or history of CHD before 55 years of age in a male first-degree relative or before 60 years of age in a female first-degree relative of the parent. [1 4] In this study, 51 patients were randomized in a 2:1 ratio to receive either mipomersen sodium (200 mg) or placebo, administered subcutaneously once weekly for 26 weeks. [1 4] The mean age of patients was 32 years (range: 12–53 years), with 7 patients younger than 18 years of age. [1 4] Most patients also received concomitant therapy with one or more antilipemic agents, including statins (98%) and ezetimibe (74%); patients did not receive concomitant LDL apheresis. [1 4] Following 26 weeks of treatment with mipomersen, LDL-cholesterol, apo B, total cholesterol, and non-HDL-cholesterol concentrations were reduced by a mean of 25, 27, 21, and 25%, respectively, compared with baseline. [1 4]

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Additional Information

Overview ® (see Users Guide). For additional information on this drug until a more detailed monograph is developed and published, the manufacturer's labeling should be consulted. It is *essential* that the manufacturer's labeling be consulted for more detailed information on usual cautions, precautions, contraindications, potential drug interactions, laboratory test interferences, and acute toxicity.

Preparations

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

Distribution of mipomersen is restricted. [1 3 9] (See Restricted Distribution Program under Dosage and Administration: General.)

Mipomersen Sodium

Routes	Dosage Forms	Strengths	Brand Names	Manufacturer
Parenteral	Injection, for subcutaneous use	200 mg/mL	Kynamro ® (available in 1-mL single-use prefilled syringes and 1-mL single-use vials)	Hospira

† Use is not currently included in the labeling approved by the US Food and Drug Administration.

RF

References

1. Genzyme Corporation. Kynamro® (mipomersen sodium) injection solution for subcutaneous injection prescribing information. Cambridge, MA; 2013 Jan.

2. Food and Drug Administration. FDA Application: Search Orphan Drug Designations and Approvals. Rockville, MD. From FDA website (http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm). Accessed [2014 01 10].

3. Kynamro® (mipomersen sodium) risk evaluation and mitigation strategy (REMS). From FDA website. Accessed 2014 Jun 26.

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15. Bell DA, Hooper AJ, Watts GF et al. Mipomersen and other therapies for the treatment of severe familial hypercholesterolemia. Vasc Health Risk Manag. 2012; 8:651-9. [PubMed 23226021]

References

Word count: **4288**

Indexing (details) Cite

SUBST	**Substance**	Substance: d(P-thio)([2′-O-(2-methoxyethyl)]rG-[2′-O-(2-methoxyethyl)]m5rC-[2′-O-(2-methoxyethyl)]m5rC-[2′-O-(2-methoxyethyl)]m5rU-[2′-O-(2-methoxyethyl)]m5rC-A-G-T-m5C-T-G-m5C-T-T-m5C-[2′-O-(2-methoxyethyl)]rG-[2′-O-(2-methoxyethyl)]m5rC-[2′-O-(2-methoxyethyl)]rA-[2′-O-(2-methoxyethyl)]m5rC-[2′-O-(2-methoxyethyl)]m5rC), DNA sodium salt
RN		CAS: 629167-92-6
MF	**Molecular formula**	C230H305N67Na19O122P19S19
LAB	**Investigational name**	ISIS 301012
TN	**Company**	Kynamro®
LAB	**Laboratory code**	ISIS 301012
CO,ORG	**Company**	Hospira
TI	**Title**	Mipomersen Sodium
LA	**Language**	English
DTYPE	**Document type**	Monograph

PUB	Publication title	American Hospital Formulary Service
PSTYPE	Publication type	Book
PD,YR	Publication date	Nov 24, 2014
	Source attribution	Drug Information Fulltext, © Publisher specific
AN	Accession number	314018
	Document URL	http://search.proquest.com/professional/docview/1634590359?accountid=137296
FAV	First available	2014-12-09
UD	Updates	2014-12-09
TOC	Table of contents	Introduction Uses Dosage and Administration Cautions Drug Interactions Description Advice to Patients Additional Information Preparations References
	Database	Drug Information Fulltext

Search fields

Field Name	Field Code	Example	Description and Notes
Accession number	AN	an(314018)	
All fields (plus full text)	--	methoxyethyl	Searches all fields including the full text.
All fields (no full text)	ALL	all(methoxyethyl)	Searches all fields *except* the full text. Use proximity and/or Boolean operators to narrow search results.
CAS® Registry Number	RN	rn(629167-92-6)	Displays in the Substance field.
Chemical name			See Substance
Classification	CC	cc(28:16.08.04) cc(“antihistamine drugs”)	
Company name	CO	co("Hospira")	
Concepts	CNC	cnc(interactions)	Generally displays in the Text field.
Document text	TX	tx(“antilipemic agents”)	
Document title	TI	ti(“mipomersen sodium”)	
Document type	DTYPE	dtype(monograph)	
First available	FAV	fav(20141209)	Indicates the first time a document was loaded into the database. It will not change regardless of how many times the record is subsequently reloaded, as long as the accession number does not change.
Generic name	GN	gn("hydrocodone bitartrate")	
Laboratory code	LAB	lab(ISIS 301012)	
Language	LA	la(english)	
Molecular formula	MF	mf(C230H305N67Na19O122P19S19)	

Field Name	Field Code	Example	Description and Notes
Publication date	PD	pd(20141124)	
Publication title	PUB	pub(american hospital formulary service)	
Publication type	PSTYPE	pstype(book)	
Publication year	YR	yr(2014) yr(2013-2015)	
References	RF	rf(genzyme)	References display in the Text field.
Subject	SU	su(adverse reaction)	
Substance	SUBST	subst("d(P-thio)([2′-O-(2-methoxyethyl)]rG-[2′-O-(2-methoxyethyl)]m5rC-[2′-O-(2-methoxyethyl)]m5rC-[2′-O-(2-methoxyethyl)]m5rU-[2′-O-(2-methoxyethyl)]m5rC-A-G-T-m5C-T-G-m5C-T-T-m5C-[2′-O-(2-methoxyethyl)]rG-[2′-O-(2-methoxyethyl)]m5rC-[2′-O-(2-methoxyethyl)]rA-[2′-O-(2-methoxyethyl)]m5rC-[2′-O-(2-methoxyethyl)]m5rC), DNA sodium salt")	Both the substance name and the CAS Registry number are displayed in this field. SUBST can be used to search both the name and the number.
Synonyms	SYN	syn("dihydrocodeinone bitartrate")	
Table of contents	TOC	toc(cautions)	
Trade name Trade name - drug	TN TNDRUG	tn(Kynamro) tndrug(kynamro)	May display in the Company, Title or the Text fields.
Updates	UD	ud(2014-12-09)	

Search tools

Field codes are used to search document fields, as shown in the sample document. Field codes may be used in searches entered on the **Basic Search**, **Advanced Search**, and **Command Line** search pages. **Limit options**, **Look up lists**, and **"Narrow results by" filters** tools are available for searching. Some data can be searched using more than one tool.

Limit Options

Date limiters are available in which you can select single dates or date ranges for the date of **publication** and **updated.**

Lookup lists

You can browse the contents of certain fields by using Look Up lists. These are particularly useful to validate spellings or the presence of specific data. Terms found in the course of browsing may be selected and automatically added to the Advanced Search form. Look Up lists are available in the search options for:

Substance

and in the fields drop-down for:

Classification, Publication

“Narrow Results By” filters

When results of a search are presented, the results display is accompanied by a list of “Narrow results by” options shown on the right-hand panel. Click on any of these options and you will see a ranked list showing the most frequently occurring terms in your results. Click on the term to apply it to (“narrow”) your search results. “Narrow results by” filters in Drug Information Fulltext include:

Publication title, Substance, Publication date

Document formats

You can **view** search results online in Brief View, Detailed View, KWIC, or Preview formats.[1]

View[2]	Description	Online	Export/ Download
Brief view result listing	Title and Publication date	✓	
Detailed view result listing	Same as Brief view plus a 3-line KWIC window	✓	
KWIC (Keyword in context)	Detailed view plus all occurrences of your search terms, highlighted within the fields where the terms occur	✓	✓
Preview	Title, Author, Publication title, Volume, Issue, Pagination, Publication date, Abstract, Subject	✓	

To **save** records, click the checkbox next to the records then click “Export/Save.” Under “Output To” choose one of the output options, e.g., Data Star Tagged, EndNote, HTML, etc. The output option you choose will determine the formats available under “Content”.[3]

Document format	Description	Online	Export/ Download
Brief citation	Bibliographic record minus Abstract, Indexing and References	✓	✓
Full text	The complete record with full text	✓[4]	✓
Custom	To design your own download format, choose the “Custom” format option in the Export/Save menu, and check the fields to be downloaded.		✓[5]

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[2] The data contained in each view may vary by database and by the type of account you have, e.g., subscriber or transactional.
[3] For example, if you choose to output in XML, you can only get the most complete record available. Text Only, PDF, RTF, and HTML output options allow the most format choices.
[4] Full text is not available for Export/Download where only A&I (abstract & indexing) data is available.
[5] The Custom export/download format is available in the following mediums only: HTML, PDF, RefWorks, RTF, Text only.