

# Drug Information Fulltext

## 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.

## Date Coverage

Current

## Geographic Coverage

United States

## 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

## 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?

## Update Frequency



Monthly

## Document Types

- Monographs

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**Fax:** +1 301-664-8857  
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Full text &lt; Back to results

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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. <sup>1 4 5 6 7 8 11 12 14 15</sup>

**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. <sup>1 4</sup> Mipomersen has been designated an orphan drug by US FDA for use in this condition. <sup>2</sup>

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. <sup>4 5 13 14 15</sup> Such excessive elevations in cholesterol concentrations put patients at high risk for premature development of atherosclerosis, cardiovascular disease, and death, if untreated. <sup>4 5 13 14 15</sup> 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). <sup>4 5 13 14 15</sup> 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. <sup>4 12 13 14 15</sup> Other non-pharmacologic treatment modalities, each with its own limitations, include LDL apheresis, portocaval shunting, and liver transplantation. <sup>4 5 13 14</sup> Mipomersen provides an LDL-receptor independent option in the treatment of homozygous familial hypercholesterolemia. <sup>1 12 15</sup>

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. <sup>1 4</sup> 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. <sup>1 4</sup> 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. <sup>1 4</sup> The mean age of patients was 32 years (range: 12–53 years), with 7 patients younger than 18 years of age. <sup>1 4</sup> 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. <sup>1 4</sup> 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. <sup>1 4</sup>

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## Additional Information

Overview <sup>®</sup> (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. <sup>1 3 9</sup> (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 <sup>®</sup> (available in 1-mL single-use prefilled syringes and 1-mL single-use vials) | Hospira      |

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

RF

### References

1. Genzyme Corporation. Kynamro<sup>®</sup> (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<sup>®</sup> (mipomersen sodium) risk evaluation and mitigation strategy (REMS). From FDA website. Accessed 2014 Jun 26.

(...)

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)

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](#)

CAS: [629167-92-6](#)

RN

**Molecular formula** C230H305N67Na19O122P19S19

**Investigational name** ISIS 301012

**Company** [Kynamro<sup>®</sup>](#)

**Laboratory code** ISIS 301012

**Company** [Hospira](#)

**Title** Mipomersen Sodium

**Language** English

**Document type** Monograph

MF  
LAB  
TN  
LAB  
CO,ORG

TI  
LA  
DTYPE

|                                 |                           |   |
|---------------------------------|---------------------------|---|
| <b>PUB<br/>PSTYPE<br/>PD,YR</b> | <b>Publication title</b>  | American Hospital Formulary Service   |
|                                 | <b>Publication type</b>   | Book  |
|                                 | <b>Publication date</b>   | Nov 24, 2014  |
| <b>AN</b>                       | <b>Source attribution</b> | Drug Information Fulltext, © Publisher specific   |
|                                 | <b>Accession number</b>   | 314018  |
|                                 | <b>Document URL</b>       | http://search.proquest.com/professional/docview/1634590359?accountid=137296   |
| <b>FAV<br/>UD<br/>TOC</b>       | <b>First available</b>    | 2014-12-09  |
|                                 | <b>Updates</b>            | 2014-12-09  |
|                                 | <b>Table of contents</b>  | Introduction<br>Uses<br>Dosage and Administration<br>Cautions<br>Drug Interactions<br>Description<br>Advice to Patients<br>Additional Information<br>Preparations<br>References |
|                                 | <b>Database</b>           | 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 <i>except</i> 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)<br>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)                |   |
| Publication date            | PD         | pd(20141124)                                 |   |

| Field Name        | Field Code | Example  | Description and Notes  |
|-------------------|------------|--|--|
| Publication title | PUB        | pub(american hospital formulary service)   |  |
| Publication type  | PSTYPE     | pstype(book)   |  |
| Publication year  | YR         | yr(2014)<br>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        | TN         | tn(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.<sup>1</sup>

| View <sup>2</sup>                   | Description  | Online | Export/Download |
|-------------------------------------|--|--------|-----------------|
| <b>Brief view result listing</b>    | Title and Publication date   | ✓      |                 |
| <b>Detailed view result listing</b> | Same as Brief view plus a 3-line KWIC window   | ✓      |                 |
| <b>KWIC (Keyword in context)</b>    | Detailed view plus all occurrences of your search terms, highlighted within the fields where the terms occur | ✓      | ✓               |
| <b>Preview</b>                      | 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”.<sup>3</sup>

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

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<sup>1</sup> To view a more complete record, click on one of the pre-defined formats listed beneath the title in your Results list, e.g., Brief Citation, Citation/Abstract, Full Text, etc.

<sup>2</sup> The data contained in each view may vary by database and by the type of account you have, e.g., subscriber or transactional.

<sup>3</sup> 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.

<sup>4</sup> Full text is not available for Export/Download where only A&I (abstract & indexing) data is available.

<sup>5</sup> The Custom export/download format is available in the following mediums only: HTML, PDF, RefWorks, RTF, Text only.