Biosimilars Info Sheet

Level 2: Regulatory and Scientific Concepts

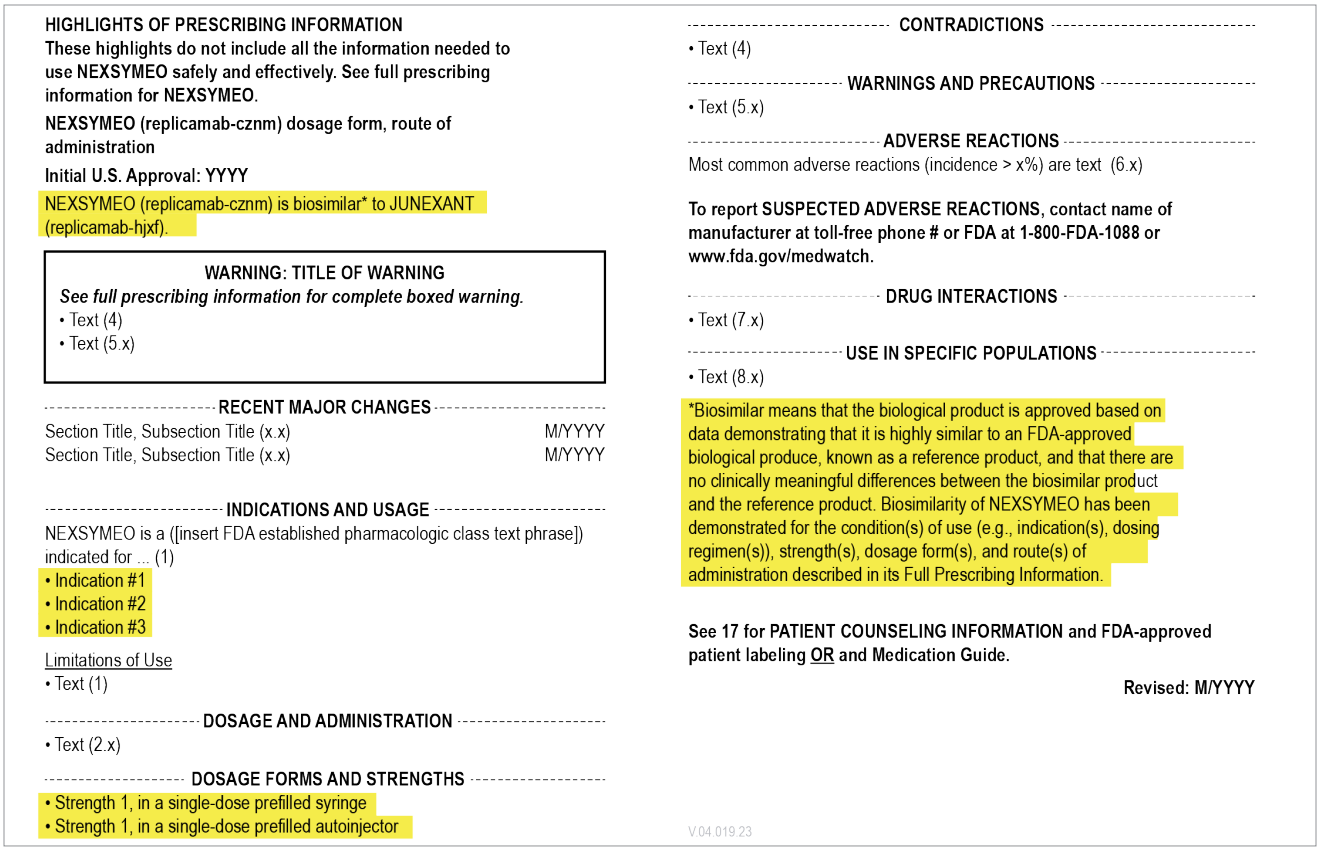
Labeling for Biosimilar and Interchangeable Biosimilar Products

Labeling for prescription medicines is FDA's primary tool for communicating drug information to health care professionals as well as patients and their caregivers. Labeling includes Prescribing Information (PI), carton and container labeling, and information for patients or caregivers (e.g., Instructions for Use).

The PI is written for health care professionals, and includes a summary of the essential scientific information needed for the safe and effective use of the product. The PI for biosimilar products (and those biosimilars approved as interchangeable, collectively referred to as biosimilars) incorporates relevant data and information from the reference product labeling.

Biosimilars are not required to have the same labeling as their reference products. The labeling should reflect currently available information necessary for the safe and effective use of the biosimilar product including preparation, administration, and storage conditions. This information may differ from that of the reference product labeling in ways that are important for prescribers or pharmacists to know. For example, a biosimilar or interchangeable biosimilar can be labeled for fewer indications or dosing regimens than the reference product. Therefore, health care professionals should review the product labeling to determine a biosimilar's approved uses and dosing regimens.

Certain sections of the PI for biosimilar and interchangeable biosimilar products that may routinely differ from the PI for their reference product are highlighted in **Figure 1**.



HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use NEXSYMEO safely and effectively. See full prescribing information for NEXSYMEO.

NEXSYMEO (replicamab-cznm) dosage form, route of administration

Initial U.S. Approval: YYYY

NEXSYMEO (replicamab-cznm) is biosimilar* to JUNEXANT (replicamab-hjxf).

WARNING: TITLE OF WARNING
See full prescribing information for complete boxed warning.
• Text (4)
• Text (5.x)

RECENT MAJOR CHANGES
Section Title, Subsection Title (x.x) M/YYYY
Section Title, Subsection Title (x.x) M/YYYY

INDICATIONS AND USAGE
NEXSYMEO is a ([insert FDA established pharmacologic class text phrase]) indicated for ... (1)
• Indication #1
• Indication #2
• Indication #3

Limitations of Use
• Text (1)

DOSAGE AND ADMINISTRATION
• Text (2.x)

DOSAGE FORMS AND STRENGTHS
• Strength 1, in a single-dose prefilled syringe
• Strength 1, in a single-dose prefilled autoinjector

CONTRADICTIONS
• Text (4)

WARNINGS AND PRECAUTIONS
• Text (5.x)

ADVERSE REACTIONS
Most common adverse reactions (incidence > x%) are text (6.x)

To report SUSPECTED ADVERSE REACTIONS, contact name of manufacturer at toll-free phone # or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS
• Text (7.x)

USE IN SPECIFIC POPULATIONS
• Text (8.x)

*Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological produce, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Biosimilarity of NEXSYMEO has been demonstrated for the condition(s) of use (e.g., indication(s), dosing regimen(s)), strength(s), dosage form(s), and route(s) of administration described in its Full Prescribing Information.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling OR and Medication Guide.

Revised: M/YYYY

V.04.019.23

Figure 1: Example Package Insert with PI for a Fictional Biosimilar Product

All PIs for biosimilars, including interchangeable biosimilars, contains a biosimilarity statement in the HIGHLIGHTS OF PRESCRIBING INFORMATION section. The statement clearly indicates that the product is biosimilar to the reference product and has an associated footnote describing biosimilarity and the basis for its approval. The PI also includes the approved INDICATIONS AND USAGE. These indications may include some or all of the indications approved for the reference product. The PI also details the approved DOSAGE FORMS AND STRENGTHS. The biosimilar labeling does not need to describe the specific studies and data collected by the biosimilar manufacturer to demonstrate that it is "highly similar to" and has no clinically meaningful differences from the reference product. Rather, biosimilar labeling should only include biosimilar-specific information when that information is necessary to inform safe and effective use of the product (e.g., when the biosimilar has different preparation, administration, or storage instructions than its reference product). Information supporting FDA's approval for biosimilar and interchangeable products can be found in reviews posted on Drugs@FDA.

Nonproprietary Naming of Biological Products

Beginning in 2017, FDA implemented a new nonproprietary naming policy for most biological products, including originator biologics, biosimilar, and interchangeable biosimilar products, to include both a "core name" and a hyphenated four letter suffix (**Figure 2**). The nonproprietary name for all approved biosimilars (or interchangeable biosimilars) share the same core name as their reference product, but each will have their own unique suffix:

- **Core name:** Component shared among biological products that contain related drug substance
- **Suffix:** Four lowercase letters that are unique and devoid of meaning
- **Nonproprietary name:** Core name + suffix

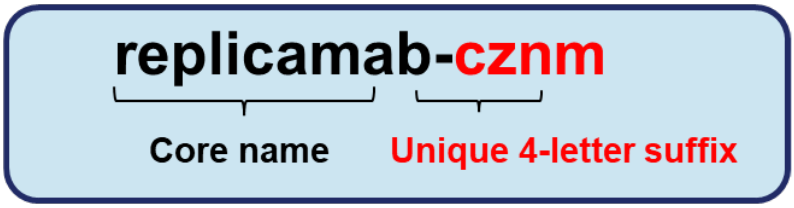


Figure 2: Example of a Fictional Biological Product with "Replicamab" as the Core Name and "cznm" as the Suffix

Product Labeling for Interchangeable Biosimilars

Information about interchangeable biosimilar products can be found in the Purple Book Database of Licensed Biological Products—a resource for patients, pharmacists, physicians, and other healthcare providers to identify approved biosimilars and interchangeable biosimilars. Because interchangeability pertains to pharmacy-level substitution, it is more appropriate to include information about interchangeability in the Purple Book, which may be easier to use as a pharmaceutical reference, rather than in product labeling, which is prescriber-focused.

The labeling and prescribing information for biosimilar and interchangeable biosimilar products is designed to provide health care providers with the necessary information to make informed decisions regarding its use in clinical practice. Health care professionals can find more information on all FDA-licensed biological products using FDA's Purple Book Database of Licensed Biological Products. Approved product labeling and approval letters are available for drugs and biological products at Drugs@FDA.