TIXAGEVIMAB/CILGAVIMAB – General Ingredients

Tixagevimab/Cilgavimab [TIXA/CILGA], a combination of two recombinant long-acting monoclonal antibodies administered as two separate consecutive injections, may not be approved or authorized for use in your country. AstraZeneca is providing you with this material as an information service and professional courtesy. Providing this information does not constitute any recommendation for use.

For US only: EVUSHELD™ (tixagevimab co-packaged with cilgavimab) is not FDA-approved and is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of EVUSHELD under Section 564(b)(1) of the Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

TIXA/CILGA is composed of two IgG1 mAbs produced in Chinese hamster ovary (CHO) cells by recombinant DNA technology. The excipients include several buffers, stabilizers, and tonicifiers in an aqueous delivery vehicle; pH 6.0.

Summary

- TIXA/CILGA final product:
  - Is composed of two human IgG1 mAbs, tixagevimab and cilgavimab, produced in CHO cells by recombinant DNA technology.
  - Does not contain any animal-derived products and excipients are of vegetable origin.
- The following potential allergens are not intentionally added to the final TIXA/CILGA product:
  - Eggs, gelatin, gluten, lactose, latex, alcohol, mercury, peanut or tree nut derivatives, preservatives, soy or thimerosal.
- No antibiotic is used during the manufacturing process.
- Tixagevimab and cilgavimab come in two separate vials which are co-packaged.
  - Both vial stoppers are made from chlorobutyl elastomer and the product contact surface contains inert FluroTec® coating, and not from natural rubber latex.
  - The vials are made from compendial grade borosilicate glass.
  - The seal is made from aluminum with a flip-off plastic cap.
- Although AstraZeneca can provide general ingredient-related information on our drug products, there are inherent limitations on the level of detail that we can provide.
  - AstraZeneca does not manufacture the raw materials used in its products, and the suppliers may periodically change.
  - Lack of contact with other ingredients during the manufacturing process cannot be guaranteed.

Drug Product Composition

Table: TIXA/CILGA Product Ingredients

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Active Ingredients</th>
<th>Antibody Quantity / 1.5 mL vial</th>
<th>Molecular Weight (Da)</th>
<th>Average Density (g/cm³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tixagevimab</td>
<td>150 mg</td>
<td>146,419</td>
<td>1.061</td>
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<tr>
<td>Cilgavimab</td>
<td>150 mg</td>
<td>148,801</td>
<td>1.060</td>
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<tr>
<td>Excipients</td>
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<tr>
<td>L-Histidine</td>
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<tr>
<td>L-Histidine hydrochloride monohydrate</td>
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<tr>
<td>Polysorbate 80ᵃ</td>
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<tr>
<td>Sucrose</td>
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<tr>
<td>Water for injection</td>
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</tbody>
</table>

ᵃPolysorbate 80 is structurally related to PEG. Cross-reactivity risk should be considered in patients with a previous allergic reaction to PEG.
Abbreviations:
CHO: Chinese hamster ovary; Da: Dalton; DNA: deoxyribonucleic acid; IgG1: immunoglobulin G-1; mAbs: monoclonal antibodies; PEG: polyethylene glycol; pH: power of hydrogen; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2; TIXA/CILGA: Tixagevimab and Cilgavimab; USP: unique selling point.

REFERENCE(S)

2. In House Data, AstraZeneca Pharmaceuticals LP. CMC E-mail communication. May 20, 2021.
3. In House Data, AstraZeneca Pharmaceuticals LP. CMC E-mail communication. May 7, 2021.