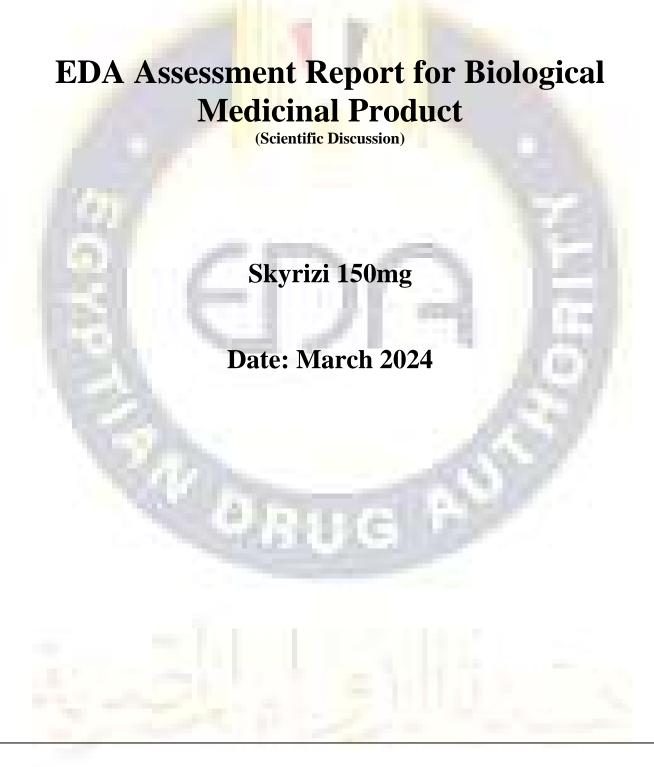
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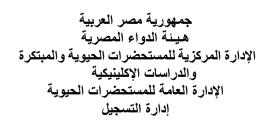


جمهورية مصر العربية هيئة الدواء المصرية الإدارة المركزية للمستحضرات الحيوية والمبتكرة والدراسات الإكلينيكية الإدارة العامة للمستحضرات الحيوية إدارة التسجيل



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Unit: Technical Assessment Unit

Assessment report

Skyrizi

Administrative information:

Trade name of the medicinal product:	Skyrizi
INN (or common name) of the active	Risankizumab 150 mg
substance(s):	
Manufacturer of the finished product	Abbvie Biotechnology Ltd, Road No.2, Km 59.2,
	Barceloneta, Puerto Rico 00617-USA
Product License holder	AbbVie Deutschland GmbH & Co. KG,
	Knollstrasse, 67061 Ludwigshafen, Germany.
Applied Indication(s):	Indicated for the treatment of moderate to severe
	plaque psoriasis in adults who are candidates for
Shared a state of the state of	systemic therapy.
Pharmaceutical form(s) and strength(s):	Solution for injection, 150mg
Route of administration	Subcutaneous(S.C)
Approved Pack	Carton box that contains a prefilled pen that consists
the second secon	of 1ml (type I) borosilicate glass PFS glass. Each
	syringe includes a staked in place (integrated) 0.5
	inch long, 27 gauge, special thin wall stainless steel
	needle, a fluoropolymer coated bromobutyl rubber
	plunger stopper and a rigid needle shield (RNS)
	composed of thermoplastic elastomer and
	polypropylene + insert leaflet
	1 41 14

List of abbreviations

CTD	common technical document
DS	Drug substance
EMA	European Medicines Agency
In C1	immunoglobulin G1

Ig G1 immunoglobulin G1 SC Subcutaneous

SC Subcutaneous

Dossier initial submission and evaluation process.

- The product was submitted for registration via Reliance model level 1.
- The dossier was initially received from the registration administration units on 26.1.2022 when the applicant provided all the reliance required documents.
- EMA detailed assessment report was provided along with List of Questions day 120 and day 180.

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- Full CTD was submitted as well.
- 1. <u>General introduction about the product including brief description of the AI, its</u> <u>mode of action and indications.</u>
 - The finished product is presented as solution for injection in Pre-filled Pen containing 150 mg of risankizumab as active substance. Other ingredients are: disodium succinate hexahydrate, succinic acid, sorbitol, polysorbate 20 and water for injection.
 - The product is available in pre-filled glass syringe with a fixed needle and needle cover, assembled in an automatic needle guard.
 - Risankizumab is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that is directed against IL-23 p19. The framework of the risankizumab antibody has been engineered with 2 mutations in the Fc
 - region to reduce Fc γ receptor and complement binding. Binding of risankizumab to IL-23 p19 inhibits the action of IL-23 to induce and sustain T helper (Th) 17 type cells, innate lymphoid cells, $\gamma\delta T$ cells, and natural killer (NK) cells responsible for tissue inflammation, destruction and aberrant tissue repair.
- 2. **Quality aspects:**

• Manufacturer(s)

-Risankizumab drug substance (DS) is manufactured, tested and released under current good manufacturing practice (cGMP) at Boehringer Ingelheim Pharma GmbH & Co KG Birkendorfer Str. 65 88397 Biberach an der Riss - Germany.

-The finished product is manufactured at: Abbvie Biotechnology Ltd, Road No.2, Km 59.2, Barceloneta, Puerto Rico 00617-USA

• Stability:

Drug Substance:

-Stability performed by: Boehringer Ingelheim Pharma GmbH & Co. KG Birkendorfer Strasse 65, 88397 Biberach an der Riss, Germany -Suggested Storage Conditions of the active substance: -70°C or below -required shelf life for the active substance is 24 months.

Drug product:

-Stability performed by: AbbVie Deutschland GmbH & Co. KG, Knollstrasse, 67061 Ludwigshafen, Germany. -Suggested Storage Conditions: Store in a refrigerator 2-8 °C. -Do not freeze.

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-Keep the Pre-filled pen in the outer carton in order to protect from light. -Approved shelf life for the finished product is 2 years.

3. Non-clinical and clinical aspects:

-The risankizumab 150 mg/mL formulation did not show any test article-related signs of local intolerance following single intravenous, paravenous, or subcutaneous administration in animals.

-New drug delivery systems for risankizumab have been developed so that the recommended 150 mg dose can be administered as a single SC injection by a PFS or an AI device using PFS as a base.

-A single 150 mg SC injection of risankizumab (150 mg/mL formulation) PFS is bioequivalent to two 75 mg SC injections of the 90 mg/mL formulation PFS and the 150 mg/mL AI (1×150 mg injection) is bioequivalent to the 150 mg/mL PFS. -In conclusion the overall benefit/risk of product name is favorable in the treatment of moderate to severe plaque psoriasis.

General Conclusion and Recommendations if any:

Based on the review of CTD modules and other supplementary documents, the product is approved.

For more information, please visit EMA published assessment report link:

https://www.ema.europa.eu/en/documents/variation-report/skyrizi-h-c-004759x-0020-g-epar-assessment-report-extension_en.pdf