



SAPV 2023/042

Date: 03-Dec-2023

Direct Healthcare Professional Communication

Cresemba® (Isavuconazonium Sulfate): Notification for expressing the strength in mg amount of both the salt/prodrug (Isavuconazonium sulfate) and active moiety (Isavuconazole)

Dear healthcare professional,

Jazeera Pharmaceutical Industries, a Hikma Pharmaceuticals affiliate, as the marketing authorization holder of the product Cresemba® (Isavuconazole), in agreement with the Saudi Food and Drug Authority (SFDA), would like to inform you of important information regarding dosing instruction for Cresemba to avoid any potential medication error.

Summary:

The approved material for Cresemba:

- **For Powder for Concentrate for Solution for Infusion:** the label claim of Isavuconazole base, which is the active moiety, was mentioned on the front panel of the outer package (as 200 mg for Powder for Concentrate for Solution for Infusion) and isavuconazonium sulfate as salt was mentioned on the side panel as (Each vial contains 372.6 mg isavuconazonium sulfate equivalent to 200 mg isavuconazole)
- **For Hard Capsules:** the label claim of Isavuconazole base, which is the active moiety, was mentioned on the principal display panel of outer package (as 100 mg for Hard capsules) and isavuconazonium sulfate as salt was mentioned on the side panel as (Each hard capsule contains 186.3 mg isavuconazonium sulfate equivalent to 100 mg isavuconazole)

This may lead to confusion and potential medication errors.

Advice for healthcare professionals:

To ensure patient safety and prevent medication errors, it is crucial for healthcare professionals to adhere to the Patient Information Leaflet (PIL) and Summary of Product Characteristics (SPC) guidelines provided with the medication where mentioned the amount of API as the following:

- **For Powder for Concentrate for Solution for Infusion:** the active substance is isavuconazole. Each vial contains 372.6 mg isavuconazonium sulfate equivalent to 200 mg isavuconazole.
- **For Hard Capsules:** the active substance is isavuconazole. Each hard capsule contains 186.3 mg isavuconazonium sulfate equivalent to 100 mg isavuconazole .

Please rest assured that patient safety is our top priority, thus, healthcare professionals, are encouraged to contact Hikma through the contact details mentioned below, should they require any further clarification or for reporting for adverse reactions:

The National Pharmacovigilance and Drug Safety Centre (NPC):

Website <https://ade.sfda.gov.sa>

Email: npc.drug@sfda.gov.sa

Fax: +966-11-205-7662

hikma.

Call center number: 19999 or QR Code:



Company contacts point

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