



## Direct Healthcare Professional Communication

December 2022

### Human Insulin – Differences between the old leaflet and the approved current leaflet

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

#### *Summary:*

- There have been some differences between the old leaflet and the approved current leaflet
- Healthcare providers should be alert for the required storage conditions required.
- Insulin should be stored at 2°C - 8°C preferably in a refrigerator but not in or close to the freezing compartment during the shelf life mentioned on the pack.
- Insulin in use can be kept at 2°C - 8°C away from heat and light for four weeks.

#### **Background on the safety concern**

All the preparations are human insulin, produced by the recombinant DNA technology, and have a similar structure and function to the normal human insulin. Human insulin preparations are presented in the following form:

#### **Human Insulin-Mix Vacsera**

Biphasic Isophane Insulin-Mix (30/70) injection. its therapeutic action starts within 30 minutes after administration, reaches its maximum effect between 2-8 hours and continues for a period ranges from 12 to 20 hours.

#### **Indication:**

Diabetes mellitus treatment in patients type I and type II when oral hypoglycemic is not sufficient.

#### **Storage:**

- Insulin should be stored at 2°C - 8°C preferably in a refrigerator but not in or close to the freezing compartment during the shelf life mentioned on the pack.
- Insulin in use can be kept at 2°C - 8°C away from heat and light for four weeks.

#### **Recommendations to Healthcare Professionals:**





There are Some differences between the old leaflet and the current approved leaflet that should be highlighted to the healthcare professionals:

**1. Name of the product:**

OLD

Human INSULIN-Mix VACSERA

(30% Regular insulin + 70% Isophanc insulin) Suspension for injection. 40 I.U. and 100 I.U.

Human INSULIN-N VACSERA

(Isophane human insulin)

Suspension for injection. 40 I.U. and 100 I.U.

*Human INSULIN-R VACSERA*

(Regular human insulin)

Solution for injection. 40 I.U. and 100 I.U

NEW

*Human Insulin Vacscra*

(30% Regular insulin \* 70% Isophanc insulin)Suspension for injection I.U 100

**2. Description:**

OLD

The description in the old leaflet describes the 3 mentioned types of insulin(Insulin-N, Insulin-R, Insulin-Mix)

NEW

The new leaflet describes only one type of Insulin (Human Insulin-Mix 1001.U)

**3. Composition:**

OLD

Composition in the old leaflet is written for the 3 types of insulin(Insulin-N, Insulin-R, Insulin-Mix)

NEW

The new leaflet, there is only one type of Insulin (Human Insulin-Mix 1001.U)

**4. Precautions:**

OLD

In the old leaflet there is an extra text concerned with the 3 types of insulin that was cancelled in the new leaflet: Insulin - h or Insulin - Mix should not be injected intravenously.

Mixing Insulin-R with other Insulin preparations:

When preparing a mixture, short acting insulin (insulin-R) should be withdrawn first. Insulin VACSERA should not be mixed with any other insulin preparations of other companies.





NEW

The Elderly Part in Precaution was removed from the leaflet.

A new paragraph was added concerning:

In the case of: The changes of adrenal, pituitary or thyroid gland functions and the deterioration of liver or kidney functions easily lead to hypoglycemia. Such designated person should take care of dosage.

**5. Storage:**

OLD

Insulin can be kept at room temperature for a month (ambient temperature)

NEW

There is a change in the Storage condition where the Insulin in use in the new' leaflet is said to be kept at 2°C - 8°C as ay from heat and light for four weeks.

**6. Presentation:**

OLD

Insulin — R. Insulin - h and Insulin - Mix (30/70) each type has two concentrations:

100 I.U. /ml (Vial of 10ml)

40 I.U. /ml (Vial of 10 ml)

NEW

The type of insulin present in the new leaflet is only:

Human Insulin Vacsera (100 I. U)

-Addition of:

Large box containing 24 medium boxes each medium box containing 12 small boxes each small box containing vial 10 & leaflet.

-Box containing vial 10 ml & leaflet.

**Call for reporting**

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: [pv.followup@edaegypt.gov.eg](mailto:pv.followup@edaegypt.gov.eg)

Online reporting: <https://primaryreporting.who-umc.org/EG>

QR Code:



Hotline: 15301

