

# Patient Card

## Important Safety Information on **ITOVEBI (INAVOLISIB)** for You and Your Healthcare Professionals

### **Important Information for the Patient**

Like all medicines, this treatment may cause side effects - you may experience some, all or none. Some could be due to **increased blood sugar levels (also known as hyperglycemia).**

- ◆ Getting medical treatment early may stop the problem from becoming more serious.
- ◆ A Doctor may monitor the sugar and ketone levels in your blood and urine and decide to give you other medicines to help reduce your symptoms.
- ◆ The Doctor who prescribed your treatment may make adjustments to the dose you are currently taking.

It is important that you **carry this card with you at all times** while you are receiving **(ITOVEBI).**

Please ensure that you show this card to all Healthcare Professionals (including doctors, nurses, pharmacists) involved in your care, and at any visits to the hospital.

 ***If you have any of these symptoms, contact a Doctor or get help right away:***

- ◆ Difficulty in breathing (i.e. fast, deep)
- ◆ Nausea and vomiting (lasting more than 2 hours)
- ◆ Confusion
- ◆ Bad stomach pain
- ◆ Very thirsty/dry mouth (signs of dehydration)
- ◆ Passing urine more often than usual or passing greater amounts of urine than usual
- ◆ Blurred vision
- ◆ Unusually increased appetite
- ◆ Weight loss
- ◆ Fruity-smelling breath
- ◆ Flushed face and dry skin
- ◆ Feeling unusually sleepy or tired

 ***Important Information for Healthcare Professionals***

Your patient is receiving **(ITOVEBI)**  
- **which may cause hyperglycemia.**

- ◆ Evaluate the patient's sugar and ketone levels in the blood and urine.
- ◆ Please refer to the Summary of Product Characteristic (SmPC) **(ITOVEBI)** for comprehensive instructions on hyperglycemia management.
- ◆ **Contact the prescribing Oncologist** for further information when possible – the Oncologist may need to modify the treatment with **(ITOVEBI).**

 **Please refer to Patient information leaflet (PIL) for further information.**

### **Adverse Events Reporting:**

If there are any suspected adverse reactions, including those during or after pre-treatment with steroids and any not listed in the Itovebi Product Information during or after Itovebi administration, please report them to:



The National Pharmacovigilance Centre  
(NPC- Saudi Food and Drug Authority (SFDA))  
Land Line: 19999.  
web-page: <http://ade.sfda.gov.sa>  
Email: [npc.drug@sfda.gov.sa](mailto:npc.drug@sfda.gov.sa)



Roche Products Saudi Arabia L.L.C.  
Direct Tel. +966 12 211 4600  
Mobile: +966 56 784 4692  
Email: [jeddah.drug\\_safety@roche.com](mailto:jeddah.drug_safety@roche.com)

*Roche Products Saudi Arabia*



**This document is approved by The Executive Directorate of Pharmacovigilance,  
at Saudi Food and Drug Authority SFDA**

## **Contact Information For You and Your Doctor**

(Prescribing Oncologist to complete)

**Date of (ITOVEBI) Initiation:**

**Patient Name and Contact Number:**

**Emergency Contact Name and  
Telephone Number:**

**Name of Primary Care Doctor and  
Contact Number:**

**Name of Oncologist and  
Contact Number:**

**After-hours Contact Number for  
the Prescribing Oncologist:**