For reporting any side effects via the National Reporting System:
National Pharmacovigilance Center (NPC) - Saudi Food and Drug Authority
SFDA call center: 19999

E-mail: npc.drug@sfda.gov.sa
Website: http://ade.sfda.gov.sa

CSL Behring:
Email: phvsa@cslbehring.com
Website: https://www.cslbehring.sa/en/report-adverse-event

Version: 2.0
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MEA-HGX-0004

Patient Card

HEMGENIX® (etranacogene dezaparvovec)

Patient's name:

Date of HEMGENIX® administration:

Carry this card with you at all times after administration of HEMGENIX® and show it to any person that may give you medical care, such as doctors and/or nurses.

Information for patients

- Please ensure to undergo regular blood tests and examinations as directed by your doctor.
- Please seek immediate medical advice for any symptoms suggestive of a blood **clot** such as sudden chest pain, shortness of breath, sudden onset of muscle weakness, loss of sensation and/or balance, decreased alertness, difficulty in speaking, or swelling of one or both legs.
- **Do not donate blood, semen, or organs, tissues, and cells for transplantation.**

Information for health care professionals

This patient has been treated with HEMGENIX®, a liver-directed gene therapy medicinal product that expresses the human coagulation Factor IX for the treatment of haemophilia B.

In case of ALT elevation within the first 3 months after HEMGENIX® treatment, the patient may need to undergo treatment with corticosteroids for minimizing the risk of hepatotoxicity with HEMGENIX®.

In case of emergency, or questions concerning treatments possibly interacting with HEMGENIX® treatment, use following contact information:

Patient's name	
Date of HEMGENIX® administration	
Haemophilia treating physician's name:	
Phone number/Email:	
Institution:	
Gene therapy physician's name (if different):	
Phone number/Email:	
Institution:	
Contact in case of emergency (patient's partner/sibling/else):	