

Patient safety card

Important safety information for patients
taking FABHALTA[®] (iptacopan)

▼ FABHALTA[®] (iptacopan) There is additional monitoring in place for FABHALTA[®] to help quickly identify new side effects. If you experience any side effects, talk to your doctor, nurse or pharmacist/ other healthcare professional. This includes any possible side effects not listed in the leaflet you will find in the package.

FABHALTA (iptacopan) SFDA approved RMP Educational Materials version
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This document is approved by The Executive Directorate of
Pharmacovigilance, at SFDA

During treatment, your immune system has a lower ability to fight certain bacterial infections (specifically from encapsulated bacteria).

These infections may cause meningitis, pneumonia, sepsis or other life-threatening infections. They can cause death if not recognised and treated early.

Keep this card with you at all times during treatment and for 2 weeks after your last dose in case of an emergency, and show it to any healthcare professional involved in your care.

Contact your doctor immediately, and show this card, in case you experience any of the following signs and symptoms of serious infection:

Fever

- With or without shivers or chills
- With a headache
- With a rash
- With chest pain and cough
- With breathlessness/fast breathing
- With high heart rate

Headache

- With feeling sick (nausea) or vomiting
- With a stiff neck or stiff back
- Confusion
- Body aches with flu-like symptoms
- Clammy skin
- Eyes sensitive to light

Information for healthcare professionals

This patient is being treated with
FABHALTA® (iptacopan).

FABHALTA® (iptacopan) may increase the patient's susceptibility to serious infections caused by encapsulated bacteria (Neisseria meningitidis, Streptococcus pneumoniae and Haemophilus influenzae Type B). These infections include meningitis, pneumonia and sepsis. Serious infections may rapidly progress and may become life-threatening if not recognised and treated early.



Recognise

Immediately evaluate
if bacterial infection is
suspected.



Treat

Immediate use of antibiotics
is vital in cases of suspected
meningitis, pneumonia or sepsis.



Inform

Please call the patient's
prescribing doctor as soon
as possible using the number
provided on the last page of
this card to receive further
information.

You can report any problem or adverse events or request additional copies of the materials through:
Patient Safety Department Novartis Pharma AG - Saudi Arabia -.
Toll Free Number: 8001240078
Phone: +966112658100
Fax: +966112658107
Email: adverse.events@novartis.com
Or by online: <https://report.novartis.com/>



Saudi Food and Drug Authority National Pharmacovigilance
Center
Unified Contact Center: 19999
Email: npc.drug@sFDA.gov.sa
Or by online: <https://ade.sFDA.gov.sa>



For more information, please refer to
FABHALTA® PIL, where further safety
information can be found.

Fabhalta PIL



Patient name:

Emergency contact name
and number:

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