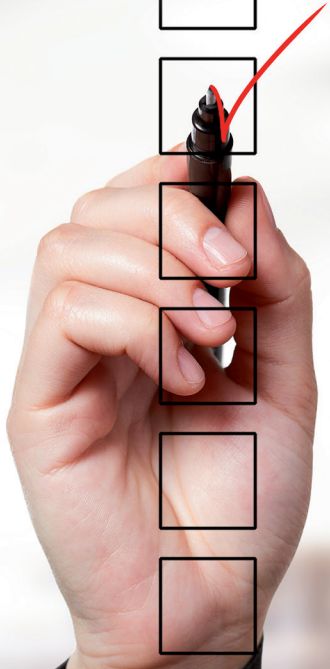


PRESCRIBING CHECK LIST



PATIENT CHECK LIST

The following topics should be discussed with the patient prior to or at the time of prescribing Lojuxta.

Dietary advice

Follow a low fat eating plan with <20% energy from fat.

Take vitamin E and essential fatty acids daily.

Avoid alcohol, grapefruit and grapefruit juice.

Lojuxta should be taken on an empty stomach, at least 2 hours after the evening meal.

Pregnancy advice

Use effective contraception.

Advise there may be a loss of effectiveness of oral contraceptives due to diarrhoea or vomiting requiring additional contraception until 7 days after resolution of symptoms.

Tell their doctor immediately if they suspect they might be pregnant.

Medical follow-up

Attend for liver monitoring tests.

Report any suspected adverse events.

PHYSICIAN CHECK LIST

The following activities should be performed prior to prescribing Lojuxta and during on-going treatment to support the safe use of the product.

Liver monitoring



Measure ALT, AST, bilirubin, alkaline phosphatase, serum albumin and gamma GT at baseline.



Measure ALT and AST (at a minimum) monthly or prior to each dose increase for the 1st year and thereafter 3 monthly.



Perform screening and monitoring for evidence of steatohepatitis/fibrosis at baseline and annually, in consultation with a hepatologist.

Patient selection



Confirm patient is diagnosed with HoFH and aged 18 years and above.



Check for contraindications including pregnancy.

Drug interactions



Check for drug interactions with CYP3A4 inhibitors, CYP3A4 inducers, p-glycoprotein substrates, coumarin anticoagulants, statins.

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.

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QPPV-Saudi@pharmaknowl.com

Call for Report any adverse drug reactions :

1. PharmaKnowl Consulting

Tel: +966112777729

Tel: +966112404409

Email: QPPV-Saudi@pharmaknowl.com

2. The National Pharmacovigilance Centre (NPC) Saudi Food and Drug Authority (SFDA):

SFDA call center: 19999 / E-mail: npc.drug@sfd.gov.sa /

Website: <http://ade.sfd.gov.sa>

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Lojuxta® (lomitapide) hard capsules Summary of Product Characteristics.



