# Lab Monitoring Guide for Healthcare Professionals

**DISCLAIMER: This material was developed by Sun Pharmaceutical, as part of the risk minimization plan for ABSORICA LD. This material is not intended for promotional use.**

| | | Abbrev. | Normal Range | Testing Frequency | Possible Effect | Comments |
|---|---|---|---|---|---|---|
| Complete Blood Count and Differential | Erythrocyte sedimentation rate | ESR | Male: 0-10 mm/h<br>Female: 0-20 mm/h | Before starting ABSORICA LD®, at first month, then as clinically indicated | ↑ Sedimentation rate | |
| | Hemoglobin | Hg | Male: 125-170 g/L<br>Female: 115-155 g/L | Baseline, first month, then as clinically indicated | ↓ Hg (Anemia) | |
| | Neutrophils | NEU | Absolute neutrophil 2.0-7.5 x $10^9$/L | Baseline, first month, then as clinically indicated | ↓ NEU (Neutropenia) | |
| | Platelet count | PLT | 130-380 x $10^9$/L | Baseline, first month, then as clinically indicated | ↓ PLT (Thrombocytopenia)<br>↑ PLT | |
| | White blood cells (Leukocytes) | WBC (LKC) | 3.5-10.5 x $10^9$/L | Baseline, first month, then as clinically indicated | ↓ WBC (↓ LKC) (Leukopenia) | |
| Urinalysis | Protein | Protein–urine | <0.2 g/24 h | As clinically indicated | ↑ Protein (Proteinuria) | |
| | Red blood cells | RBC–urine | ≤3/high power field | As clinically indicated | ↑ Red blood cells | |
| | White blood cells | WBC–urine | ≤5/high power field | As clinically indicated | ↑ White blood cells | |
| Lipids | Fasting cholesterol | Chol. | 3.5-5.2 mmol/L | Baseline, first month, then as clinically indicated and at end of treatment | ↑ Cholesterol levels | Dose reduction or cessation of therapy may reduce the increase in cholesterol |
| | Fasting triglycerides | TG | ≤1.7 mmol/L | Baseline, first month, then as clinically indicated and at end of treatment | ↑ TG levels | Dose reduction or cessation of therapy may reduce the increase in TG levels<br>If serum triglycerides are >9 mmol/L, patient is at risk of acute pancreatitis<br>Discontinue therapy if uncontrolled hypertriglyceridemia or symptoms of pancreatitis occur |
| | High-density lipoproteins | HDL | Male: >1.0 mmol/L<br>Female: >1.3 mmol/L | Baseline, first month, then as clinically indicated and at end of treatment | ↓ HDL levels | Dose reduction or cessation of therapy may reduce the decrease in HDL levels |
| Liver Function | Alanine aminotransferase (serum) | ALT | 17-63 IU/L | Baseline, first month, then at 3-month intervals | ↑ ALT | * |
| | Alkaline phosphatase (serum) | ALP | 50-136 IU/L | Baseline, first month, then at 3-month intervals | ↑ ALP | *<br>If normalization does not readily occur, or if hepatitis is suspected, discontinue therapy and further investigate the etiology |
| | Aspartate aminotransferase (serum) | AST | 15-37 IU/L | Baseline, first month, then at 3-month intervals | ↑ AST | * |
| Pregnancy | Serum or Urine | ß-hCG serum<br>ß-hCG urine | <5 IU/L | Two negative pregnancy tests before starting ABSORICA LD therapy; the first pregnancy test should be conducted at initial assessment when the patient is qualified for ABSORICA LD therapy by the physician; the second pregnancy test should be performed within 11 days prior to initiating therapy; then monthly, including 1 month following discontinuation of treatment | Major human fetal abnormalities | Urine or serum pregnancy test with a sensitivity of at least 25 mIU/mL with a negative result, performed in a licensed laboratory |
| Blood Sugar | Fasting glucose (plasma) | | 4.0-6.0 mmol/L | Before starting ABSORICA LD, at first month, then as clinically indicated | ↑ Fasting blood sugar | Known or suspected diabetics should have periodic blood sugar determinations |
| Renal Function | Creatine phosphokinase (serum) | CPK | Male: 30-250 IU/L<br>Female: 30-190 IU/L | Baseline, first month, then as clinically indicated | ↑ CPK, particularly in those patients undertaking vigorous physical activity† | 2 to 4 weeks of therapy cessation may reduce the increase in CPK† |
| | Urate, as uric acid (serum) | | Male: 208-400 µmol/L<br>Female: 155-400 µmol/L | Baseline, first month, then as clinically indicated | ↑ Uric acid (hyperuricemia) | |

*Increases in about 15% of ALT, AST, ALP baseline levels have been reported.

†CPK elevation is based on the results of one study. In an open-label clinical trial (N=217) of a single course of therapy with ABSORICA LD for severe recalcitrant nodular acne in pediatric patients 12 to 17 years, transient elevations in CPK were observed in 12% of patients, including those undergoing strenuous physical activity in association with reported musculoskeletal adverse events such as back pain, arthralgia, limb injury, or muscle sprain. In these patients, approximately half of the CPK elevations returned to normal within 2 weeks and half returned to normal within 4 weeks. No cases of rhabdomyolysis were reported in this trial.

The reference values provided in these tables should be used as guidelines only. Reference values vary based on several factors, including the demographics of the healthy population from which specimens were obtained and the specific methods and/or instruments used to assay these specimens. Laboratories that are accredited by the College of American Pathologists (CAP) are required to establish and/or validate their own reference values at least annually. Thus, any given result should be interpreted based on the reference value of the laboratory in which the test was done; the laboratory typically provides these values with the test result.

**References:** Sun Pharmaceutical Industries Limited. ABSORICA LD Product Monograph, 22 June 2023.

Medical Council of Canada. Clinical laboratory tests—adult normal values. Accessed April 1, 2022. https://mcc.ca/objectives/normal-values/

For full prescribing and monitoring information, please consult the ABSORICA LD Product Monograph.

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