

Safety Notice

Medical Devices

Sulfasalazine Interference with laboratory tests

Priority 2 – Warning

HPRA Safety Notice: SN2019(31)

Issue Date: 14th November 2019

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Various manufacturers	SD38584

ISSUE

The HPRA is raising awareness of the risk of incorrect results due to sulfasalazine interference with some laboratory tests.

Sulfasalazine or its metabolites may interfere with ultraviolet absorbance, particularly at 340nm, and may cause interference with some laboratory assays that use NAD(H) or NADP(H) to measure ultraviolet absorbance around that wavelength. As a consequence, individuals who are taking medications containing sulfasalazine may have clinically significant incorrect laboratory test results.

ACTION OR RECOMMENDATIONS

The HPRA advises that Health Care Providers:

- 1 Be aware that some laboratory tests are potentially affected and incorrect test results may be generated if sulfasalazine or its metabolites are present in the patient's specimen.
- 2 If a patient is taking sulfasalazine consult the laboratory before ordering tests.
- 3 If results of laboratory tests do not match the clinical presentation and/or other investigations, the possibility of error or interference, including sulfasalazine interference, should be considered.

- 4 Report any adverse events/incidents associated with these tests to the relevant manufacturer and the HPRA.
- The HPRA advises that patients:**
- 1 Before undergoing any laboratory tests, tell your doctor or the laboratory personnel if you are taking or have recently taken a sulfasalazine containing medication as it may affect results of some laboratory tests
 - 2 Discuss any concerns you may have with your health care provider.
- The HPRA advises that Laboratory Personnel:**
- 1 Maintain awareness of this interference if any of your tests measure absorbance in the 340nm range.
 - 2 Read and follow the instructions for use provided by the manufacturer. Contact the manufacturer of the test if you have questions regarding sulfasalazine interference.
 - 3 Forward a copy of this Safety Notice to all those that need to be aware within your organisation or to any organisation/person to which/whom these tests have been transferred.
 - 4 Report any adverse events/incidents associated with these tests to the relevant manufacturer and the HPRA.

TARGET GROUPS	
A&E Departments Biochemistry Departments Carers General Practitioners Hospital Laboratories Hospital Managers / CEOs Hospital Pharmacies Laboratory Managers Laboratory Staff	Laboratory Technicians Medical Scientists Members of the Public Pharmacists Phlebotomy Clinics Purchasing Managers Risk Managers

BACKGROUND

Sulfasalazine (SSZ), is a medication used to treat rheumatoid arthritis, ulcerative colitis and Crohn's disease.

Laboratory assays at risk of sulfasalazine interference may include urea, ammonia, LDH, and glucose. It is possible that alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatine kinase muscle/brain (CK-MB), glutamate dehydrogenase (GLDH), or thyroxine may also show interference when sulfasalazine is given at high doses.

A number of Field Safety Corrective Actions have been undertaken by different manufacturers highlighting the risk of inaccurate test results as a result of sulfasalazine interference. The topic of sulfasalazine interference was also discussed at the [Pharmacovigilance Risk Assessment Committee \(PRAC\)](#) in the European Medicines Agency. PRAC agreed that the marketing authorisation holders for sulfasalazine-containing products amend the product information leaflet to reflect the risk of sulfasalazine interference with laboratory tests.

The HPRA advises that healthcare providers and laboratory personnel be vigilant for patients prescribed sulfasalazine. If a laboratory result does not match the clinical presentation and/or

other investigations, the possibility of error or interference, including sulfasalazine interference should be considered.

MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to the contact details found on the device labelling / instructions for use.

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie