

Erba Lachema s.r.o.



**BEZBJEDONOSNO OBAVJEŠTENJE NA TERENU**  
**FSN\_16\_01**  
**Maj 2016**

**Interferencija lijekova na testove bazirane na Tinder reakciji**

Cat. No.	EL ERP Code	Product Name	Pack Name
BLT00065	12000176	CREATININE ENZYMATIC	CREA ENZ 204
XSYS0085	12000193	CREATININE ENZYMATIC	CREA ENZ 200
BLT00025	12000048	GLUCOSE	GLU 500
BLT00026	12000049	GLUCOSE	GLU 4x250
BLT00027	12000050	GLUCOSE	GLU 1000
XSYS0012	12000051	GLUCOSE	GLU 440
XSYS0069	12000087	GLUCOSE	GLU 576 XL-1000
BLT00028	12000001	HDL DIRECT	HDL 80
XSYS0043	12000003	HDL DIRECT	HDL C 160
XSYS0078	12000096	HDL DIRECT	HDL C 360 XL-1000
BLT00030	12000179	HDL CHOLESTEROL DIRECT	HDL C DIRECT 240
BLT00034	12000055	CHOLESTEROL	CHOL 5x50
BLT00035	12000056	CHOLESTEROL	CHOL 1000
BLT00036	12000057	CHOLESTEROL	CHOL 250
XSYS0009	12000020	CHOLESTEROL	CHOL 440
XSYS0070	12000088	CHOLESTEROL	CHOL 576 XL-1000
XSYS0044	12000007	LDL DIRECT	LDL C 80
BLT00041	12000005	LDL DIRECT	LDL 80
BLT00042	12000182	LDL CHOLESTEROL DIRECT	LDL C DIRECT 80
BLT00043	12000183	LDL CHOLESTEROL DIRECT	LDL C DIRECT 240
BLT00057	12000074	TRIGLYCERIDES	TG 100
BLT00058	12000075	TRIGLYCERIDES	TG 1000
BLT00059	12000076	TRIGLYCERIDES	TG 250
XSYS0041	12000077	TRIGLYCERIDES	TG 440
XSYS0071	12000089	TRIGLYCERIDES	TG 576 XL-1000
XSYS0072	12000090	URIC ACID (SINGLE REAGENT)	UA 576 XL-1000
BLT00062	12000080	URIC ACID (SINGLE REAGENT)	UA SINGLE 200
XSYS0042	12000081	URIC ACID (SINGLE REAGENT)	UA 440
XSYS0021	12000023	URIC ACID	UA 275
BLT00063	12000191	URIC ACID AOD	UA 500
BLT00064	12000192	URIC ACID AOD	UA 500 S

Erba Lachema s.r.o.



**Objašnjenje:**

N-acetilcistein (NAC), acetoaminophen i Metamizol upravlja u terapijskim koncentracijama, će uzrokovati smetnje u tzv Trinder reakcija. Trinder reakcija se zasniva na reakciji boja u kojima se formira vodonik peroksid ( $H_2O_2$ ) i nakon toga reagira s amino-antipirinom, derivatom fenola i peroksidaze kao katalizator. Reakcije peroksidaze su poremećene u različitom obimu pod uticajem gore navedenih lijekova.

**Uticaj na rezultate pacijenata: interferencija N-acetilcisteina (NAC), acetaminofena i Metamizola uzrokuje lažno niske rezultate.**

**Mjerenja:**

Gore navedeni Erba Lachema s.r.o. proizvodi su pogođeni. Ova informacija služi za označavanje ili identifikaciju, dok ne budu na raspolaganju odgovarajući IFU. Odgovarajući komentar će biti postavljena u sekciji "interferencije" svih IFU-a za navedene proizvode. **Za gore navedene testove, uzorkovanje krvi treba uraditi prije davanja pomenutih lijekova.**

**Molimo vas da odmah obavijestiti sve korisnike pomenutih proizvoda.**

Erba Lachema s.r.o. je objavila Bezbjedonosno Obavijesštenje na terenu nadležnim organima Evropske unije. Od korisnika izvan EU se traži da odrade potrebne aktivnosti kao bi obavijestili nadležne u svojim zemljama.

Po važećim propisima dužni smo pružiti kompletan lanac dokaza svih korektivnih mjera za naše proizvode. Iz tog razloga želimo da vas zamolimo da ispunite i potpišete potvrdu u prilogu koju ste primili i prosljedite ovu informaciju svim uključenim korisnicima.

Molimo pošaljite nam potvrdu na e-mail do 10.06. 2016.

Izvinjavamo se zbog mogućih neugodnosti i nadamo se Vašem razumjevanji i podršci.

Srdačan pozdrav,

Tehnički tim Erbe

## FIELD SAFETY NOTICE

FSN\_16\_01

May 2016

### Drug interferences in tests based on Trinder reaction

#### Products:

Cat. No.	EL ERP Code	Product Name	Pack Name
BLT00065	12000176	CREATININE ENZYMATIC	CREA ENZ 204
XSYS0085	12000193	CREATININE ENZYMATIC	CREA ENZ 200
BLT00025	12000048	GLUCOSE	GLU 500
BLT00026	12000049	GLUCOSE	GLU 4x250
BLT00027	12000050	GLUCOSE	GLU 1000
XSYS0012	12000051	GLUCOSE	GLU 440
XSYS0069	12000087	GLUCOSE	GLU 576 XL-1000
BLT00028	12000001	HDL DIRECT	HDL 80
XSYS0043	12000003	HDL DIRECT	HDL C 160
XSYS0078	12000096	HDL DIRECT	HDL C 360 XL-1000
BLT00030	12000179	HDL CHOLESTEROL DIRECT	HDL C DIRECT 240
BLT00034	12000055	CHOLESTEROL	CHOL 5x50
BLT00035	12000056	CHOLESTEROL	CHOL 1000
BLT00036	12000057	CHOLESTEROL	CHOL 250
XSYS0009	12000020	CHOLESTEROL	CHOL 440
XSYS0070	12000088	CHOLESTEROL	CHOL 576 XL-1000
XSYS0044	12000007	LDL DIRECT	LDL C 80
BLT00041	12000005	LDL DIRECT	LDL 80
BLT00042	12000182	LDL CHOLESTEROL DIRECT	LDL C DIRECT 80
BLT00043	12000183	LDL CHOLESTEROL DIRECT	LDL C DIRECT 240
BLT00057	12000074	TRIGLYCERIDES	TG 100
BLT00058	12000075	TRIGLYCERIDES	TG 1000
BLT00059	12000076	TRIGLYCERIDES	TG 250
XSYS0041	12000077	TRIGLYCERIDES	TG 440
XSYS0071	12000089	TRIGLYCERIDES	TG 576 XL-1000
XSYS0072	12000090	URIC ACID (SINGLE REAGENT)	UA 576 XL-1000
BLT00062	12000080	URIC ACID (SINGLE REAGENT)	UA SINGLE 200
XSYS0042	12000081	URIC ACID (SINGLE REAGENT)	UA 440
XSYS0021	12000023	URIC ACID	UA 275
BLT00063	12000191	URIC ACID AOD	UA 500
BLT00064	12000192	URIC ACID AOD	UA 500 S

### **Explanation**

N-acetylcysteine (NAC), acetoaminophen and metamizole administered in therapeutic concentrations, will cause interferences in so-called Trinder reaction. Trinder reaction is based on colour reaction in which hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) is formed and subsequently reacts with amino-antipyrine, phenol derivate and peroxidase as catalyst. Peroxidase reactions are disturbed to different extents by above mentioned medications.

**Impact on patient results: interference by N-acetylcysteine (NAC), acetoaminophen and metamizole causes falsely low results.**

### **Measures:**

The above-mentioned Erba Lachema s.r.o. products are affected. This information serves as labelling or identification until the appropriate updated package inserts are available. A corresponding note will be inserted in the section "interferences" of all package inserts for the products mentioned. **To carry out the above-mentioned tests, blood withdrawal should be performed prior to administration of drugs.**

**Please inform all users of the affected products immediately.**

Erba Lachema s.r.o. has announced The Field Safety Notice to the relevant authorities of the European Union. Customers outside the EU are asked to handle necessary announcements to authorities in their countries.

Under current regulations we are obliged to provide a complete chain of evidence of all corrective measures for our products. For this reason we would like to ask you to fill in and sign the attached confirmation that you have received and communicated this information to all concerned customers.

Please send it back to us by e-mail by June 10, 2016.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

Best regards,

Erba technical team