TABLE of available clinical Literature
for Nipruss® Product aspects

Please note:

1) The list is subject to permanent update
2) Please contact us for availability of the articles
3) Contact Altamedics: md@altamedics.de

CLINICAL PHARMACOLOGY

PHARMACODYNAMICS


ClinicalTrials.gov Identifier: NCT00135668

ClinicalTrials.gov Identifier: NCT00621816


Martindale The Extra Pharmacopoeia 1996. Cardiovascular Agents. Sodium Nitroprusside 943-945


PHARMACODYNAMIC DRUG INTERACTIONS


Sapropterine EPAR 2017 Kuvan® EMA/350999/2017; EMEA/H/C/000943

SmPC ADCIRCA 2013; EMA EPAR, WC500032789


USPDI. USP Monographs: Sodium Nitroprusside for Injection
http://www.pharmacopeia.cn/v29240/usp29nf24s0_m76940.html. 2016

PHARMACOKINETICS

ABSORPTION

⁻ Per definitionem 100% as administered via IV

DISTRIBUTION


Schulz V.: Clinical Pharmacokinetics of Nitroprusside, Cyanide, Thiosulphate and Thiocyanate. Clinical Pharmacokinetics, 9, 1984, 239-251

Schulz, V. et al., Toxizität von Natriumnitroprussid bei therapeutischer Anwendung ohne und mit Natriumthiosulfat, klein. Wochenzeitschrift. 60, 1982: 1393-1400

METABOLISM

Cohn JN, Burke LP. Nitroprusside. Ann Intern Med 1979;91: 752-7


Schulz, V., Akute und subakute Toxizität von Nitroprussidnatrium, Intensivmed. 16, 1979: 320-325

Schulz V.: Clinical Pharmacokinetics of Nitroprusside, Cyanide, Thiosulphate and Thiocyanate. Clinical Pharmacokinetics, 9, 1984, 239-251

Schulz, V. et al., Toxizität von Natriumnitroprussid bei therapeutischer Anwendung ohne und mit Natriumthiosulfat, klein. Wochenzeitschrift. 60, 1982: 1393-1400

ELIMINATION


Schulz V.: Clinical Pharmacokinetics of Nitroprusside, Cyanide, Thiosulphate and Thiocyanate. Clinical Pharmacokinteics, 9, 1984, 239-251

Schulz, V. et al., Toxizitat von Natriumnitroprussid bei therapeutischer Anwendung ohne und mit Natriumthiosulfat, klein. Wochenzeitschrift. 60, 1982: 1393-1400

EXCRETION

Schulz V.: Clinical Pharmacokinetics of Nitroprusside, Cyanide, Thiosulphate and Thiocyanate. Clinical Pharmacokinteics, 9, 1984, 239-251

PHARMACOKINETIC DRUG INTERACTIONS

n.a.
OVERVIEW OF EFFICACY

**Hypertensive crisis:**


Blumenfeld JD, Laragh JH. Management of hypertensive crisis: the scientific basis for treatment decisions Am J Hypertens. 2001; 14: 1154-67


**Controlled intra-operative hypotension**


Coltart D.J.: Haemodynamic effects of sodium nitroprusside (Nipruuss), following cardiac surgery. Clinical Trials Journat, 1979,16 No.2, 54-58


Kaufman L.: Controlled hypotension in anaesthesia produced by sodium nitroprusside (Nipruess) Clinical Trials Journal, 1979,17 No.2, 49-53


Martindale 2012 (last reviewed 2010-08-24; last modified 2011-08-13)


EFFICACY DATA FROM CLINICAL TRIALS


Coltart D.J.: Haemodynamic effects of sodium nitroprusside (Nipruß), following cardiac surgery. Clinical Trials Journal, 1979,16 No.2, 54-58


Freiberger NA, Tellor KB, Stevens AM. Comparison of Clevidipine Versus Sodium Nitroprusside for the Treatment of Postoperative Hypertension in Cardiac Surgery Patients. Hosp Pharm. 2016 Jun;51(6):461-7


Young JD. Nitric oxide and related vasodilators. Can·J. Anaesth., 1997,44 No.5, 23-28

ADMINISTRATION IN CHILDREN AND ADOLESCENTS


**Hypertensive crisis**


Benzing G., Helmsworth Ja, Schrieber JT, Loggie J, Kaplan S. Nitroprusside after Open-Heart Surgery Supported in part by the American Heart Association, Circulation 54(3); 1976: 467-471


http://clinicaltrials.gov/show/NCT00135668

http://clinicaltrials.gov/show/NCT00621816


Spence JD. New Treatment Options for Hypertension During Acute Ischemic or Hemorrhagic Stroke. Current Treatment Options in Cardiovascular Medicine 2007, 9:242–246


**Controlled intra-operative hypotension**


Case presentation/casuistics


Hypertension in pregnancy

Abalos E, Duley L, SteynDW, Henderson-Smart DJ. Antihypertensive drug therapy for mild to moderate hypertension during pregnancy. Cochrane Database Syst Rev 2001:CD002252

Guideline: European Society for Hypertension (ESH)/European Society for Cardiology ESC 2013 ESH/ESC Guidelines for management of arterial hypertension


Lane DA, Lip GY, Beevers DG. Improving survival of malignant hypertension patients over 40 years, Am J Hypertens 2009 (22): 1199-1204


**DOSAGE**


Schulz, V., Akute und subakute Toxizitat von Nitroprussiddnatrium, Intensivmed. 16, 1979: 320- 325

Schulz V.: Clinical Pharmacokinetics of Nitroprusside, Cyanide, Thiosulphate and Thiocyanate. Clinical Pharmacokinetics, 9, 1984, 239-251


**Children and adolescents**


US FDA Pediatric Advisory committee 2017
CURRENT GUIDELINE RECOMMENDATIONS


Guideline: European Society for Cardiology, ESC 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

Guideline: European Society for Hypertension (ESH)/European Society for Cardiology ESC 2013 ESH/ESC Guidelines for management of arterial hypertension

Guideline: European Society of Cardiology 2011 ESC Guidelines on the management of cardiovascular diseases during pregnancy


Guideline: European Society of Cardiology/European Society for Cardio-Thoracic Surgery 2017 ESC/EACTS Guidelines for the management of valvular heart disease

Guideline: European Society of Cardiology 2017 Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation

Guideline: German Society of Cardiology -Cardiovascular Research e.V. 2010 German-Austrian S3-Guideline „Infarction-related cardiogenic shock - diagnosis, monitoring and therapy“

Guideline: German Medical Association (BAEK); Association of German Medical Associations National Association of Statutory Health Insurance Physicians (KBV); Association of Scientific Medical Societies (AWMF); Drug Commission of the German Pharmacists (AMK) National Management Guideline Chronic Heart insufficiency 2nd edition 2017, Version 2 AWMF-Register-No.: nvl-006

Guideline: German Society for Paediatric Cardiology Guideline (S2k) Pediatric Cardiology, Pediatric Nephrology and Paediatrics: Arterial hypertension in childhood and adolescence, No. 023-040, 2013

Guideline: German Society for Vascular Surgery (DGG) 2010 Guideline Aortic dissection (Guideline for the diagnosis and treatment of type B dissections)

Guideline: German AMWMF (Association of Scientific Medical Societies e.V.), composed of 177 scientific societies (+ 3 associated) from all areas of medicine S3 Guideline for intensive medical care Cardiac surgery patient (Hemodynamic and cardiovascular monitoring)

Guideline: American Heart Association, AHA 2015 AHA Guideline Pediatric advanced life support
OVERVIEW OF SAFETY


Cyanide and Thiocyanate toxicity


Cohn JN, Burke LP. Nitroprusside. Ann Intern Med 1979;91: 752-7

Cole PV and Vesey CJ. Sodium Thiosulphate Decreases Blood Cyanide Concentrations After The Infusion Of Sodium Nitroprusside Br. J. Anaesth. (1987), 59, 531-535


Safety in children and adolescents


WHO-UMC, 01-2018

Overdose of Sodium Nitroprusside


Schulz, V., Akute und subakute Toxizitat von Nitroprussidnatrium, Intensivmed. 16, 1979: 320- 325
Schulz V.: Clinical Pharmacokinetics of Nitroprusside, Cyanide, Thiosulphate and Thiocyanate. Clinical Pharmacokinetics, 9, 1984, 239-251

Schulz, V. et al., Toxizität von Natriumnitroprussid bei therapeutischer Anwendung ohne und mit Natriumthiosulfat, klein. Wochenzeitschrift. 60, 1982: 1393-1400


**Carboxyhaemoglobinaemia**


**Regional myocardial blood flow (RMBF)**


**Updated informative texts (SmPC safety part 4.2 to 4.9):**

**Posology and method of administration**


Cohn JN, Burke LP. Nitroprusside. Ann Intern Med 1979;91: 752-7

Comparator product US 2016


Martindale 2012 (last reviewed 2010-08-24; last modified 2011-08-13)


Nipride package insert (Roche—US), 10/90, 1990


Schulz, V., Akute und subakute Toxizität von Nitroprussidnatrium, Intensivmed. 16, 1979: 320- 325

Schulz V.: Clinical Pharmacokinetics of Nitroprusside, Cyanide, Thiosulphate and Thiocyanate. Clinical Pharmacokinteics, 9, 1984, 239-251

Schulz, V. et al., Toxizität von Natriumnitroprussid bei therapeutischer Anwendung ohne und mit Natriumthiosulfat, klein. Wochenzeitschrift. 60, 1982: 1393-1400


Elderly patients


Coltart D.J.: Haemodynamic effects of sodium nitroprusside (Nipruess), following cardiac surgery. Clinical Trials Journal, 1979,16 No.2, 54-58

Paediatric population


NCT00135668

Public law Best Pharmaceuticals for Children Act 2002

USFDA Pediatric Advisory committee 2017 Pediatric Focused Safety Review: Sodium Nitroprusside (Nitropress®) Pediatric Advisory Committee Meeting March 6, 2017


**Contraindications**


Martindale The Extra Pharmacopoeia 1996. Cardiovascular Agents. Sodium Nitroprusside 943-945


Schulz V.: Clinical Pharmacokinetics of Nitroprusside, Cyanide, Thiosulphate and Thiocyanate. Clinical Pharmacokinteics, 9, 1984, 239-251


**Special warnings and precautions for use**


Baskin SI and Brewer TG. Cyanide Poisoning. In: Cpt 10, Medical Aspects of Chemical and Biological Warfare (1997), pp. 271-286

Blumenfeld JD, Laragh JH. Management of hypertensive crisis: the scientific basis for treatment decisions Am J Hypertens. 2001; 14: 1154-67


Cohn JN, Burke LP. Nitroprusside. Ann Intern Med 1979;91: 752-7

Cottart D.J.: Haemodynamic effects of sodium nitroprusside (Nipruss), following cardiac surgery. Clinical Trials Journal, 1979,16 No.2, 54-58


SmPC ADCIRCA 2013; EMA EPAR, WC500032789


Young JD. Nitric oxide and related vasodilators. Can·J. Anaesth., 1997,44 No.5, 23-28
Interaction with other medicinal products and other forms of interaction


Fertility, pregnancy and lactation

Abalos E, Duley L, SteynDW, Henderson-Smart DJ. Antihypertensive drug therapy for mild to moderate hypertension during pregnancy. Cochrane Database Syst Rev 2001:CD002252


Effects on ability to drive and use machines

QRD-template, Version 10, 02/2016

Undesirable effects


Overdose


Schulz, V., Akute und subakute Toxizität von Nitroprussidnatrium, Intensivmed. 16, 1979: 320- 325

Schulz V.: Clinical Pharmacokinetics of Nitroprusside, Cyanide, Thiosulphate and Thiocyanate. Clinical Pharmacokinteics, 9, 1984, 239-251

Schulz, V. et al., Toxizität von Natriumnitroprussid bei therapeutischer Anwendung ohne und mit Natriumthiosulfat, klein. Wochenzeitschrift. 60, 1982: 1393-1400


BENEFIT AND RISK CONCLUSION


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Schulz V.: Clinical Pharmacokinetics of Nitroprusside, Cyanide, Thiosulphate and Thiocyanate. Clinical Pharmacokinetics, 9, 1984, 239-251
LITERATURE REFERENCES - all

Abalos E, Duley L, SteynDW, Henderson-Smart DJ. Antihypertensive drug therapy for mild to moderate hypertension during pregnancy. Cochrane Database Syst Rev 2001:CD002252


Blumenfeld JD, Laragh JH. Management of hypertensive crisis: the scientific basis for treatment decisions Am J Hypertens. 2001; 14: 1154-67


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Cole PV and Vesey CJ. Sodium Thiosulphate Decreases Blood Cyanide Concentrations After The Infusion Of Sodium Nitroprusside Br. J. Anaesth. (1987), 59, 531-535

Coltart D.J.: Haemodynamic effects of sodium nitroprusside (Nipruss), following cardiac surgery. Clinical Trials Journal, 1979,16 No.2, 54-58


Drug.com http://www.drugs.com/mmx/nitroprusside-sodium.html; Rxlist.com 2010


Guideline: European Society for Cardiology, ESC 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

Guideline: European Society for Hypertension (ESH)/European Society for Cardiology ESC 2013 ESH/ESC Guidelines for management of arterial hypertension

Guideline: European Society of Cardiology 2011 ESC Guidelines on the management of cardiovascular diseases during pregnancy


Guideline: European Society of Cardiology/European Society for Cardio-Thoracic Surgery 2017 ESC/EACTS Guidelines for the management of valvular heart disease

Guideline: European Society of Cardiology 2017 Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation

Guideline: German Society of Cardiology -Cardiovascular Research e.V. 2010 German-Austrian S3-Guideline „Infarction-related cardiogenic shock - diagnosis, monitoring and therapy“

Guideline: German Medical Association (BAEK); Association of German Medical Associations National Association of Statutory Health Insurance Physicians (KBV); Association of Scientific Medical Societies (AWMF); Drug Commission of
the German Pharmacists (AMK) National Management Guideline Chronic Heart insufficiency 2nd edition 2017, Version 2 AWMF-Register-No.: nvl-006

Guideline: German Society for Paediatric Cardiology Guideline (S2k) Pediatric Cardiology, Pediatric Nephrology and Paediatrics: Arterial hypertension in childhood and adolescence, No. 023-040, 2013


Guideline: German AMWMF (Association of Scientific Medical Societies e.V.), composed of 177 scientific societies (+ 3 associated) from all areas of medicine S3 Guideline for intensive medical care Cardiac surgery patient (Hemodynamic and cardiovascular monitoring)

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Young JD. Nitric oxide and related vasodilators. Can·J. Anaesth., 1997,44 No.5, 23-28

SmPC

Altamedics SmPC Nipruss ® February 2014 and March 2018 (update ongoing)