Edukační materiály

Guide for Health Care Professionals
on the risks associated to Normosang® administration
(thrombosis, extravasation and necrosis) and
the precautions to take in order to avoid them

PREVENTION

Although it is recognized that extravasation, thrombosis and necrosis are the conditions associated with the intravenous administration of medications the risk must be proactively managed with the aim of preventing an incident.

Awareness of Risk Factors

The risk is increased in the following cases:
- elderly patients can be more at risk due to:
  - Interference with the cannula when the patient is confused or agitated.
  - Reduced pain sensation.
  - Fragile skin and veins.
- patients suffering from decreased sensation or circulation.
- inadequate visibility of the cannula and surrounding tissue.
- central venous access devices (CVADs).

Therefore, additional vigilance is required.

<u>Porphyria patients may have additional risk due to:</u>
- Fragile, mobile veins which are difficult to cannulate.
- Repeated venipunctures or cannula sites due to previous treatments.

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Risk factors for thromboembolic events are:
- Age ≥40 years
- Obesity
- History of venous thromboembolism
- Cancer
- Bed rest ≥5 days
- Major surgery

MANAGEMENT OF THE RISKS

Since Normosang® is potentially irritating to tissues; it should be administered carefully as it is indicated in the Normosang® SmPC (see section 4.2. Posology and method of administration; 4.4. Special warnings and precautions for use).

MANAGEMENT OF EXTRAVASATION

If an extravasation is suspected treatment must begin as soon as possible.

Early detection and starting treatment within 24 hours can significantly reduce tissue damage.

Procedure for the IMMEDIATE management of <u>peripheral extravasation</u>

1. Stop and disconnect the infusion immediately. DO NOT remove the cannula. Cap off the syringe on the giving set.
2. Explain to the patient what you suspect has happened and the procedure to deal with it.
3. Leave the cannula/ needle in place and try to aspirate as much of the drug as possible from the cannula with a 10ml luer lock syringe. Try to draw blood from the cannula.
4. Mark around the affected area with an indelible pen.
5. Remove the cannula/needle.
6. DO NOT apply direct manual pressure to suspected extravasation site.
7. Place a piece of dry gauze on the affected skin.
8. Apply cold compress to affected area for 20 to 30 minutes. Apply the compress firmly, but without undue pressure.

9. Repeat cold compress four times daily for 24 – 48 hours.
10. Use hydrocortisone cream 1% if local inflammation occurs.
11. Administer pain relief (if required) as prescribed.
12. Encourage patient to move limb and elevate for 48 hours.
13. Arrange follow up out-patient/in-patient appointment for the patient and document in the notes.

Procedure for the IMMEDIATE management of extravasation via a central venous access device (CVAD)

1. Stop and disconnect the infusion immediately. DO NOT remove the central venous catheter (central line), PICC line or portacath. Cap off the syringe on the giving set.
2. Explain to the patient what you suspect has happened and the procedure to deal with it.
3. Leave the CVAD in place and try to aspirate as much of the drug as possible from the cannula with a 10ml luer lock syringe. Try to draw blood through the CVAD.
4. Mark around the affected area with an indelible pen.
5. DO NOT apply direct manual pressure to suspected extravasation site.
6. Place a piece of dry gauze on the affected skin.
7. Apply cold compress to affected area for 20 to 30 minutes. Apply the compress firmly, but without undue pressure.
8. Repeat cold compress four times daily for 24 – 48 hours.
9. Use hydrocortisone cream 1% if local inflammation occurs.
10. Administer pain relief (if required) against a valid signed prescription.
11. Arrange for line removal.
12. Encourage patient to move limb and elevate for 48 hours.
13. Arrange follow up out-patient/in-patient appointment for the patient and document in notes. All patients with CVAD extravasations must return for assessment of the affected area within 48 hours following the extravasation.

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MANAGEMENT OF THROMBOSIS, NECROSIS

Management of thrombosis and necrosis should be performed after thorough clinical evaluation by the treating physicians. The general therapeutical principles for these conditions should be applied, taking into account the specific patients' condition and following the prescription of safe porphyria medications. The list of safe drugs in porphyria could be found at:

www.cardiff-porphyria.org

www.drugs-porphyria.org

Any suspicion of a serious or unexpected adverse reaction and other facts relevant for the health of patients must be reported to the State Institute for Drug Control.
Details on reporting can be found at:
http://www.sukl.cz/nahlasit-nezadouci-ucinek.
The address for reporting is Státní ústav pro kontrolu léčiv, odbor farmakovigilance, Šrobárova 48, Prague 10, 100 41, email: farmakovigilance@sukl.cz

All cases of extravasation, thrombosis or necrosis with human hemin (Normosang®) could be reported also to Recordati Rare Diseases Pharmacovigilance department at:

RRDPharmacovigilance@recordati.com

Pharmacovigilance Department
RECORDATI RARE DISEASE
Immeuble Le Wilson
70, avenue du Général de Gaulle
92800 Puteaux, France
Tel.: +33 1 47 73 64 58
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The currently effective SmPC is available from the website of the State Institute for Drug Control under the Medicines database section at
http://www.sukl.cz/modules/medication/search.php

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