

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S4

**NORMOSANG 25 mg/ml, concentrate for solution for infusion**

**Hemin**

**Sugar free**

**Read all of this leaflet carefully before you are given NORMOSANG**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

### **What is in this leaflet**

1. What NORMOSANG is and what it is used for
2. What you need to know before you use NORMOSANG
3. How to use NORMOSANG
4. Possible side effects
5. How to store NORMOSANG
6. Contents of the pack and other information

#### **1. What NORMOSANG is and what it is used for**

NORMOSANG contains hemin, which is a substance derived from human blood. NORMOSANG is used to treat sudden attacks that occur in patients suffering from acute hepatic porphyria; the disease is characterised by liver accumulation of compounds (including porphyrins and its toxic precursors). There are three types of hepatic porphyria whose medical names are: acute intermittent porphyria, porphyria variegata and hereditary coproporphyria. This accumulation leads to symptoms of the disease including pain (mainly abdomen, back and thighs), nausea, vomiting and constipation.

## 2. What you need to know before you use NORMOSANG

### **NORMOSANG should not be administered to you:**

- if you are allergic to hemin or any of the other ingredients of this medicine (listed in section 6)
- if you are breastfeeding your baby
- if you are a child.

### **Warnings and precautions**

- Before treatment with NORMOSANG, your doctor should confirm an attack of hepatic porphyria by series of clinical and biological criteria:
  - suggestive family or personal history
  - suggestive clinical signs
  - quantitative determination of delta-amino-laevulinic acid and porphobilinogen (specific markers of the disease) in urine.
- The sooner NORMOSANG treatment is started after the onset of an attack, the greater its efficacy.
- As a result of NORMOSANG infusions, abdominal pain and other gastrointestinal symptoms generally disappear within 2 - 4 days. Neurological complications (such as paralysis and psychological disorders) are less affected by the treatment.
- You will be monitored during the whole course of the treatment, because porphyria attacks are often associated with various effects on the heart and circulation, and on the nervous system.
- Do not:
  - make sudden changes to your normal diet, in particular, do not stop eating for long periods
  - take medicines such as oestrogens (e.g. oral contraceptives), barbiturates (medicines which help you to sleep and sometimes used to treat epilepsy) or steroids (body hormone-like medicines), because this can bring on an attack or make the attack worse.

*Please ask your doctor or pharmacist for advice on the medicines you should not take (now and in the future).*

- To prevent vein irritation, NORMOSANG will be administered by infusion in a large vein (blood vessel) of your arm or in a vein in your chest over a period of at least 30 minutes. After the infusion, the vein shall be rinsed with a saline solution.
- A blood clot (known as a venous thrombosis) can block the vein used for infusion.

- If your cannula is in place for long time, vascular damage may occur and could lead to an unintended migration of NORMOSANG outside the vein (extravasation). This migration may cause a skin discolouration.
- In order to diminish the risk of extravasation, the nurse/doctor will test your cannula before the infusion and will check it regularly during the infusion.
- NORMOSANG can give your blood an unusual colour.
- To limit the risk of iron compound increase in your blood, NORMOSANG should not be used as a preventive treatment of the acute porphyria attacks.
- Hemin contains iron. It can sometimes happen that iron builds up in the body after several years of treatment with repeated infusions of NORMOSANG. Your doctor may perform blood tests from time to time to check the level of iron in your body.
- Standard measures to prevent infections resulting from the use of medicines prepared from human blood or plasma, such as NORMOSANG, include selection of donors, screening of individual donations for specific markers of infections and the inclusion of effective manufacturing steps for the inactivation/ removal of viruses. Despite this, when medicines prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.
- The measures taken are considered effective for enveloped viruses such as HIV, HBV and HCV.

It is strongly recommended that every time that NORMOSANG is administered to you, that your name and batch number of NORMOSANG are recorded in order to maintain a link between you and the batch of the product.

### **Children and adolescents**

NORMOSANG should not be given to children and adolescents because its safety has not been established.

### **Other medicines and NORMOSANG**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

NORMOSANG may weaken the effect of medicines such as oestrogens (e.g. oral contraceptives), barbiturates (medicines which help you to sleep and sometimes used to treat epilepsy) or steroids (body hormone-like medicines).

### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using NORMOSANG.

You should not use NORMOSANG when you are breastfeeding.

It is not known if there is a risk in using NORMOSANG during pregnancy. However, mothers treated with NORMOSANG have delivered normal babies.

NORMOSANG has not been studied during breastfeeding. However, since a lot of medicines are passed into the breastmilk, you should inform your doctor when you are breastfeeding and ask for advice before NORMOSANG is administered to you.

### **Driving and using machines**

NORMOSANG is not expected to affect your ability to drive or to use machines.

However, it is not always possible to predict to what extent NORMOSANG may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which NORMOSANG affects them.

### **NORMOSANG contains ethanol (alcohol)**

NORMOSANG contains 11,78 vol. % ethanol (alcohol), i.e. up to 1000 mg per daily dose (one ampoule), equivalent to 23,6 ml beer or 9,8 ml wine per daily dose.

This can be harmful for those suffering from alcoholism. To be taken into account in pregnant or breastfeeding women, children and high risk groups such as patients with liver disease, or epilepsy.

Ask your doctor for advice before NORMOSANG is administered to you, if you suffer from one of the above conditions.

### **3. How to use NORMOSANG**

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself NORMOSANG. It will be given to you by a person who is qualified to do so.

Your doctor will tell you how long your treatment with NORMOSANG will last. If you have the impression that the effect of NORMOSANG is too strong or too weak, tell your doctor or pharmacist.

The dose to be administered will be calculated from your body weight and is about 3 mg per kg of body weight per day, but not more than 250 mg (1 ampoule) per day. This calculated amount of NORMOSANG will be diluted with a saline solution (0,9 % sodium chloride) in a glass bottle and this will form a dark coloured solution.

The solution will be administered by infusion in a large vein (blood vessel) of your arm or in a vein in your chest over a period of at least 30 minutes. The infused solution can give your blood an unusual colour.

After the infusion, the vein shall be rinsed with a saline solution. Usually, you will receive one infusion per day for four days.

If after this first course of treatment with NORMOSANG, the symptoms are not relieved, your doctor can decide exceptionally to start a second course of treatment.

#### **If you have received more NORMOSANG than you should**

Since a health care provider will administer NORMOSANG, he / she will control the dosage. However, in the event of overdose your doctor will manage the overdose.

#### **If you forget to use NORMOSANG**

Since a healthcare provider will administer NORMOSANG, it is unlikely that the dose will be missed.

#### **4. Possible side effects**

NORMOSANG can have side effects.

Not all side effects reported for NORMOSANG are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NORMOSANG, please consult your healthcare provider for advice.

Anaphylactoid reactions are sudden and potentially life-threatening reactions that may occur less frequently.

If any of the following happens, the NORMOSANG infusion must be stopped and the doctor must be contacted immediately:

- facial oedema
- dyspnoea

- tightness in the chest
- tachycardia
- low blood pressure
- urticaria
- spontaneous loss of consciousness (caused by insufficient blood to the brain).

Tell your doctor if you notice any of the following:

*Frequent side effects:*

- after repeated treatments, access to veins in your arm may become difficult, which may mean that a tube needs to be placed in a chest vein
- if administered in too small a vein, pain, swelling and inflammation can be caused.

*Less frequent side effects:*

- the amount of an iron compound (called ferritin) may increase in the blood following repeated treatments over several years; to limit the risk of iron compound increase, NORMOSANG should not be used as a preventive treatment of the acute attacks
- fever and serious allergic reactions (rash, tongue swelling) including anaphylactoid reaction.

*Side effects with unknown frequency:*

- headache
- venous thrombosis (clots formation in the peripheral or central veins) including injection site thrombosis
- leakage of the infusion to the surrounding tissue (extravasation)
- skin damage (necrosis) at the injection site
- skin redness at the site of injection (injection site erythema)
- skin itching at the site of injection (injection site pruritus)
- increase in the blood level of creatinine (a substance excreted by the kidneys)
- change in skin colour (discolouration).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of NORMOSANG.

## **5. How to store NORMOSANG**

Store all medicines out of reach of children.

Store in a refrigerator (2 °C – 8 °C).

Do not use NORMOSANG after the expiry date which is stated on the ampoule label and carton after EXP. The expiry date refers to the last day of that month.

Keep the ampoule in the outer carton in order to protect from light.

After dilution, the solution should be used within 1 hour.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Return all unused medicine to your pharmacist.

## **6. Contents of the pack and other information**

### **What NORMOSANG contains**

- The active substance is hemin (25 mg/ml). A 10 ml ampoule contains 250 mg of hemin. After dilution of one 10 ml ampoule in 100 ml of 0,9 % sodium chloride solution, the diluted solution contains 2 273 micrograms per ml of hemin.
- The other ingredients are arginine, ethanol (96 %), propylene glycol and water for injections.

### **What NORMOSANG looks like and contents of the pack**

NORMOSANG is presented as a concentrate for solution for infusion (10 ml in colourless glass ampoule with a white break ring – pack size of 4).

NORMOSANG is a dark coloured solution even after dilution of the concentrate for solution for infusion.

### **Holder of Certificate of Registration**

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