

## Nitrus® 0.4% w/w Ointment safety card

### - Method of administration :

**The recommended dose is approximately 375 mg (1.5 mg GTN). of ointment applied to anal canal every 12 hours.**

A finger covering, such as cling film or a finger cot, may be placed on the finger to be used to apply the ointment. (Finger cots to be obtained separately from local pharmacy or surgical supplies retailer or cling film from local store.) The finger is placed alongside a 2.5cm dosing line which is provided on the outside carton in which Nitrus® is supplied, and a strip of ointment the length of the line is expressed onto the end of the finger by gently squeezing the tube. The amount of ointment expressed is approximately 375 mg (1.5 mg GTN). The covered finger is then gently inserted into the anal canal to the distal interphalangeal joint of the finger and applied circumferentially to the anal canal.

The dose is to be applied intra-anally every twelve hours. Treatment may be continued until the pain abates, up to a maximum of 8 weeks.

**Nitrus® is not recommended for use in children and adolescents below 18 years of age due to a lack of data on safety and efficacy.**

### - Precautions:

- Nitrus® should be used with caution in patients who have severe hepatic or renal disease.
- Patients should be advised to change position slowly when changing from lying or sitting to upright to minimize postural hypotension.
- If the physician elects to use glyceryl trinitrate ointment for patients with cardiac disorders e.g. acute myocardial infarction or congestive heart failure, careful clinical and hemodynamic monitoring must be used to avoid the potential hazards of hypotension and tachycardia
- Treatment should be stopped if bleeding associated with hemorrhoids increases.
- Concomitant treatment with anti-hypertensive drug, vasodilator and tricyclic anti-depressants should be carefully considered before treatment with Nitrus® Ointment.

### - Contraindications:

- Hypersensitivity to the active substance "glyceryl trinitrate" or to any of the excipients.
- Concomitant treatment with phosphodiesterase type 5 (PDE5) inhibitors e.g sildenafil citrate, tadalafil, vardenafil and other organic nitrates with nitric oxide (NO) donors, such as other long-acting GTN products, isosorbide dinitrate and amyl or butyl-nitrite.
- Postural hypotension, hypotension or uncorrected hypovolemia as the use of glyceryl trinitrate in such states could produce severe hypotension or shock.
- Increased intracranial pressure (e.g. head trauma or cerebral hemorrhage) or inadequate cerebral circulation.
- Migraine or recurrent headache.
- Aortic or mitral stenosis.
- Hypertrophic obstructive cardiomyopathy.
- Constrictive pericarditis or pericardial tamponade.
- Marked anemia.
- Closed-angle glaucoma.

### - Pregnancy and lactation:

- Nitrus® should not be used during pregnancy and it's not recommended in breastfeeding.

*(This card focuses on major safety information for medicinal products in order to minimize possible side effects that arise from improper use of medicinal products).*

### **Pharmacovigilance Department**

#### **CONTACT DETAILS OF THE QPPV:**

**Phone:** (962)/(6) 5233349/113

**email:** [e.alkhatatbeh@sana-pharma.com](mailto:e.alkhatatbeh@sana-pharma.com).

**You can Also Report problems of Sana pharmaceutical products online via following link:**

<http://www.sana-pharma.com/?q=node/3646>