Prophylaxis of angina pectoris.

Nitroderm TTS 5: Glyceryl Trinitrate 25mg/patch

Nitroderm TTS 10: Glyceryl Trinitrate 50mg/patch

למידת מתא של טון בולט לזרעים ו튼יولاد העדכניים עדכניים, משרד הבריאות וה俸ים

בברכה,

יוסף יואב

רוקחת ממונה
Contraindications

Known hypersensitivity to nitroglycerin and related organic nitrates or any excipient of Nitroderm TTS.

Acute circulatory failure associated with marked hypotension (shock).

Conditions associated with elevated intracranial pressure.

Myocardial insufficiency due to obstruction, as in aortic or mitral stenosis or constrictive pericarditis.

Concomitant use of Nitroderm TTS and phosphodiesterase type 5 (PDE5) inhibitors such as sildenafil is contraindicated, because PDE5 inhibitors may amplify the vasodilatory effects of Nitroderm TTS resulting in severe hypotension. The time course and dose dependence of this interaction have not been studied. Appropriate supportive care has not been studied, but it seems reasonable to treat this as a nitrite overdose, with elevation of the extremities and with central volume expansion.

Severe hypotension (systolic blood pressure less than 90 mmHg).

Severe hypovolemia.

The onset of action of transdermal nitroglycerin is not sufficiently rapid for this product to be useful in aborting an acute attack.

Allergy to the adhesives used in nitroglycerin patches has also been reported, and it similarly constitutes a contraindication to the use of this product.

Precautions

Severe hypotension, particularly with upright posture, may occur with even small doses of nitroglycerin. This drug should therefore be used with caution in patients who may be volume depleted or who, for whatever reason, are already hypotensive. Hypotension induced by nitroglycerin may be accompanied by paradoxical bradycardia and increased angina pectoris.

Hypoxaemia

Caution should be exercised in patients with arterial hypoxemia (including G6PD deficiency induced forms) due to severe anemia, because in such patients the biotransformation of
nitroglycerin is reduced. Similarly, caution is called for in patients with hypoxemia and ventilation/perfusion imbalance due to lung disease or ischemic heart failure. In patients with alveolar hypoventilation a vasoconstriction occurs within the lung to shift perfusion from areas of alveolar hypoxia to better ventilated regions of the lung (Euler–Liljestrand mechanism). Patients with angina pectoris, myocardial infarction, or cerebral ischemia frequently suffer from abnormalities of the small airways (especially alveolar hypoxia). Under these circumstances vasoconstriction occurs within the lung to shift perfusion from areas of alveolar hypoxia to better ventilated regions of the lung. As a potent vasodilator, nitroglycerin could reverse this protective vasoconstriction and thus result in increased perfusion of poorly ventilated areas, worsening of the ventilation/perfusion imbalance, and a further decrease in the arterial partial pressure of oxygen.

In industrial workers who have had long-term exposure to unknown (presumably high) doses of organic nitrates, tolerance clearly occurs. Chest pain, acute myocardial infarction, and even sudden death have occurred during temporary withdrawal of nitrates from these workers, demonstrating the existence of true physical dependence.

Driving and using machines

Nitroderm TTS, especially at the start of treatment or dose adjustments, may impair the reactions or might rarely cause orthostatic hypotension and dizziness (as well as exceptionally syncope after overdosing). Patients experiencing these effects should refrain from driving or using machines.

When driving or using machines, patients should be aware that Nitroderm TTS, especially at the start of treatment, may cause dizziness.

In industrial workers who have had long-term exposure to unknown (presumably high) doses of organic nitrates, tolerance clearly occurs. Chest pain, acute myocardial infarction, and even sudden death have occurred during temporary withdrawal of nitrates from these workers, demonstrating the existence of true physical dependence.

Adverse drug reactions from spontaneous reports and literature cases

The following adverse drug reactions have been derived from post-marketing experience with Nitroderm TTS via spontaneous case reports and literature cases. Because these reactions are reported voluntarily from a population of a certain size, it is not possible to reliably estimate their frequency which is therefore categorized as not known. Within each System-Organ Class, adverse drug reactions are presented in order of decreasing seriousness.
Cardiac disorders: palpitation

Skin and subcutaneous tissue disorders: rash generalized

Table 7-2 Adverse drug reactions from spontaneous reports and literature (frequency not known)

Cardiac disorders: Palpitation.

Skin and subcutaneous tissue disorders: Rash generalized.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form (http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.health.gov.il) or by email (adr@MOH.HEALTH.GOV.IL).

Interactions

The possibility that the ingestion of acetylsalicylic acid and non-steroidal anti-inflammatory drugs might diminish the therapeutic response to Nitroderm TTS cannot be excluded.

The non-steroidal anti-inflammatory drugs except acetyl salicylic acid may diminish the therapeutic response of Nitroderm TTS.

Concurrent administration of Nitroderm TTS with amifostine and acetyl salicylic acid may potentiate the blood pressure lowering effects of Nitroderm TTS.

Women of child-bearing potential, pregnancy, breast-feeding and fertility

Fertility

There is no data available on the effect of Nitroderm TTS on fertility in humans.
In rats, there were no effects on fertility, viability, growth or development of offspring at doses up to approximately 38mg/kg/day (see section 13 Non-clinical safety data).

Overdosage

Hemodynamic effects

The ill effects of nitroglycerin overdose are generally the results of nitroglycerin’s capacity to induce vasodilation, venous pooling, reduced cardiac output, and hypotension. These hemodynamic changes may have protean manifestations, including increased intracranial pressure, with any or all of persistent throbbing headache, confusion, and moderate fever; vertigo; palpitations; visual disturbances; nausea and vomiting (possibly with colic and even bloody diarrhea); syncope (especially in the upright posture); air hunger and dyspnea, later followed by reduced ventilatory effort; diaphoresis, with the skin either flushed or cold and clammy; heart block and bradycardia; paralysis; coma; seizures; and death. Methaemoglobinemia has also been reported following accidental overdosage.

Laboratory determinations of serum levels of nitroglycerin and its metabolites are not widely available, and such determinations have, in any event, no established role in the management of nitroglycerin overdose.

No data are available to suggest physiological maneuvers (e.g. maneuvers to change the pH of the urine) that might accelerate elimination of nitroglycerin and its active metabolites. Similarly, it is not known which – if any – of these substances can usefully be removed from the body by hemodialysis.

No specific antagonist to the vasodilator effects of nitroglycerin is known, and no intervention has been subject to controlled study as a therapy of nitroglycerin overdose. Because the hypotension associated with nitroglycerin overdose is the result of venodilatation and arterial hypovolemia, prudent therapy in this situation should be directed toward increase in central fluid volume. Passive elevation of the patient’s legs may be sufficient, but intravenous infusion of normal saline or similar fluid may also be necessary.

The use of epinephrine or other arterial vasoconstrictors in this setting is likely to do more harm than good. Hypotension or collapse can be treated by elevation or, if necessary, compression bandaging of the patient’s legs.

In patients with renal disease or congestive heart failure, therapy resulting in central volume expansion is not without hazard. Treatment of nitroglycerin overdose in these patients may be subtle and difficult, and invasive monitoring may be required.
Instructions for use and handling

Each Nitroderm TTS patch is sealed in a separate sachet with a tear-off edge to facilitate removal. After removing the white protective backing, apply the Nitroderm TTS patch to a clean, non-hairy, dry area of intact skin on the trunk or upper arm. Hold the patch in position for 10-20 seconds with the palm of the hand. Switch application sites daily, wait several days before using the same area again.

Each transdermal patch must be removed from the individual package immediately prior to use.

1. **לעומת מיועד התרופה?**

התרופה מיועדת לשימוש חוץ שחזה (angina pectoris) 
(אנגיינה פקוטריס).

התרופה מעניקה תרופה ברにな_implיק רפואית
(טרופה פעילה) ומקל על המחלים של מחלות
(קרם וטרפומיט) של רקמה אחת על רקמה.

2. **למג旗帜 החוסר בתכשיט**

אף על פי כן, פנו לём ממלא תכשיטים למתופוטים
(אלרגים) לתרופה. 

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(אלרגים) לתרופה. 

וֹני tarnת על מים קרים. 

(90 mm/Hg) 

(90 mm/Hg) 

עוממת בים-מכ דם סיסטומלי מתוח מ-

עוממת בים-מכ דם סיסטומלי מתוח מ-


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בנהוג ברך, הפעלת מכוניות מסוכנות וebbבריכת פעילות המוחבית ענור.

4. תופעת לוי

5. ידNealאת תמרות

יש להשתתף بمיתקע MiיידNealאת התמחות.

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