# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

Panash Cream 0.25%

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains
Thiocolchicoside 2.5 mg

For full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Pale yellow to yellow color, viscous cream.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Lumbosacral sciatica (back pain), cervical-brachial neuralgia (pain and contracture of the neck, shoulder and upper limbs), stubborn stiff neck, post-traumatic and post-operative pain syndromes.

Adjuvant treatment of painful muscle contractures in acute spinal pathology in adults and adolescents from 16 years onwards.

### 4.2 Posology and method of administration

**Route of administration:** Topical

**Posology**
Apply a quantity of cream according to the size of the area by gently rubbing in the affected skin area and surrounding area to be treated 2-3 times day. The treatment duration varies, but for most acute cases usually 7-10 days treatment is enough for recovering. The treatment duration is determined by a physician.

**Children. The medicine is not recommended in children under 17 years.**

### 4.3 Contraindications
Thiocolchicoside must not be used;-

- In patients hypersensitive to the active substance or to any of the excipients listed in section 6.1
-Flaccid paralysis,

- Muscular hypotonia.
- During the entire pregnancy period
- During lactation
- In women of childbearing potential not using contraception.
- Thiocolchicoside should be prescribed cautiously to people with H/O seizure.

**4.4 Special warnings and precautions for use**

- Thiocolchicoside is not recommended for use in children.
- Treatment should be appropriately reduced in the event of occurrence of side effects.
-The use, especially if prolonged, the products for topical use may give rise to sensitization phenomena. If they occur, you must stop treatment and appropriate therapy instituted.
Panash cream contains propylene glycol: May cause skin irritation.

**4.5 Interaction with other medicinal products and other forms of interaction**

None are known.

**4.6 Fertility, pregnancy and lactation**

*Pregnancy*

There are limited data on the use of thiocolchicoside in pregnant women. Therefore, the potential hazards for the embryo and foetus are unknown.
Studies in animals have shown teratogenic effects.
Panash cream is contraindicated during pregnancy and in women of childbearing potential not using contraception (see section 4.3).

*Breast-feeding*

Since it passes into the mother's milk, the use of thiocolchicoside is contraindicated during breastfeeding (see section 4.3).

*Fertility*

In a fertility study performed in rats, no impairment of fertility was seen at doses up to 12 mg/kg, i.e. at dose levels inducing no clinical effect. Thiocolchicoside and its metabolites exert aneugenic activity at different concentration levels, which is a risk factor for impairment of human fertility.

**4.7 Effects on ability to drive and use machines**

Although after the administration of Panash Cream somnolence should be considered a very rare occurrence, it is necessary to take account of this possibility.

**4.8 Undesirable effects**

- They are reported cases of rash and skin rash. See, also, paragraph 4.4

- Rare cases of drowsiness have been reported (see Effects on ability to drive and usemachines)

**4.9 Overdose**

No overdosage symptoms have been reported in patients treated with Thiocolchicoside. Should overdosage occurs, medical supervision and symptomatic measures are recommended.

**5. PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

*Pharmacotherapeutic group*

Pharmacotherapeutic group: muscle relaxant, ATC code: MO3BX03

Thicolchicoside is a semi-synthetic sulphurated derivative of colchicoside, with myorelaxant pharmacological activity.

*Mechanism of action*

In-vitro, thicolchicoside only binds to GABA-A and strychnine-sensitive glycine receptors.Thiocolchicoside acting as a GABA-A receptor antagonist, its myorelaxant effects could be exerted at the supra spinal level, via complex regulatory mechanism, although a glycinergic mechanism of action cannot be excluded. The characteristics of the interaction ofthiocolchicoside with GABA-A receptors are qualitatively and quantitatively shared by its main circulating metabolite, the glucuronidated derivative.

**5.2 Pharmacokinetic properties**

Following topical administration of Panash at recommended doses, the plasma levels of thiocolchicoside were below the minimum level determined.

This shows that after topical administration it has no systemic absorption and therefore also the level of tolerability is good.

**5.3 Preclinical safety data**

Thiocolchicoside safety profile has been assessed in vitro, an in vivo following intramuscular and oral administration. Thicolchicoside was well tolerated following oral administration for periods of up to 6 months in both the rat and the non-human primate when administered at repeated doses of less than or equal to 2 mg/kg/day in the rat and less or equal to 2.5 mg/kg/ day in non-human primate, and by the intra muscular route in the primate at repeated doses up to 0.5 mg/kg/day for 4 weeks.

At higher doses, thiocolchicoside induced diarrhea and convulsions in both rodents and non rodents after acute administration by oral route. After repeated administration, thiocolchicoside induced gastro-intestinal disorders (enteritis, emesis) by oral route, and emesis by i.m. route. The compound did not induce adverse effect on fertility. By contrast, a teratogenic effect and perinatal toxicity was demonstrated. No evidence for teratogenic effects of thiocolchicoside was described at doses up to 3 mg/kg/day. Thiocolchicoside was shown to be devoid of mutagenic potential when used at the therapeutic dose.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Carbomer (carbopol 940), disodium edentate, isopropyl alcohol, propylene glycol, glycerol, sodium hydroxide, purified water, light liquid paraffin, isopropyl myristate, polyoxyl 40 hydrogenated castor oil.

### 6.2 Incompatibilities

None known.

### 6.3 Shelf life

2 Years

### 6.4 Special precautions for storage

Store in dry place, Temperature below 30°C. Protected from direct sunlight. Do not Freeze.

### 6.5 Nature and contents of container

30 gm of cream in aluminum collapsible tubes. Each tube in the carton along with insert.

### 6.6 Special precautions for disposal and other handling

None

## 7. MARKETING AUTHORISATION HOLDER

Kusum Healthcare Pvt. Ltd.

## 8. MARKETING AUTHORISATION NUMBER(S)

TAN 22 HM 0340

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORIZATION

21/09/2022

## 10. DATE OF REVISION OF THE TEXT