

Summary of Product Characteristics (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Nino Gentian Violet Paint

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Gentian violet Paint 60ml

Each ml contains:

Crystal Violet B.P 0.5g

3. PHARMACEUTICAL FORM

Topical Liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Gentian violet paint is an antiseptic dye used to treat fungal infections of the skin (e.g., ringworm, athlete's foot), also in the treatment of burns, boils. It also has weak antibacterial effects and may be used on minor cuts and scrapes to prevent infection.

4.2 Posology and Method of Administration

Topical

RECOMMENDED DOSE

Apply topically on affected area

DOSAGE SCHEDULE

Apply once/twice a day or as directed by a Physician

4.3 Contraindications

Do not put on open or deep wounds, animal bites, or severe burns. This medicine may stain clothing or skin.

4.4 Special Warnings and Special Precautions for Use

If you are allergic to gentian violet; any part of gentian violet; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.

4.5 Interaction with other medicinal products and other forms

This medicine may interact with other drugs or health problems. Tell your Physician about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take gentian violet with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your Physician.

4.6 Fertility, pregnancy and lactation

Gentian Violet Levels and Effects while Breastfeeding

Gentian violet (crystal violet) was used in the past to treat oral and nipple thrush during breastfeeding. Gentian violet is potentially toxic to the mucous membranes, causing ulceration, and potentially tattooing the skin. It can also interact with DNA, is carcinogenic and mutagenic in animals, and occasionally causes allergic sensitization, with cross-reactions to other triphenylmethane dyes. Its use has been severely curtailed by authorities in Australia, Canada, England and France. It is also very messy, staining skin and clothing. A 2001 survey of the members of the Academy of Breastfeeding Medicine (ABM) found that gentian violet is rarely (1 to 2% of respondents) used by breastfeeding experts for initial treatment of oral thrush and is very infrequently (3 to 4% of respondents) used for recurrent or persistent thrush. ABM guidelines for treating *Candida* infection of the nipples state that an aqueous solution of gentian violet of less than 0.5% can be used for no more than 7 days on the nipple. However, safer alternatives for treating thrush are available.

Effects in Breastfed Infants;

Gentian violet has caused oral ulceration in breastfed infants treated with 1% or 2% solution applied to the mouth and tongue for thrush.

A 2-week-old exclusively breastfed infant was treated for oral thrush with aqueous 1% gentian violet solution twice daily for 1 day. The parents discontinued it because they thought it was causing airway discomfort. After 2 days, it was restarted at 4 times a day. Cough and difficulty feeding developed after 1 day and the infant was then admitted to the hospital, ultimately requiring intubation.

4.6 Effects on ability to drive and use machines

None.

4.7 Undesirable effects

In patients who are allergic to gentian violet, they may experience rash, hives, itchy skin, redness of the skin, wheezing, swelling of the mouth, face, lips, tongue or throat.

4.8 Overdose

None applicable

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiseptic Dye

Gentian violet is a mutagen, a mitotic poison, and a clastogen. Gentian violet has been used in medicine for almost 100 years: as an antiseptic for external use, as a topical antibiotic, as a topical antifungal agent, and more recently, as a blood additive to prevent transmission of Chagas' disease. It is thought to work by binding to the DNA of target organisms and causing disruption, mutation or inhibition of DNA replication.

Mechanism of Action ;In aqueous solutions Gentian violet (GV) dissociates into positive (GV+)and negative ions (Cl-) that penetrate through the wall and membrane of both gram-positive and gram-negative bacterial cells. The GV+ interacts with negatively charged components of bacterial cells including the lipopolysaccharide (on the cell wall), the peptidoglycan and DNA. A similar cell penetration and DNA binding process is thought to take place for fungal cells as well. Because Gentian violet is a mutagen and mitotic poison, cell growth is consequently inhibited. A photodynamic action of gentian violet, apparently mediated by a free-radical mechanism, has recently been described in bacteria and in the protozoan *T. cruzi*. Evidence also suggests that gentian violet dissipates the bacterial (and mitochondrial) membrane potential by inducing permeability. This is followed by respiratory inhibition. This anti-mitochondrial activity might explain gentian violet's efficacy towards both bacteria and yeast with relatively mild effects on mammalian cells.

5.2 Pharmacokinetic properties

Metabolism; primarily hepatic, mostly demethylation

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

None.

6.3 Shelf life

36 months unopened.

6.4 Special precautions for storage

Store in a cool dry place not more than 30°C.

6.5 Nature and contents of container

60ml amber Pet bottle with 28mm ROPP Metal-cap.

6.6 Special precautions for disposal and other handling

None

7. MARKETING AUTHORISATION HOLDER

Nino Pharm & Chem Co. Ltd
1, Nino Crescent Era Town,
Off Badagry Expressway,
Ojo LGA Lagos.

