



SUMMARY OF PRODUCT CHARACTERISTICS



1. Name of the medicinal Product

1.1 Name of the medicinal Product

Gentian Violet

1.2 Strength

Crystal Violet 0.5%w/v

1.3 Pharmaceutical Form

Topical Dye paint

Easy flowing purple color liquid filled in PET bottle.

2. Qualitative and Quantitative Composition

2.1 Qualitative declaration

Each 60ml of Esoma Gentian Violet contains;

Crystal Violet.

2.2 Quantitative declaration

S/N	INGREDIENT	SPECIFICATION	QUANTITY in 60ml	REASON for INCLUSION
1	Crystal Violet	BP	0.5%w/v	Antiseptic dye.

3. Pharmaceutical Form

Topical Dye paint

Easy flowing purple color liquid filled in PET bottle.

4. Clinical Particulars

4.1 Therapeutic Indications

Indicated in the treatment of fungal infections of the skin, ringworm, athlete's foot, may be used on minor cuts and scrapes to prevent infection.

Dosage

As directed.



4.2 Posology and Method of Administration

Using a cotton swab, apply enough gentian violet to cover only the affected area.

If you are applying this medicine to affected areas in the mouth, avoid swallowing any of the medicine.

If you are using this medicine in a child's mouth, make sure you understand exactly how to apply it so that it is not swallowed. If you have any questions about this, check with your health care professional.

Do not apply an occlusive dressing (airtight covering, such as kitchen plastic wrap) over this medicine. It may cause irritation of the skin.

To help clear up your infection completely, keep using this medicine for the full time of treatment, even if your condition has improved. Do not miss any doses.

Pediatric population

Appropriate studies on the relationship of age to the effects of gentian violet have not been performed in the pediatric population. However, this medication is not expected to cause different side effects or problems in children than it does in adults.

4.3 Contraindications

Gentian violet has been contraindicated in persons with these conditions; canker sores, vaginal irritation as well as triphenylmethane analogues allergies or any known hypersensitivities to the dye.

4.4 Special Warnings and Special Precautions for Use

Gentian Violet should be applied only to damaged skin, diseased skin and to skin wounds or open injuries. Not for application to ulcerative lesions as this could result in permanent staining of the skin. It is necessary to wash hands after usage as medication can stain skin and clothing. Gentian violet is for EXTERNAL USE ONLY.

4.5 Interaction with other medicinal products and other forms of interaction

No significant interactions known or found for this drug. Caution always advised with multiple medications.

4.6 Fertility, Pregnancy and Lactation

Systemic absorption unknown, avoid topical use on nipple.

4.7 Effects on ability To Drive and use Machines

None.

4.8 Undesirable Effects

Even though very rare, may cause skin irritation not present before the use of the medicine. Consult



your doctor if any side effect occurs with the use of this medicine.

4.9 Overdose

No case of overdose has been reported.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Gentian violet is a green dye that forms a violet solution in water. It comprises a mixture of crystal and methyl violet which are aniline derivatives. It possesses antifungal and anthelmintic activities as well as bactericidal and bacteriostatic activities against gram-positive bacteria. It is used in medicine as an antiseptic for external use, as a topical antibiotic and a topical antifungal agent.

5.2 Pharmacokinetic Properties

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, 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. 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.

5.3 Preclinical Safety Data

No other relevant preclinical data is available.

6. Pharmaceutical Particulars

6.1 List of Excipients

Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months unopened.

6.4 Special Precautions for Storage

Store below 30°C, protect from light.



6.5 Nature and Contents of Container

60ml: PET bottle with white 28mm plastic cap.

6.6 Special precaution for disposal and other handling

Dispose waste or unused product in accordance with local requirements.

7. Registrant (Marketing Authorization Holder And Manufacturing Site Addresses)

7.1 Name and Address of Marketing Authorization Holder

Esoma Pharmaceutical Ltd

Plot 54 cadastral zone 07-05 Extension 2, kubwa, Abuja.

Tel: 08036786233

Email: esomapharmacy@gmail.com

7.2 Name and Address of manufacturing site(s)

Esoma Pharmaceutical Ltd

Plot 54 cadastral zone 07-05 Extension 2, kubwa, Abuja.

Tel: 08036786233

Email: esomapharmacy@gmail.com

7.3 Marketing Authorization Number

To be included after obtaining first registration.

7.4 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

8. Date of Revision of the Text

9. Dosimetry (If Applicable)

Not Applicable

10. Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable