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## **SUMMARY OF PRODUCT CHARACTERISTICS GENTIAN VIOLET**

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# SUMMARY OF PRODUCT CHARACTERISTICS

## GENTIAN VIOLET

### 1. Name of the medicinal product

GENTIAN VIOLET

### 2. Qualitative and quantitative composition

Label Claim:	
Crystal Violet	0.5% w/v

For a full list of excipients, see section 6.1.

### 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.

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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 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**

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Not relevant.

### **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 known.

### **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 effects occurs with the use of this medicine.

### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

### **4.9 Overdose**

Treatment of poisoning involves aspiration and lavage and appropriate symptomatic measures.

## **5. Pharmacological properties**

### **5.1 Pharmacodynamic 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.

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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<sup>+</sup>) and negative ions (Cl<sup>-</sup>) that penetrate through the wall and membrane of both gram-positive and gram-negative bacterial cells. The GV<sup>+</sup> 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 cell.

#### **5.3 Preclinical safety data**

No data available.

### **6. Pharmaceutical particulars**

#### **6.1 List of excipients**

ISO PROPYL ALCOHOL

#### **6.2 Incompatibilities**

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None known

#### 6.3 Shelf life

36 months

#### 6.4 Special precautions for storage

Do not store above 30°C

#### 6.5 Nature and contents of container

Bottle:	Amber Glass
Closures:	28mm ROPP, tamper evident, child resistant.
Pack Sizes:	60 ml.

#### 6.6 Special precautions for disposal and other handling

No special requirements.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required (these should be disposed of in line with local requirements). These measures will help to protect the environment.

### 7. Marketing authorisation holder

AICON PHARMACEUTICAL LTD, PLOT NO Q38,  
KWANAR DAWAKI INDUSTRIAL ESTATE  
KM 12 KANAO-KADUNA EXPRESS WAY  
KUMBOTSO LGA, KANO STATE.

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### **GENTIAN VIOLET**

#### **8. MANUFACTURER**

AICON PHARMACEUTICAL LTD, PLOT NO Q38,  
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KUMBOTSO LGA, KANO STATE.