SPORIN

Ophthalmic Emulsion

Ciclosporin

سپورِن

Ophthalmic Emulsion

سائیکلوسپورِن

COMPOSITION:

Each ml contains: Ciclosporin.....0.5mg. B.P Specification.

DESCRIPTION:

Sporin (ciclosporin ophthalmic emulsion) 0.05% contains a topical calcineurin inhibitor immunosuppressant with anti-inflammatory effects. Ciclosporin's chemical name is Cyclo[[(E)-(2S,3R,4R)-3 hydroxy-4-methyl-2-(methylamino)-6-octenoyl]-L-2-aminobutyryl-N-methylglycyl-N-methyl-L-leucyl-L-valylN-methyl-L-leucyl-L-alanyl-D-alanyl-N-methyl-L-leucyl-N-methyl-L-leucyl-N-methyl-L-valyl].

CLINICAL PHARMACOLOGY

Mechanism of Action: Ciclosporin is an immunosuppressive agent when administered systemically. In patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca, ciclosporin emulsion is thought to act as a partial immunomodulator. The exact mechanism of action is not known.

Pharmacokinetics: Blood ciclosporin concentrations were measured using a specific high pressure liquid chromatography-mass spectrometry assay. Blood concentrations of ciclosporin, in all the samples collected, after topical administration of Sporin 0.05%, twice daily, in humans for up to 12 months, were below the quantitation limit of 0.1 ng/mL. There was no detectable drug accumulation in blood during 12 months of treatment with Ciclosporin ophthalmic emulsion.

INDICATIONS :

Sporin Ophthalmic emulsion is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.

CONTRAINDICATIONS:

Sporin is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients in the formulation.

ADVERSE REACTIONS:

Most common adverse reactions following the use are ocular burning, conjunctival hyperemia, discharge, epiphora, eye pain, foreign body sensation, pruritus, stinging, and visual disturbance.

PRECAUTIONS:

Pregnancy and Lactations:

The drug should be used in pregnancy and lactation only if suggested by the physician.

Geriatric Use:

No overall difference in safety or effectiveness has been observed between elderly and younger patients.

Pediatric:

Safety and efficacy have not been established in pediatric patients below the age of 16.

Use with Contact Lenses:

Ciclosporin should not be administered while wearing contact lenses. If contact lenses are worn, they should be removed prior to the administration of the emulsion. Lenses may be reinserted 15 minutes following administration of Ciclosporin ophthalmic emulsion.

DOSAGE AND ADMINISTRATION:

Instill one drop of SPORIN ophthalmic emulsion twice a day in each eye.

SPORIN can be used concomitantly with artificial tears, allowing a 15-minute interval between products.

PRESENTATION:

SPORIN Ophthalmic emulsion eye drops are supplied in 10ml plastic dropper bottle.

INSTRUCTIONS:

Protect form heat & Sunlight.
Store Below 30°C.
Use within four weeks after opening.
Keep out of the reach of children.
Shake well before use.

خوراک:

۱ قطرہ دن میں دو مرتبہ متاثرہ آنکھ/آنکھوں میں ڈالیں
یا ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دھوپ اور گرمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
استعمال سے پہلے اچھی طرح ہلائیں۔

انتباہ: پہلی دفعہ بوتل کھولنے کے بعد دوا کو چار ہفتوں تک استعمال کیا جا سکتا ہے۔

Manufactured by:
Vega Pharmaceuticals (Pvt.) Ltd.
30 Km, Multan Road, Lahore, Pakistan.