

Sonoin^{Gel}
(Isotretinoin)

سنونین جیل
(آکسٹروئیتینائن)

COMPOSITION:

Each gram contains:
Isotretinoin0.5mg

(BP Specifications)

DESCRIPTION:

Isotretinoin is a retinoid derivative of vitamin A used in the treatment of severe recalcitrant acne.

INDICATIONS:

Sonoin Gel (Isotretinoin) is indicated for the topical treatment of mild to moderate inflammatory and non-inflammatory acne vulgaris.

MECHANISM OF ACTION:

Isotretinoin is structurally and pharmacologically related to Vitamin A which regulates epithelial cell growth and differentiation.

The pharmacological action of isotretinoin remains to be fully elucidated. When used systemically it suppresses sebaceous gland activity and reduces sebum production; it also affects comedogenesis, suppresses Propionibacterium acnes and reduces inflammation.

When applied topically, the mode of action of isotretinoin is probably comparable with its stereoisomer, tretinoin.

Isotretinoin stimulates mitosis in the epidermis and reduces intercellular cohesion in the stratum corneum; it contests the hyperkeratosis characteristic of acne vulgaris and aids desquamation, preventing the formation of lesions. Tretinoin also mediates an increased production of less cohesive epidermal sebaceous cells, this appears to promote the initial expulsion and subsequent prevention of comedones.

DOSAGE & ADMINISTRATION:

Adults and adolescents

Apply Isotretinoin Gel sparingly over the whole affected area once or twice daily. Patients should be advised that 6-8 weeks of treatment may be required before a therapeutic effect is observed.

Patients should be advised that excessive application will not improve efficacy, but may increase the risk of skin irritation.

If undue irritation (redness, peeling, or discomfort) occurs, patients should reduce frequency of application or temporarily interrupt treatment. The normal frequency of application should be resumed once the irritation subsides.

Treatment should be discontinued if the irritation persists.

Hands should be washed after application.

Due to the flammable nature of Isotretinoin Gel, patients should avoid smoking or being near an open flame during application and immediately after use.

Pediatric population

The safety and efficacy of Isotretinoin Gel in children under 12 years of age has not been established since acne vulgaris rarely presents in this age group.

Elderly patients

There are no specific recommendations for use in the elderly. Acne vulgaris does not present in the elderly.

PHARMACOKINETICS:

Percutaneous absorption of isotretinoin from the gel is negligible. After applying 20g per day of isotretinoin 0.05% gel to acne of the face, chest and back for 30 days, HPLC assays for isotretinoin and tretinoin demonstrated non-detectable levels in the plasma samples

(<0.02µg/ml). Applying ¹⁴C isotretinoin in a cream base on the healthy skin of volunteers resulted in only 0.03% of the topically applied dose being recovered through estimating the radioactivity of blood, urine and faecal samples.

WARNINGS & PRECAUTIONS:

- * Isotretinoin should be used with caution in patients with a history of local tolerability reactions or photo allergy.
- * Use with caution in patients with a personal or family history of skin cancer.
- * Contact with the mouth, eyes, mucous membranes, abraded or eczematous skin should be avoided.
- * Care should be taken not to let the medicine accumulate in skin fold areas and in the nasolabial folds.
- * Butylated hydroxytoluene may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.
- * Due to the irritant nature of isotretinoin, caution should be used when applying to sensitive areas of skin, such as the neck, or in patients with concomitant rosacea or perioral dermatitis.
- * Concomitant topical acne therapy should be used with caution because a cumulative irritant effect may occur. If irritancy or dermatitis occur, reduce frequency of application or temporarily interrupt treatment and resume once the irritation subsides. Treatment should be discontinued if the irritation persists.

* As isotretinoin may cause increased sensitivity to sunlight, sunlamps should not be used and deliberate or prolonged exposure to sunlight should be avoided or minimised. When exposure to strong sunlight cannot be avoided, patients should be advised to use a sunscreen product and wear protective clothing.

Pregnancy

Isotretinoin Gel is contraindicated in pregnancy, or in women planning a pregnancy. If the product is used during pregnancy, or if the patient becomes pregnant while taking this drug, treatment should be discontinued.

A small number of temporally associated congenital abnormalities have been reported during clinical use of topical tretinoin. Although no definite pattern of teratogenicity and no causal association have been established from these cases, they include reports of the rare birth defect category, holoprosencephaly (defects associated with incomplete midline development of the forebrain). The significance of these reports in terms of risk to the foetus is uncertain, since these effects have not been reproduced.

Breast-feeding

There is insufficient information on the excretion of topically applied isotretinoin in human milk. A risk to the newborns/infants cannot be excluded.

A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from isotretinoin therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

SIDE EFFECTS:

In normal use, Isotretinoin Gel may cause stinging, burning or irritation; erythema and peeling at the site of application may occur.

If undue irritation occurs, treatment should be interrupted temporarily and resumed once the reaction subsides. If irritation persists, treatment should be discontinued. Reactions will normally resolve on discontinuation of therapy.

(Common side effects): Application site erythema, skin exfoliation, pain of skin, application site pruritus, skin irritation, skin tenderness, skin burning sensation, application site stinging, dry skin.

(Rare side effects): skin hyperpigmentation, skin hypopigmentation, photo-sensitivity reaction.

DRUG INTERACTIONS:

Concomitant application of oxidising agents, such as benzoyl peroxide, should be avoided since they may reduce the efficacy of topical isotretinoin. If combination therapy is required, the products should be applied at different times

of the day e.g. one in the morning and the other in the evening.

CONTRAINDICATIONS:

Hypersensitivity to the active substance, isotretinoin, or to any of the excipients. isotretinoin gel is contraindicated in pregnancy and in women planning a pregnancy.

OVER DOSAGE:

Oral ingestion of a 30g tube of topical isotretinoin would result in less exposure than achieved with the recommended dosage of oral isotretinoin. Consequently, the theoretical occurrence of symptoms of overdosage (e.g. hypervitaminosis A) is highly unlikely. These include severe headaches, nausea or vomiting; drowsiness, irritability and pruritus.

STORAGE & INSTRUCTIONS:

Store below 25°C.

Protect from heat, sunlight and moisture. Keep away from the reach of the children.

Replace cap firmly after use.

Contents are flammable. Keep away from fire, flame or heat. Do not leave in direct sunlight. This product should be used within two months after opening and discard any unused portion.

To be sold on the prescription of a registered medical practitioner only.

خوراک و ہدایات:

متاثرہ حصے پر دن میں ایک سے دو بار لگائیں یا ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

۲۵ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

درد، جھیر، جڑ میں نہ رکھیں۔ دھوپ، گرمی، نمی اور نمند ہونے سے بچائیں۔

بچوں کی پہنچ سے دور رکھیں صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔

HOW SUPPLIED:

Sonoin Gel

10g tube.

Manufactured by:

PHARMASOL

PRIVATE LIMITED

Plot # 549, Sundar Industrial Estate,
Lahore, Pakistan.