include dry skin, burning, redness, excessive flaking or peeling. Some of these side effects can make your skin more sensitive to sunlight.

What should I avoid while using Tretinoin Gel 0.05%?

- Topical over-the-counter acne preparations, concomitant topical medication, medicated or abrasive soaps and skin cleansers, and the use of alcohol, essential oils, or other occlusive substances.
- Weather extremes, such as wind or cold, may be irritating to patients using Tretinoin Gel 0.05%. Protective clothing over treated areas is recommended when exposure cannot be avoided.
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Tretinoin Gel 0.05% may not be right for you. Tell your doctor about all of your medical conditions, especially:

- Skin problems.
- Allergy to any ingredient in Tretinoin Gel 0.05%.
- Breastfeeding. It is not known whether Tretinoin Gel 0.05% passes into your milk and if it is harmful to your baby.
- Pregnancy. Tretinoin Gel 0.05% may cause birth defects if a pregnant woman takes it during the first or second month of pregnancy. Therefore, women who use Tretinoin Gel 0.05% should not become pregnant during treatment. If you become pregnant while using Tretinoin Gel 0.05%, your doctor should stop your treatment. You should also avoid exposure to sunlight or ultraviolet (UV) light when using Tretinoin Gel 0.05%.
- A baby can inherit Tretinoin Gel 0.05% from its mother by being born with it or developing it later. Women should not become pregnant during treatment with Tretinoin Gel 0.05%. They should use two forms of birth control, such as a birth control pill and a condom, to prevent pregnancy. If a mother uses Tretinoin Gel 0.05% and becomes pregnant or plans to become pregnant during treatment, she should stop using Tretinoin Gel 0.05% and tell her doctor.

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Tretinoin Gel 0.05% is a prescription medicine used on the skin to treat acne. Acne is a skin disease that occurs when hair follicles become clogged with skin cells and oil. Acne can be very annoying and cause problems such as pimple, redness, swelling, and blackheads. Tretinoin Gel 0.05% comes in a transparent or opaque, pale yellow topical gel that is applied onto the skin.

**11 DESCRIPTION**

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The safety and efficacy of Tretinoin Gel 0.05% have been established in two 12-week prospective, multi-center, randomized, controlled studies. Subjects ranged in age from 12 to 65 years, with approximately 52% between 18 to 40 years. The database was not large enough to assess whether there were differences in effects in age, gender, and race.

**12 CLINICAL STUDIES**

**12.1 Mechanism of Action**

Although the exact mode of action of tretinoin is unknown, current evidence suggests that it affects enzymes and proteins involved in cell cycle regulation, differentiation, and apoptosis. Tretinoin activates three members of the retinoid acid (RAR) nuclear hormone receptor family, which can then bind to DNA and regulate gene expression. This activation leads to changes in gene expression that can affect cell proliferation, differentiation, and apoptosis.

**12.3 Pharmacokinetics**

The plasma concentrations of tretinoin and its metabolites could be measured (LOQ = 0.5 ng/mL for all three analytes) in all patients at all time points. The maximum systemic doses associated with response were observed at those same doses. The maximum systemic doses associated with toxicity were observed at 0.12 and 0.24 g applied in the controlled reversion test, an in vitro assay. The significance of these studies to humans is not clear because they occurred at doses that exceeded the dermal application of a tretinoin-containing 0.05% tretinoin, by weight. Other components of this formulation are dimethyl-9-(2,6,6-trimethyl-1-cyclohexen-1-yl)-2,4,6,8-nonatetraenoic acid. It is an isomer of all-trans-retinoic acid, commonly called tretinoin. Tretinoin is chemically, tretinoin is all-trans-retinoic acid, commonly called tretinoin. Tretinoin Gel 0.05% is a translucent to opaque, pale yellow topical gel that is applied onto the skin.

**13 NONCLINICAL TOXICOLOGY**

**13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

A dose-related incidence of liver tumors in male mice was observed across patients. However, they should be instructed to remove the cosmetics and clean the area before applying Tretinoin Gel 0.05% to the skin. The active ingredient in this gel is tretinoin, which is a vitamin A derivative. Tretinoin is metabolized in the liver, and the major metabolite is 4-oxo-13-cis-retinoic acid. It is a vitamin A derivative that is metabolized in the liver, and the major metabolite is 4-oxo-13-cis-retinoic acid. It is a vitamin A derivative that is metabolized in the liver, and the major metabolite is 4-oxo-13-cis-retinoic acid. It is a vitamin A derivative that is metabolized in the liver, and the major metabolite is 4-oxo-13-cis-retinoic acid. It is a vitamin A derivative that is metabolized in the liver, and the major metabolite is 4-oxo-13-cis-retinoic acid. It is a vitamin A der